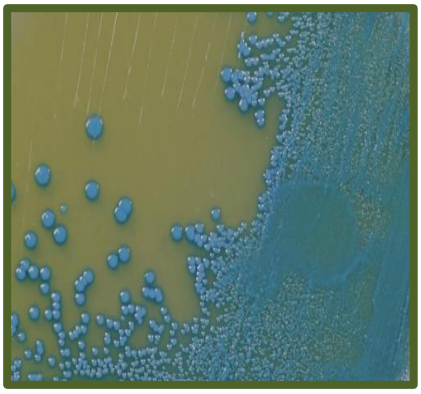
CONTROLLING PATHOGENS IN DAIRY PROCESSING ENVIRONMENTS

GUIDANCE FOR THE U.S. DAIRY INDUSTRY



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The Innovation Center for U.S. Dairy® (IC), formed in 2008, provides a forum for the dairy industry to work together pre-competitively. Collectively, the IC represents over 500 dairy manufacturers and over 80 percent of the U.S. milk supply. One important IC initiative is the Food Safety Team, which helps assure dairy products are safe by providing resources and training in all facets of dairy manufacturing. The IC Food Safety Team is very active with over 100 experts from 50 organizations involved across multiple platforms. Learn more at: www.usdairy.com/foodsafety. If you have specific questions, please email innovationcenter@usdairy.com.

Acknowledgements

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U.S. Dairy Stewardship Commitment

U.S. dairy processors can use this guidance as a supplementary resource for reporting on their food safety programs in the U.S. Dairy Stewardship Commitment.

The U.S. Dairy Stewardship Commitment (Stewardship Commitment) was developed by the Innovation Center for U.S. Dairy® (Innovation Center) to support dairy farmers, cooperatives and processors who voluntarily choose to work across the industry to advance sustainability leadership and transparently report progress. It aligns and quantifies industry action on important sustainability and social responsibility areas to affirm and illustrate U.S. dairy's longstanding values of responsible production, nourishing communities, and continuous improvement.

As a shared reporting tool, the Stewardship Commitment quantifies industry action through a collection of indicators and metrics—at the field, farm, and processor levels—that provide credible and science-based measures to track continuous improvement in sustainability and social responsibility areas. Food Safety is a processor level indicator that tracks the implementation and reassessment of validated, verifiable food safety programs and management systems in dairy processing facilities**. Dairy processors can use this guidance to inform robust food safety programs and following it is now a part of the Food Safety metric of the U.S. Dairy Stewardship Commitment.**

To learn more about the U.S. Dairy Stewardship Commitment, including the benefits of adopting, opportunities to get engaged, and other available tools and resources, visit commitment.usdairy.com.

Below are the current two metrics that comprise the Food Safety portion of the Stewardship Commitment. Upon adoption of this guide as an addition to the Food Safety portion of the Stewardship Commitment, the third metric will be incorporated.

U.S. Dairy Stewardship Commitment Food Safety Metrics	
Indicator	**Metric**
Food Safety	• Do you have validated, verifiable food safety programs and management systems in place? (Y/N) • Do you frequently reassess your food safety programs to ensure efficacy and to reflect new food safety tools/practices and ensure continuous improvement? (Y/N) • Have you committed to follow the Controlling Pathogens in Dairy Processing Environments guidance to the extent applicable for your company and products? (Y/N)

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To the Reader

This environmental Pathogen Control Guidance Document has been prepared for the food industry by subject matter experts who work daily in the dairy industry. This document is not intended to be a "How To", but rather to be informative. It is intended to build knowledge and communicate best practices for a wide spectrum of food safety practitioners: hourly employees, engineers, quality professionals, senior staff, contractors, suppliers, and more.

Furthermore, this document is designed to provide guidance to better control pathogens in both wet and dry processing environments. Specific considerations for wet and dry products and processing will be included for each principle. It is crucial in all environs to understand the necessity to control water, moisture, and humidity.

With the diverse information needs of this group, and the obligation to present scientific principles and best practices, this document employs a simple graphic to guide the reader. The graphic symbolizes the basic programs that are recommended to be employed in concert to establish effective pathogen control in a dairy manufacturing facility. This is the **Pathogen Control Equation**[1]:

Core principles of the Pathogen Control Equation will be discussed in depth to help identify focused practices which are essential to effective pathogen control. The maturity of a firm's food safety culture impacts how effectively the principles of the equation are implemented and followed. According to the 2009 book *Food Safety Culture: Creating a Behavior-Based Food Safety Management System* by Frank Yiannas: "While having a FSMS (Food Safety Management System) is critical, food safety culture looks beyond just processes to human behavior." Challenges implementing the Pathogen Equation principles may be attributed to the maturity of the Food Safety Culture of your company. There are many sources available you can utilize to understand and develop the Food Safety Culture (FDSC) of your company. The position paper by GFSI: A Culture of Food Safety, available on the mygfsi.com website and the New Era of Smarter Food Safety page available on the FDA website are excellent sources of FSC information.

Years of experience and science-based best practices from multiple food categories have been summarized as the following core principles:

Principle #1: Separate Raw from Ready-to-Eat

History has shown that there is a greater likelihood of finding pathogens or spoilage organisms in uncontrolled or raw manufacturing areas than in controlled production or Ready-to-Eat (RTE) areas. Managing the flow of personnel, supplies, air movement and equipment significantly reduces the potential for cross-contamination. Additional measures may be necessary in the manufacturing of dry RTE products including added controls for high hygiene areas.

Principle #2: Good Manufacturing Practices and Controlled Conditions

Following Good Manufacturing Practices (GMPs) is one of the most fundamental expectations in the food industry to prevent contamination of products. GMPs apply to both personnel and production practices. Surfaces in a dairy production facility can be wet from manufacturing conditions; this moisture can support microbial harborage and growth. Thus, floors and other similar surfaces should be dry, well maintained, and free of cracks. Harborage points are locations where pathogens may survive, and they are usually difficult to reach with routine cleaning.

Principle #3: Sanitary Facility and Equipment Design

Sanitary design involves the design, construction, and installation of equipment and facilities in a manner to support effective and efficient cleaning and sanitizing. Surfaces which are difficult to clean can be challenging and/or overlooked during a sanitation cycle, resulting in microbial harborage and growth. It is important to fully assess cleanability and identify continuous improvements to facility and equipment design. Quality, food safety, and engineering professionals should spend time observing and possibly performing cleaning duties during the sanitation process to build a practical knowledge.

Principle #4: Effective Cleaning and Sanitation Procedures and Controls

Cleaning and sanitation need to always be effective. Effective and enhanced cleaning procedures have been proven to compensate for poor facility or equipment design until improvements can be implemented. Effective sanitation is critical to maintaining pathogen control in the plant environment. A standard protocol for cleaning with 7 steps has proven to be both efficient and effective in maintaining sanitary conditions. This approach will be discussed in detail in this section.

Principle #5: Environmental Pathogen Monitoring

Robust and effective environmental monitoring programs (EMP) measure the success of a dairy plant pathogen control program by assessing the conditions during and after production. EMP is a means to verify that your preventive controls, GMPs, sanitary design and sanitation programs are effective. An environmental monitoring program helps you understand your manufacturing environment and make improvements as indicated by the testing results.

Focusing on these five core principles provides consistent control and long-term stability for pathogen management programs. Users of this document will find it flexible enough to be studied completely or in sections, depending on the reader's interests and needs.

This environmental Pathogen Control Guidance is offered by the Food Safety Operating Committee of the Innovation Center for U.S. Dairy. It is part of a broad set of food safety education initiatives designed to strengthen manufacturing practices in all dairy processing facilities with the goal of reducing food safety risks.

More information regarding hands-on workshops and user resources is available at www.usdairy.com/foodsafety. Thank you for sharing in the industry's commitment to advance food safety performance every day.

The Food Safety Committee
Innovation Center for U.S. Dairy

INTRODUCTION

This guidance is intended to be applicable to dairy food processing settings that include both foods manufactured in wet processing conditions and low water activity foods manufactured in a dry processing operation.

DAIRY PATHOGENS OF CONCERN

A complex relationship exists between the microbiology of milk and milk products and their processing environments. Industry must understand the microbial ecology of processing environments and raw materials to implement proper controls that protect the safety of its products. The microbial diversity within a processing plant depends on and is directly influenced by various factors including raw materials, processes, products, workers' activities, infrastructure, and cleaning regimens. For example, rooms where raw milk is received, stored, and handled would exhibit a wider microbial diversity than rooms in which pasteurized or dry milk products are handled. If pathogens are present in the environment and not managed properly, unsafe food can be produced resulting in illness, outbreaks, and recalls.

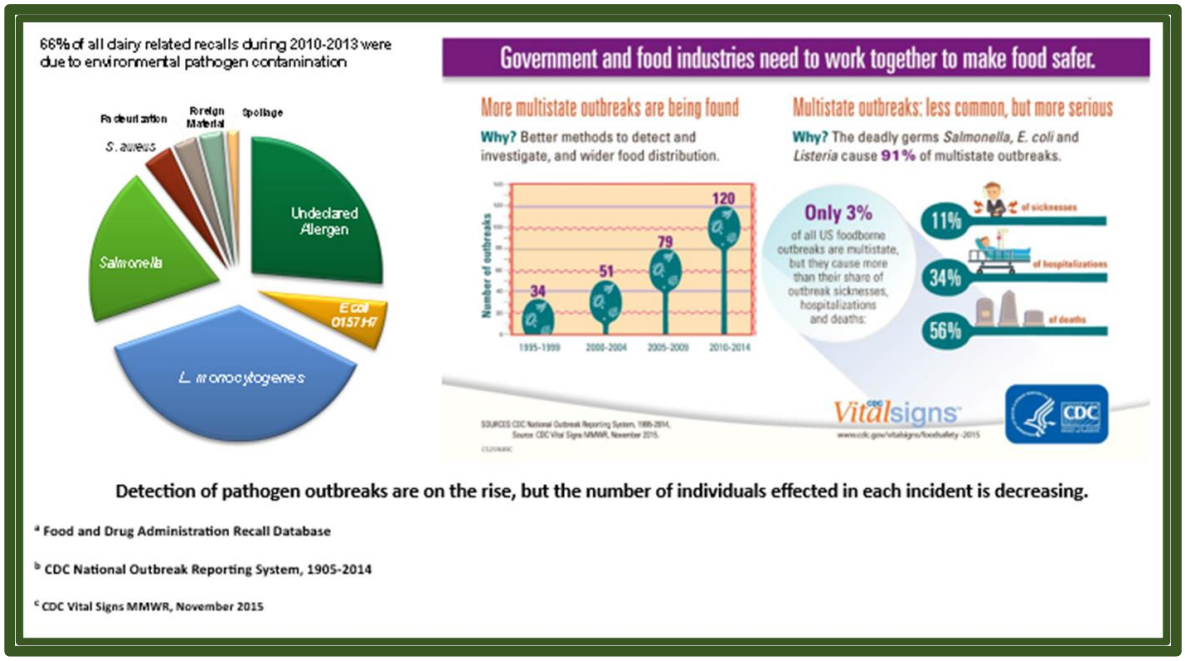


Figure 1. Pathogen Recall and Outbreak History

ENVIRONMENTAL PATHOGENS OF CONCERN

Only a few pathogens of concern associated with milk and milk products typically originate from the production environment: *Listeria monocytogenes (Lm), Salmonella* ssp. (subspecies) and most recently *Cronobacter sakazakii*. These pathogens often enter the plant via raw materials or from human traffic and once present have been widely reported to persist in processing plant niches for years and in some cases decades if proper controls are not in place. *Listeria monocytogenes* is one of the most virulent foodborne pathogens, with 20% to 30% of listeriosis cases resulting in death. Because *L. monocytogenes* grows at refrigeration temperatures and can tolerate a higher salt environment than other bacteria, it can be found in cool wet areas of the dairy processing plant where pasteurized products are handled and stored. These also include salty environments such as rooms and equipment where brine and salted cheese drippings may collect. In the absence of effective sanitation, *L. monocytogenes* can form strong biofilms which protect it from cleaners and sanitizers.

Salmonella and *C. sakazakii* are also environmental pathogens of concern primarily in dry dairy powder production operations. *C. sakazakii* is of particular concern when the dry dairy powder is intended to be used without further heat treatment in products intended for infant nutrition or immuno-comprised adults because it can cause sepsis (blood infection) or meningitis and, in some cases, death. These two pathogens share the same ecology and inhabit the same growth niches. They have been known to persist in dry dairy powder plant environments for many years.

Table 1. Quick Facts on Dairy Foods Pathogens of Concern

Pathogens of Concern	Cause of Illness	General Dairy	Low a_w Dairy Foods
Bacillus cereus	Ingestion of toxin	Yes	Yes
Cronobacter sakazakii	Infection	Rare	Yes
Listeria monocytogenes	Infection	Yes	Rare*
Pathogenic *E. coli*	Infection followed by toxin	Yes	No
Salmonella	Infection	Yes	Yes
Staphylococcus aureus	Toxin	Yes	Yes

*Can be a risk if mishandled during intermediate steps when foods or ingredeints become hydrated

OTHER PATHOGENS OF CONCERN FOR DAIRY

Other dairy pathogens of concern may include pathogenic *Escherichia coli (E. coli), Staphylococcus aureus (Staph aureus),* and spore forming organisms such as *Clostridium botulinum*, *Clostridium perfringens*, and *Bacillus cereus.* These pathogens are not typically tested for in the environment and are more associated with raw ingredients or lack of proper in-process/final product temperature control, which allows growth. Following the Pathogen Control Equation for control of *Salmonella*, *Cs*, and *Lm* will help maintain sanitary conditions with respect to these other pathogens of concern for dairy.

Table 2. General Characteristics and Growth Conditions for Pathogens Addressed in this Document

	Temperature Requirement °F (°C)							
Target organism	Minimum growth	Maximum growth	Optimum growth	pH	Water activity	Aerobic or Anaerobic	Spore former	Max. % water phase salt
Enterobacteriaceae	41 (5.2)	121 (49.4)	95-109(35-43)	3.7-9.5	0.94-0.99	Aerobe/Facultative anaerobe	No	8
Cronobacter	42 (5.5)	120 (48)	95-109 (35-43)	3.7-9.5	0.94-0.99	Aerobe/Facultative anaerobe	No	8
Salmonella	41 (5.2)	115 (46.2)	95-109 (35-43)	3.7-9.5	0.94-0.99	Aerobe/Facultative anaerobe	No	8
E.coli	44 (6.5)	121 (49.4)	95-104 (35-40)	4.0-10.0	0.95-0.99	Aerobe/Facultative anaerobe	No	6.5
Listeria	31 (-0.4)	113 (45)	99 (37)	4.4-9.4	0.92	Aerobe/Facultative anaerobe	No	10
C. perfringens	50 (10)	126 (50)	109-117 (43-47)	5.0-9.0	0.93-0.99	Anaerobe	Yes	7
C. botulinum • Proteolytic ABF	50 (10)	118 (48)	95-104 (35-40)	4.6-9.0	0.94	Anaerobe	Yes	10
• Non-proteolytic BEF	38 (3.3)	113 (45)	82-86 (28-30)	5.0-9.0	0.97	Anaerobe	Yes	5
Staph aureus • Growth	45 (7)	122 (50)	99 (37)	4.0-10.0	0.83-0.99	Aerobe/Facultative anaerobe	No	20
• Toxin	50 (10)	118 (48)	104-113 (40-45)	4.0-9.8	0.85-0.99	--	--	10
Bacillus cereus	39 (4)	131 (55)	86-104 (30-40)	4.3-9.3	0.92	Aerobe/Facultative anaerobe	Yes	10

International Commission on Microbiological Specifications for Foods. 1996: *Microorganisms in Foods 5: Microbiological Specifications of Food Pathogens.* Blackie Academic and Professional, New York.

QUICK FACTS ABOUT TOXIN-PRODUCING SPOREFORMERS

Clostridium botulinum and *Bacillus cereus* are the two toxin-producing spore formers of concern in dairy products. The ability to form endospores make them particularly heat resistant; therefore, they can survive pasteurization temperatures resulting in their presence in finished products. If dairy products are not formulated properly, cooled at an appropriate rate, and/or are temperature abused during or after production, these pathogens may grow and produce toxins in the product resulting in illness and potentially, death.

INDICATOR TESTING AND ITS ROLE IN CONTROLLING PATHOGENS

This guide will focus on best practices in monitoring the plant environment for pathogens. A key part of this program is indicator testing. Indicator testing is designed to monitor the effectiveness of plant sanitation and hygiene practices and can indicate where conditions are right for pathogens to grow, and/or if there is a loss of control in the plant environment. Indicator organisms require similar growth conditions as the pathogen of interest in the plant environment and may be within the same genus. They are a non-hazardous species but could represent larger groups of organisms. Monitoring for indicator organisms helps identify areas in the

plant where conditions could allow a pathogen to grow and allows for corrective actions to be taken before a pathogen issue exists.

In the US dairy industry, non-specific coliform testing is widely used to confirm sanitary condition of product and process conditions. Total *Enterobacteriaceae* (EB), is another useful indicator population because it includes all of the coliform bacteria plus additional Gram-negative organisms, such as Salmonella. While not an indicator organism nor specific for any particular organism, ATP testing (adenosine triphosphate; see glossary) is widely used as an immediate verification of cleaning and sanitation effectiveness before starting up production. ATP is left behind by most biological material, including bacteria, milk, animal tissue and plant residues. Elevated levels of ATP levels or populations of these indicators (coliforms or EB) may alert processors that special action or deep cleaning is needed before more serious issues arise. Elevated ATP levels, compared to established baseline levels, collected after cleaning may indicate that additional sanitation actions are needed before resuming operations. Testing for indicator organisms in the environment and/or finished product can be used to monitor and document the effectiveness of sanitation and zoning controls, and that the production environment has been maintained under hygienic control.

Indicator testing is not a replacement for pathogen monitoring; however, it provides supplemental information. Verifying that a processing environment is under control requires additional testing for specific pathogens of concern. See “Developing a Pathogen Monitoring Plan” section for more details.

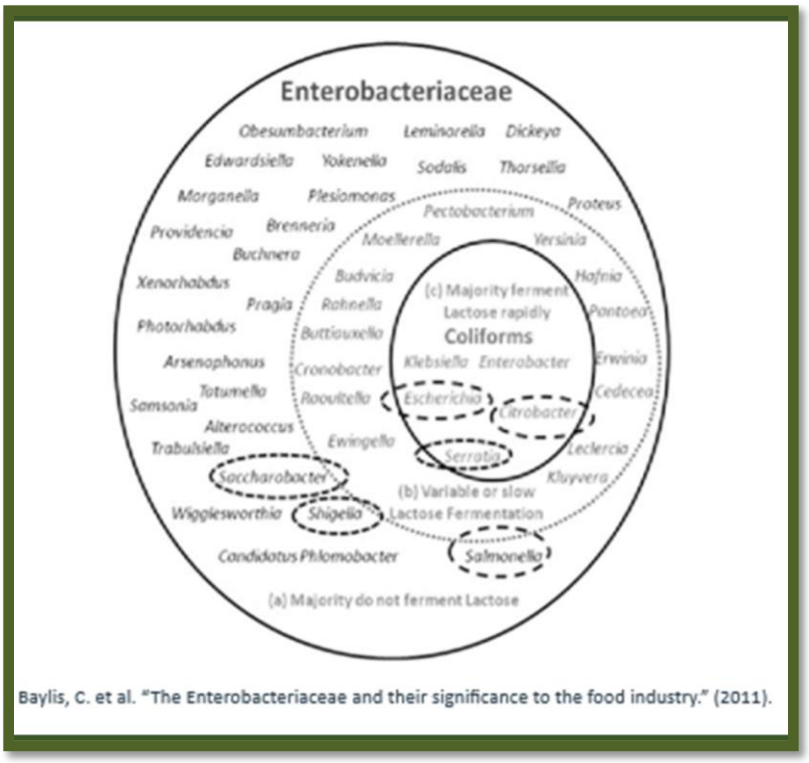


Figure 2. Total Enterobacteriaceae includes several species of gram-negative bacteria

THE ROLE OF FINISHED PRODUCT TESTING

Finished product testing alone does not ensure food safety. If finished product testing is conducted, it should be considered an additional layer of verification testing. Experts advise that processors focus on preventive controls and employ pathogen environmental monitoring to verify their effectiveness. Product testing alone is not considered effective as a means of verifying process control for many reasons, most notably:

- ✓ Pathogens are generally unevenly distributed within contaminated product and finished product testing may miss pockets of contamination.[6]
- ✓ Cross-contamination events are often sporadic in nature, meaning that only a small number of samples would be expected to be contaminated. The lower the incidence rate of contamination, the lower the probability that a sampling plan will be expected to detect a pathogen.
- ✓ The specificity and sensitivity of the testing assay is important to consider. Testing assays are not perfect and depending on the sample matrix, may be prone to false negatives or false positives. Therefore, using a test assay validated for the product matrix being testing is very important.
- ✓ Practical considerations for sampling. Generally, the more samples you collect and test within a lot, the greater your probability of finding a contaminant. In order to find contaminants at low incidence rates within a lot, the number of samples that must be collected to achieve high probability (>95%) of detection will be product limiting and costly.

SPECIAL CONSIDERATIONS FOR FINISHED PRODUCT TESTING IN DRY DAIRY MANUFACTURING

- ✓ Auto Sampler Reliability Calculator

  An autosampler reliability calculator is useful in determining the confidence level of finding a pathogen attained through a given sample size and production lot size. An example of a calculator is located in **Appendix D**.

- ✓ Sample Testing Size

  Sample size will be dependent on if there is a lethal step for *Salmonella* between sample collection, testing and the consumption of the product. See **Appendix E** for more detailed information.

HAZARD ANALYSIS AND PREVENTATIVE CONTROLS – FOOD SAFETY PLANS

Pathogens of concern should be identified as specific biological hazards controlled by your Food Safety Plans. Pasteurization is an effective control for all vegetative pathogens including *Listeria spp.*, *Salmonella spp.*, *E. coli, Staphylococcus aureus*, *Cronobacter spp.* In addition, some products may incorporate hurdles to pathogen growth such as pH, water activity, live cultures, antimicrobials/inhibitors, or formulating within prescribed formula boundaries (i.e., processed cheese). This guide focuses on preventing recontamination, through the Pathogen Equation, and should complement or be part of an existing Food Safety Plan. For a more complete understanding of Food Safety principles and application, please consult "References and Additional Resources" section.

REGULATORY IMPLICATIONS

In the U.S., the Food and Drug Administration (FDA) has established a regulatory "zero tolerance" policy for the presence of *Listeria monocytogenes* (*Lm)* and Salmonella in any RTE food (less than detectable levels in a specified sample size). FDA states that food can be adulterated by "yeast, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.[7]" This means that any refrigerated RTE food that tests positive for *Lm*, *Salmonella* or pathogen may be deemed adulterated and cannot be shipped or sold. Other pathogens such as Shiga toxin-producing *E. coli*, *Staphylococcus aureus*, and *Cronobacter sakazakii* should also be considered as part of any biological risk assessments.

The FDA's final rule on Preventive Controls for Human Food, stemming from the Food Safety Modernization Act, includes requirements for environmental pathogen monitoring based on documented risk assessment. Manufacturers will need to review the rationale behind their monitoring and testing programs, fully document activities, results, and corrective actions, and should be prepared to explain their program.

CONTROL OF PATHOGENS USING THE PATHOGEN EQUATION

PRINCIPLE #1: SEPARATE RAW FROM READY-TO-EAT

History has shown that there is a greater likelihood of finding spoilage organisms or pathogens in uncontrolled or raw manufacturing areas than in production or ready-to-eat (RTE) areas. Managing the flow of personnel, supplies, air, and equipment significantly reduces the potential for cross-contamination. Hygiene zoning to address this traffic flow is critical in controlling cross-contamination in product manufacturing environments. When establishing separations in food plants, it is important to understand pathogen survival and how it can be introduced into the environment and/or product.

Hygienic Zoning To Control Cross Contamination

Areas with raw, unprocessed materials should be physically separated from pasteurized product and processing areas and processing equipment. Raw milk should always be presumed contaminated, and pathogens can be present in other incoming materials or carried by people. Failure to control the flow of materials can lead to direct contamination, growth, and persistence in the environment. *Listeria, Salmonella, and Staphylococcus aureus* can be readily transported, transferred, and spread throughout a facility, where they may then find niches suitable for growth or biofilm formation. *Listeria* and *Salmonella* have been detected in almost every part of dairy processing plant including processing and packaging equipment, employees, facility structures, transportation equipment, bulk ingredient containers, maintenance tools, processing water, and pallets. It is important to determine all potential routes of pathogen entry into the processing facility. A mechanism to aid in controlling and reducing the flow of pathogens is hygiene zoning.

Hygiene zoning provides separation of hygiene levels in a plant based on the risk to finished products and their further processing requirements. It is applied to prevent cross over of pathogens from raw or un-processed areas to those areas where kill steps are applied, and the final product is packaged for later consumption (RTE) or further use in final products that may or may not have kill steps in place.

REMEMBER

Hygiene zoning *- is the process of creating barriers to protect areas and product of increased sensitivity from environmental contamination.*

Pathogen Environmental Monitoring zoning *– is different and is the act of defining areas of the plant to monitor for pathogens based on proximity to product and product contact surfaces. More information available on PEM zoning in* ***Principle #5***

Zoning requires the use of barriers. Most often these barriers are physical such as walls or curtains; however, in some locations, visual separation control such as use of different colored smocks by personnel is the only practical method. Zoning is only effective through proper training and disciplined actions, that eventually become routine and part of the food safety culture. General activities (examples: trash removal, lab personnel, leadership, etc.) associated with people's traffic patterns also require consideration as they should be controlled through hygiene zoning and job assignments.

When developing zoning it is important to understand the risks and sources of cross-contamination. Consider people's traffic patterns, supplies/material flow through plant, air and utilities, equipment movement, and planned and unplanned hygienic zone breaches. Anything transitioning through the plant should be included in a risk assessment to develop adequate hygiene controls for managing the transitions. The zoning concept can be employed to clearly separate wet from dry areas (critical in dry product operations), dirty from clean, raw from RTE, non-critical to critical processing steps, basic hygiene from medium and to high hygiene areas. There should always be an intermediate zone between a basic and high hygiene zone; a buffer which is often referred to as an airlock or hygiene junction room.

Establishing Hygiene Zones

Zone development can be complicated and overthought. Keep things simple, logical, and practical. The barriers must apply to everyone entering that zone. When developing zones consider who and what must enter the zone and how the airlock/junction room will impact job functions and tasks. Job assignments may have to be reviewed and modified for effective implementation of a hygiene junction. Installing a hygiene junction zone, in the end, reduces the amount of people entering the room since it takes more steps and efforts to complete entry and excludes some unnecessary entry.

In general, each facility determines how many zones are necessary to ensure food safety at the highest risk room of the process. Three zones are commonly used. However, four zones are common in facilities with high hygiene areas. The principle of hygiene zones tends to be universal, but terminology can vary among companies. Table 3 contains some common definitions of terms used to describe hygienic zones within a manufacturing plant.

Table 3. Hygiene Level (Zone names may differ by company, but processes that fall into each are typically similar)

Hygiene Level	Typical Processes
Critical; High Hygiene; Extra Care	Filler equipment, direct product contact or open product, no subsequent kill step
High; Ready-to-Eat	Wet filling rooms, pasteurized product, no subsequent kill step
Medium; Non-Ready-to- Eat; Basic GMP	Further heat treatment required, preliminary processing of product, possibly raw materials being introduced, corridors, pasteurizer rooms, and control rooms
General; Low	Warehousing and receiving, raw ingredient storage, maintenance
Raw	Raw milk silos, raw milk receiving

Traffic Controls

Pathogens can be readily transferred by the movement of people and materials and must be controlled by developing traffic patterns with strict controls based on the hygiene level of the facility. Staphylococcus is predominately carried and transferred by people so establishment of hygiene controls, especially handwashing programs, is crucial. This organism is most prevalent in high traffic areas or places where items are frequently handled/touched by hand.

A written facility flow diagram should be developed to define areas by their hygienic zoning requirements (e.g., general/low/basic, RTE, high hygiene, and transitional areas) that show human and material flows. Note: The terminology used may vary by individual company or with conformance to specific audit schemes (e.g., BRC, SQF). Good examples of diagrams typically include:

- ✓ Hygienic zone designations.
- ✓ Incoming materials and outgoing finished product.
- ✓ Personnel routes including: job responsibilities, entry/exit, breaks.
- ✓ Equipment and conveyor positions.
- ✓ Drainage and floor slopes.
- ✓ Rework handling.
- ✓ Usage and storage of cleaning equipment, utensils, spare parts, and tools.
- ✓ Waste collection and removal.
- ✓ Air flows should be considered with additional specific details mapped separately (air should flow from most sensitive areas to least sensitive areas).
- ✓ Potential areas at risk of a hygienic breach (Ensure documented plans are in place to manage breach and regain control).

Separation of raw product areas from finished product areas can be achieved by using barriers to restrict traffic. Physical barriers (walls, railings, transition benches) are the most effective choice, but separation can also be achieved through floor markings, transition spaces, floor sloping, drainage barriers, and controlled airflow. It is also possible to create separation through the use of "scheduling." This involves removing finished product before handling raw and then performing cleaning/sanitizing before reintroducing finished product. Other techniques to help maintain separation include footwear and uniform changes, use of smocks, pallet exchanges, and removal of outer/exposed packaging materials. Footwear sanitizing at transition points can also be a control measure. Fork trucks can also pose a challenge to separation of raw and RTE. If they are not segregated, fork truck wheel cleaning and sanitizing programs should be documented, executed, and audited.

It is recommended that drains are eliminated in sensitive dry areas to eliminate the risk of water introduction. If drains are present in dry areas, it is advised that they are covered or sealed. If drains in these areas are not covered it is important to establish a program to evaluate the drains periodically to ensure the p-traps maintain a level of water/sanitizer to ensure nothing aerosols into the room from the drain line and to prevent the drain from failing.

Traffic flows should be designed to avoid having people and equipment from different zones travel on common paths whenever possible. Consider routine, as well as occasional traffic, including forklifts, waste removal, Management personnel, QA personnel, carts, maintenance personnel, and sanitation activities. Include traffic flow on *all* shifts. Evaluate who does what and why along with the frequency of tasks. A best practice is to periodically review traffic flows to understand how people actually flow through the plant and make changes to limit or to improve traffic flows. Consider the traffic concerns associated with each zone:

Table 4. Hygiene Level and Mitigation Strategies

Hygiene Level	Mitigation Efforts
Critical	Room access restricted, shoe and/or clothing change from all other zones, keep dry areas dry, wet sanitation areas are kept dry during production
High	Room access restricted, shoe and/or clothing change from Medium or Low zone, limit water use
Medium	Limited access, shoe change from Low zone may be desired, controlled traffic patterns
Low	Isolate from processing areas and transfer of material to higher critical zones with care, normal locker access

Finished product areas should be protected from potential cross-contamination sources of pathogens such as raw materials, pallets, raw product bins, and cross traffic (product carts, forklifts, workers, invasive maintenance activity/tools). Consider zone designations for specific transport equipment (forklifts, pallet jacks, carts) and using only “first time” or properly maintained plastic pallets in high hygiene areas. A best practice is for maintenance to have dedicated tools and toolboxes for high hygiene/critical zones and separate tools for raw and RTE applications.

Storage areas should be separate and/or clearly marked to prevent co-mingling of raw and processed product. If storage space is constrained, processed product should always be positioned above raw to reduce the potential for contamination falling or dripping onto finished goods.

Color coding of smocks/coveralls, hairnets, shoes, and tools is a best practice for visual verification of raw/RTE to ensure personnel separation compliance and to prevent uncontrolled traffic flow through RTE areas.

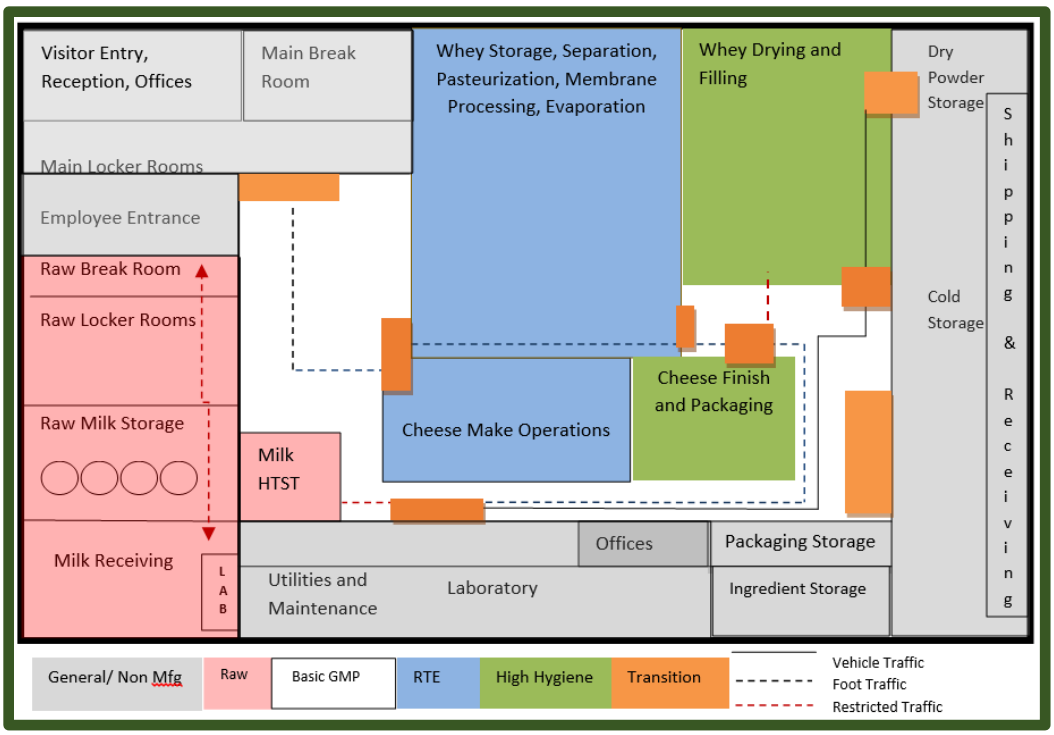


Figure 3. An example of dairy plant floor plan with traffic patterns mapped and operations segregated by hygiene requirements

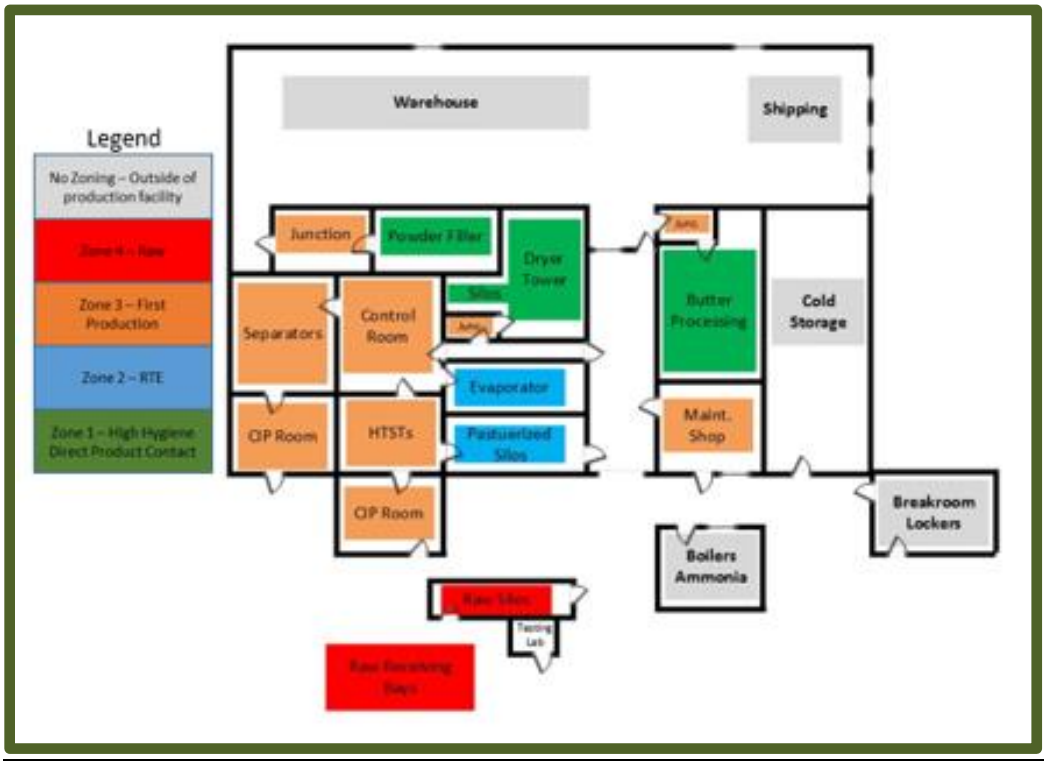


Figure 4. An example of a Powder and Butter operation with hygiene zoning and hygiene junction rooms/airlocks

Controlling Air Flow

Controlling air, both environmental and compressed, is very important to manage and monitor if good hygienic zoning is to be maintained. Best practices for controlling the air in a dairy processing plant are covered in more detail in **Principle #3 Sanitary Facility and Equipment Design**.

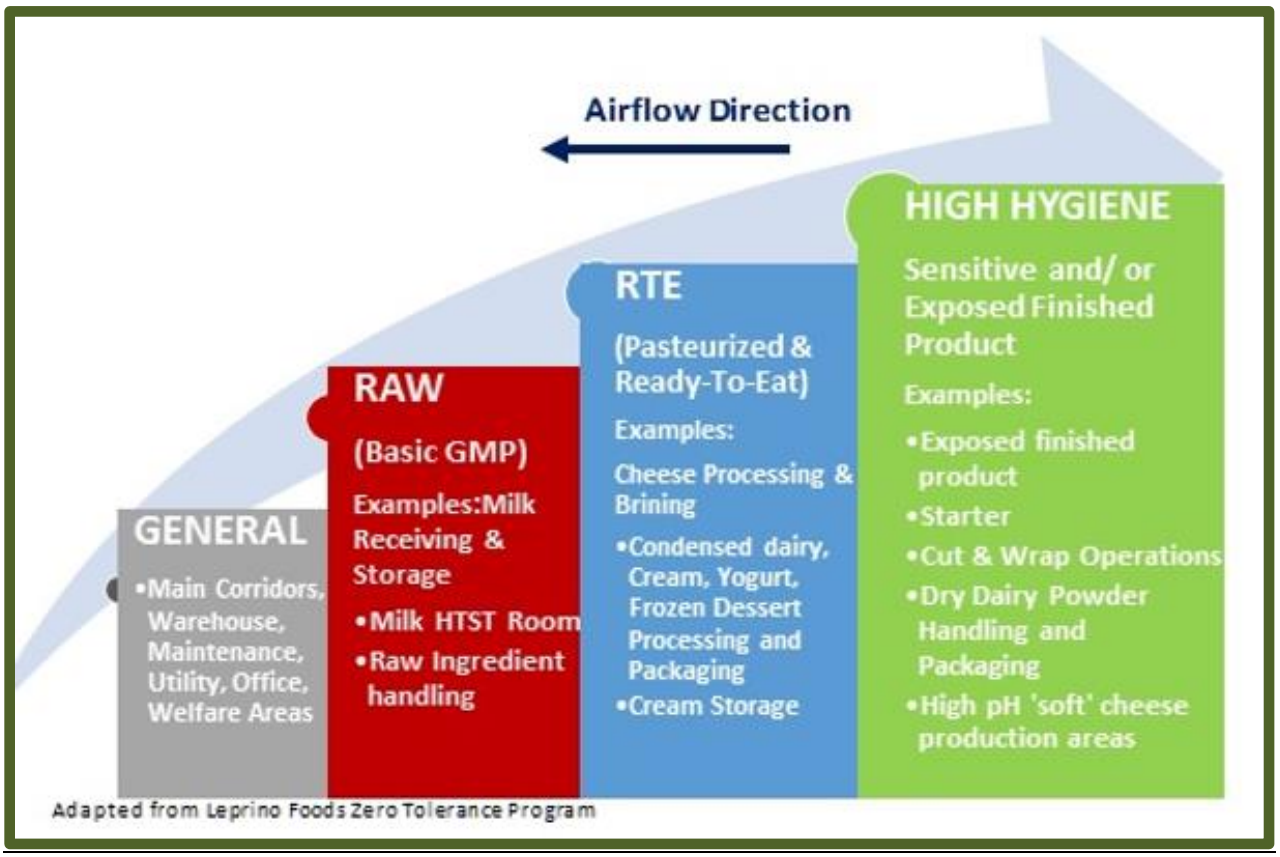


Figure 5. Air Flow based on Hygiene Zone for room air flow

Equipment and Tool Controls

Maintenance and/or installation of equipment should be handled differently based on the defined hygiene zone. Tools and equipment entering RTE, Critical and High Hygiene zones should be cleaned, sanitized, and inspected before entry. Alternatively, a captive tool program can be put in place to ensure that these areas have a designated set of tools required for any task required in that room. It is important to ensure that those tools are kept locked, clean, and part of a master sanitation schedule. All pathogens of concern need moisture to thrive and are also transient. New equipment should be evaluated to ensure it isn't a source of contamination before being brought into a manufacturing environment.

Captive Footwear

Captive footwear, or shoes that do not leave a dedicated area, can be an effective means of reducing pathogens into higher hygiene areas. Factors contributing to a successful captive shoe program include:

- ✓ Hygienic design of the captive shoe (a non-fabric shoe without laces is ideal)
- ✓ Cleaning frequency of the shoes and storage racking
  - Frequency and type of cleaning will be dependent on the environment in which the shoes are used (i.e., wet vs. dry)
- ✓ Cleanliness of the transition area floor
  - Ensure that separate tools (mops or brooms) are used on the higher hygiene side of the transition from the lower hygiene area to avoid cross contamination.
  - Alternatively, a clean mop can be used on the higher hygiene area and then used on the lower hygiene side thereafter.

Captive shoes and transition areas should be included in the environmental monitoring program to assess the efficacy of the program. Organisms to monitor for should include indicator organisms and pathogens of concern for the processing area. If pathogens are found on both sides of the transition and/or there is no reduction in indicator organisms, the program should be reviewed to insure employees are following the program as designed. Additionally, environmental monitoring can be a good indication if cleaning frequency and type of cleaning is sufficient.

Floor Mitigation Tools – Footbaths and Foamers

There are several floor mitigation tools, both dry and wet, that are available on the market today to provide effective control of foot traffic cross-contamination against all environmental pathogens of concern.

- ✓ Wet – Chemical Footbaths and Foamers

  Chemical footbaths and foamers can help to prevent entry of contamination from outside the facility and between raw and RTE areas via footwear. Foamers and footbaths must be properly designed and managed to be effective. Foamers can be very effective because they spray the fresh chemicals in a designed pattern at a designated frequency. Footbaths can also be effective, but they can become sources of contamination if not properly managed. Footbaths may be used where foamers are not an option, such as when a drain is not located nearby. Footbaths are designed to bathe the soles and sides of footwear as the employee walks through a pool of sanitizing solution.

  Chlorine and other chemicals dissipate and become less effective from organic loads due to traffic through the footbath, therefore the sanitizing solution must be frequently emptied and refilled with the proper-strength sanitizer. Footbath “mats” and surrounding floor areas should be cleaned and sanitized on a regular basis and footbath mats should be replaced if cracked or worn.

Remember

Manage doorways and transitions to reduce the risk of hygienic breaches from foot and vehicle traffic with floor foamers or spraying devices that are timed or motion triggered. Sanitizer solutions should be controlled to assure:

- *Depth of foam (2 inches to cover soles of shoes)*
- *Width to cover entire transition area*
- *Length to cover at least one full wheel rotation*
- *Concentration monitored to ensure effectiveness*
- *Proper foam structure to prevent rapid draining*

One concern within productions areas where wet sanitizers are needed is some areas are intended to be kept dry to limit the potential for *Listeria* or *Salmonella* growth. For low water use areas, a dry floor treatment such as alkaline peroxide or granular quaternary ammonium can be a useful solution; shoe changes or captive footwear may also be helpful.

- ✓ Dry – Chemical Foot Controls
  The dry floor chemical products are typically quaternary ammonia or alkaline peroxide-based powders. These products are typically not EPA registered sanitizers and frequently labeled as a disinfectant meaning they make no claim of their efficacy. The quaternary ammonia product in most cases requires moisture to activate efficacy. Conversely, alkaline peroxide-based products do not require moisture to become effective. These dry products are in direct-dry-floor applications or replace the liquid in foot baths at entrances or wherever mitigation is required but limiting moisture is beneficial. Your sanitizer chemical supplier is an important resource for identifying appropriate chemical controls.

<u>Thermal Inactivation</u>

Another method of first defense against pathogens for dairy foods is proper pasteurization, which kills most pathogen microorganisms of concern. Pasteurization often defines the transition of a material from "raw" to a "RTE" food. Once pasteurized, it is important to prevent post-pasteurization contamination of in-process or finished product. Industry history indicates several *Salmonella* and listeriosis outbreaks have been traced to post-pasteurization contamination from either the processing environment and/or contaminated ingredients.

For manufacturers adding inclusions (nuts, fruit, berries, spices, flavors, etc.) post-pasteurization into ice cream, cheese, yogurt, or similar products, it is also critical to make sure that those inclusions do not introduce pathogens. A documented supplier preventive control may be required based on a hazard analysis. An example of control for inclusions could be to require the supplier to perform some form of lethal treatment to control pathogens of concern and provide a Certificate of Analysis (COA's) for acceptable pathogen test results for these ingredients. For further details about supply chain preventive controls and supply chain programs please refer to Title 21 CFR Part 117 - FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food[14]. Supplier preventive control information is found in Subpart G.

PRINCIPLE #2: GOOD MANUFACTURING PRACTICES AND CONTROLLED CONDITIONS

Good Manufacturing Practices (GMPs), Personnel, and Behaviors

People are one potential source of cross-contamination as they interact with products and/or the manufacturing environment. Employees and visitors who enter production areas must be trained on GMP hygiene controls before entering, and everyone must always comply with designated practices. In addition, production facilities should have policies and procedures for identifying and excluding ill employees who present a food safety risk from working in food processing areas.

Handwashing is fundamental in any GMP program, as hands may come into direct contact with products and/or product contact surfaces. Hands must be washed before starting work, before entering production areas, when transitioning across hygienic zones, and whenever they may become contaminated or soiled. Examples include:

- ✓ After touching unclean surfaces, e.g., floors, the bottom of items which have been on the floor, outer packaging layers, pallets, waste cans, or other non-sanitized surfaces.
- ✓ After leaving the production area/line for any reason or visiting the restroom.
- ✓ After coughing or sneezing into hands or scratching/touching exposed skin.
- ✓ After employees go on breaks.

The use of sanitary gloves is common in manufacturing environments. While gloves minimize direct human contact with foods and shield employees' skin from soil, they must be cleaned and sanitized in the same manner as hands. Soiled or damaged gloves should be replaced as they could be just as contaminated as unwashed hands. As a best practice, hands should be washed prior to donning gloves.

Tools and utensils used in processing areas should be inspected, cleaned, and sanitized on a regular basis to avoid cross-contamination. Immediate cleaning and sanitizing are required if they have contacted non-sanitized surfaces including gloves, tables, equipment, walls, or floors.

It is important to wear clean uniforms, smocks, Personal Protective Equipment (PPE = safety glasses, bump caps) and footwear when entering processing areas. Footwear and uniforms for use in processing plants should not be worn outside the plant. Employees should change their uniforms at the end of each shift or more frequently if soiled. Sanitation workers should change into clean uniforms or coverings when transitioning from heavy cleaning to the sanitizing phase.

Note: PPE equipment should be donned prior to washing hands to avoid re-contamination after washing Also, ensure used PPE does not become a vector by providing proper disposal containers, removal area, and clear instructions on how to dispose of used PPE.

Footwear requires special attention to ensure that contamination is not tracked into the production facility. Footwear should be non-porous and designed to be easily cleanable, cleaned regularly, and replaced when cracked or worn. Avoid deep treads or cleats which are difficult to clean and sanitize and can allow microbial harborage or growth. Care must also be taken to balance cleanliness with functionality and personnel safety (slips and falls). Best practice is to issue visitors and contractors either disposable foot covers or sanitized reusable footwear. Document reused footwear as part of the sanitation program.

Maintenance and Repair Activities

Maintenance activities and any repairs of equipment, storage areas and other infrastructure in and around processing rooms should be done with adequate controls to prevent environmental contamination. Because maintenance staff and contractors work throughout the plant, sometimes in or near product zones, it is imperative for them to follow GMPs and take extra precautions to protect products and the plant environment. See "Maintenance Best Practices" box on this page and **Appendix C** – example construction plan and checklist.

Controlled Conditions

Floors, ceilings, walls, and other infrastructure should be clean, as dry as possible during production, and in good condition. Active care must be taken to reduce microbial harborage to prevent the growth and spread of pathogens:

- ✓ Floor grout, caulk, seals, and other joints must be maintained. Any deterioration should be repaired as soon as noticed to prevent creating pathogen harborage areas.
- ✓ Control and eliminate condensation. This is particularly important on or above open product, equipment, tanks, or conveyors. Condensate is known to cause contamination of product or product contact surfaces. Equipment and room temperatures should avoid dew point conditions.

Maintenance Best Practices

- ***Tools:*** *Implement a documented procedure to ensure tools are cleaned, inspected, and sanitized regularly. Tools used in RTE areas must be properly cleaned and sanitized. A best practice is dedicated, color-coded tools for RTE areas to minimize the likelihood of cross-contamination.*
- ***Equipment:*** *Implement a documented "Clean Before Use" program to ensure that product contact surfaces and food handling equipment are cleaned, sanitized, and inspected before placing back into service.*
- ***Hygienic Zones:*** *Maintenance and contractor employees who have worked outside the facility, in "raw," or waste areas, must change into clean plant attire prior to entering production areas.*
- ***Construction/Maintenance:*** *Work on floors and walls in or near processing rooms must be done with contamination controls in place and/or rerouting of traffic. A "Food Safety Construction Plan" (**Appendix C**) should be developed and shared with affected employees prior to major construction or renovations.*
- *See **Appendix C** — Food Safety Construction Plan SOP and Checklist*

Figure 6. Avoid contamination from condensation

> ***Remember***
>
> *Dairy plant operators must ensure that in-process products are handled with appropriate time/temperature controls. This is especially important during equipment downtime and reworking processes.*

- ✓ Overhead areas must be cleaned and sanitized at appropriate intervals. HVAC units should have easily cleaned cabinets and coils. Access to these units should be outside the controlled production areas or with a complete hygiene junction for anyone servicing them. Be sure to clean and monitor drip pans.
- ✓ The use of high-pressure water hoses and compressed air during production should be avoided to prevent movement of debris from non-product contact areas, such as floors, to product contact surfaces such as conveyors, shelves/boards used to age cheeses, packaging materials, or product vessels. Debris and spilled food should be physically removed or squeegeed to drains rather than pushed with a hose/water. Avoid creating liquid or powder aerosols that may be drawn into air handling systems. Duct work should be cleanable in the event aerosols are drawn into an air handling system.
- ✓ Water intrusions, e.g., roof leaks, leaks from upper floors, egress water should be treated as unplanned system breaches and can contaminate production areas or provide growth conditions and must be addressed as soon as evident. A best practice is to have documented plans for unscheduled events listed above so immediate action can be taken.
- ✓ Refer to Table 2 for the specific moisture and temperature growth requirements of each pathogen. Many dairy plants have adopted a “dry floor” policy whereby the use of water is severely limited during production to help control environmental pathogens. If wash down hoses are required during production, a good practice is to only allow sanitizer hoses to be used. In addition, most plants conduct interdictive (limited clean up between full sanitation cycles) cleaning at a predetermined frequency to limit nutrients for pathogen growth.

<u>Controlling Temperature and Humidity</u>

It is important to follow all time-temperature controls and protocols for ingredients, in-process materials, finished and processed products. Written programs should be in place to ensure compliance at all times including unplanned events, equipment downtime, and rework operations. Manufacturing plant temperature and humidity should be controlled at levels appropriate for each processing step and the products being produced.

Special Considerations for Dryer Production Areas

There are differences between wet and dry processing spaces. In dryer buildings and dry powder spaces, hot temperatures and dry conditions are better, with many dryer buildings operated at 110°F and less than 35% relative humidity (RH). In some drying operations, the building's condition can negatively influence the operation of the dryer by creating possible danger zones because of condensation formation in certain areas, such as baghouses and fluid beds. However, the conditions where dryers and powder storage areas operate the safest from a pathogen control perspective may not be ideal for the comfort of people working in these rooms.

Remote monitoring of operations in high hygiene areas via cameras and other indirect methods during operation is recommended. Operator "rounds" through these areas should be limited to what is absolutely necessary. Alternatively, venting, and other means of cooling those areas are recommended during non-operation or maintenance times in the building. It is also important to note that most dry powder buildings and other related spaces, especially in older plants, were not necessarily designed for wet washing. Special procedures for cleaning these spaces will need to be developed.

Training and Documentation

All dairy manufacturing employees should be aware of and trained on their role in controlling pathogens in the manufacturing environment and finished product. Training should occur upon initial hire, prior to new job assignments, and reinforced on a defined frequency, i.e., yearly. It is important to have a standard operating procedure (SOP), so everyone receives the same training. The SOP needs to be reviewed periodically to add or remove content due to changes in procedures or the process. Documentation and record retention of food safety training of employees is important to maintain and have accessible.

Key Points for Training and Documentation include:

- ✓ Awareness of *Listeria, Salmonella,* and/or other pathogens and the risk they pose to consumers.
- ✓ Understanding the importance of controlling the plant environment through effective cleaning and sanitation practices.
- ✓ Identifying, cleaning, and eliminating niche areas and potential harborage points.
- ✓ Preventing cross-contamination in the facility.
- ✓ The importance of controlling and remediating planned and unplanned system breaches.
- ✓ Identifying likely sources of pathogens in the processing/packaging facility and behaviors that might spread pathogens in the plant environment.
- ✓ Encouraging an effective environmental monitoring program and detection of pathogens in the environment when they are present. Detection should never be discouraged.
- ✓ Understanding the pathogen control practices and GMPs relevant to the specific job the employee will be performing.

PRINCIPLE #3: SANITARY FACILITY AND EQUIPMENT DESIGN

Proper sanitary design of facilities and equipment is an important and proactive step in environmental pathogen control. Proper design and maintenance will reduce risks and reduce the ongoing efforts required to assure effective cleaning and sanitation. Ideally, facilities and equipment will be designed for optimal cleanability with minimal potential growth niches or harborage sites. Harborage sites are locations in the facility or on equipment where pathogens may survive the actions of cleaning and sanitation. A growth niche is a harborage site whose environment is suitable for growth of a microbial hazard. Older plants and equipment may require modifications and upgrades to meet good sanitation standards and some equipment will require full disassembly for proper cleaning. Standard Sanitation Operating Procedures (SSOPs) must be written to compensate for any design/condition deficiencies. See **Appendix A & Appendix B** for Equipment Design and Facility Design Checklists.

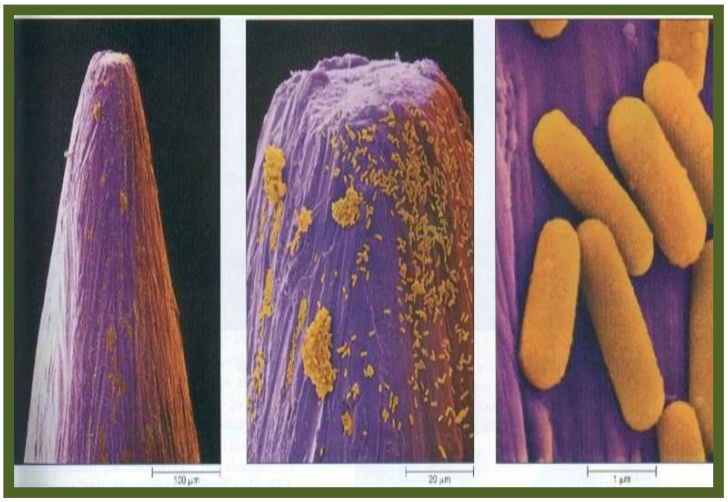


Figure 7. Size of bacteria compared to a pin head

Bacteria are very small (about 0.001 mm), making any crack, crevice, or gap a potential harborage location.[8] Without adequate control programs, pathogens may grow and become entrenched in any equipment or plant areas that might trap moisture or food debris. Areas known to harbor pathogens include drains, cracked floors, condensation on walls/ceilings/pipes, damp pipe insulation, hoist chains, unsealed electrical conduits, wrapped/bundled cords, sandwich joints, electrical/hydraulic junction boxes and pockets in poorly epoxied floors. Almost any equipment can harbor pathogens. Examples that have been historically associated with *Listeria* species include cooling units, drip pans, difficult-to-access surfaces, difficult- to-clean pieces of equipment such as conveyors, motor housings, bearings, undersides of equipment, pallet jacks, forklifts, and

seasonal/limited-use equipment. Design details/workmanship considerations include welding seams, cracks in stainless steel, washers, bolt threads, hollow rollers, hollow framework/legs, overlapped materials, and press-fit parts. *Salmonella* and *Cronobacter sakazakii* survive in dry conditions and have been found in floors and on equipment.

Sanitary Facility Design Considerations

Both the 3-A Sanitary Standards[9] and the Pasteurized Milk Ordinance[3] (PMO) provide good references for design. Both were developed by the dairy industry working with State and Federal regulators and offer excellent guidance for fluid (and dry) products and "inside the pipe" processing considerations. There are also a number of situations and equipment types that do not fit the formal standards and sometimes equipment that meets the 3-A and/or PMO standards have sanitary design flaws that need to be managed. For these cases, a series of Sanitary Design Principles and checklists (**Appendix A & Appendix B**) have been developed and refined by industry professionals working with the North American Meat Institute (NAMI), Grocery Manufacturers Association (GMA), and the Innovation Center for U.S. Dairy (IC). Following these guides will help to ensure that infrastructure and equipment can be cleaned, sanitized, and inspected with minimal degradation from repeated exposure to food and cleaning/sanitizing chemicals or excessive temperatures.

High-level design considerations include:

- ✓ Equipment and facilities must be cleanable and resistant to deterioration by cleaning/sanitizing chemicals.
- ✓ Facility design should address separation of raw from RTE areas.
- ✓ Cleaning type (wet vs. dry) and frequency (daily, weekly, etc.) influence design. For example, packaging equipment placed in a wet-cleaned room must be completely wet-clean capable.
- ✓ Silo storage (e.g., raw milk) may need to be in well-ventilated, completely wash-down capable rooms. Silo/wall interfaces must be sealed and well maintained.
- ✓ Freezers and coolers must be cleanable after spills. Condensate must be minimized and controlled.

Guidance by specific design area includes:

- ✓ Floors

Floors should be constructed to prevent harborage, impervious to chemicals and water, easily cleanable, resistant to wear, and resistant to corrosion. Proper design and maintenance of floors and drains is critical to prevent moisture accumulation and associated microbial growth.

Floors in wet-washed areas should prevent pooling and be appropriately sloped to a drain. All floor joints and cracks should be sealed. Tile, dairy brick, or vitrified tile (a special brick with smaller pores) are recommended in areas with heavy equipment traffic or high temperature liquid exposure. A minimal grout line is preferred as it prevents premature degradation when exposed to water and/or chemicals. Worn or missing grout should be immediately addressed to protect the subfloor underneath and prevent water from seeping underneath and becoming a harborage spot for bacteria. Flooring professionals can perform a "tap-test," which is a technique where tiles are tapped with a solid object, resulting in differences in audible tone. Experience with this method allows the expert to determine floor conditions including floor tile delamination from the subfloor. This information is mapped to set maintenance and replacement plans. Monolithic floors

(e.g., urethane or epoxy-coated) require maintenance for any cracking, lifting, or peeling, and deficiencies must be addressed quickly to eliminate harborage points. Expansion joints should be limited in number, but sufficient enough to prevent cracking. Closely monitor junctions and points where equipment is mounted to the floor. Pyramid bases (structures with a square base and four sloping triangular sides that meet at one point) around equipment legs and feet are not recommended because water, food, and bacteria could get trapped under and inside the pyramid.

The best flooring material for your application will vary based on multiple factors. A qualified professional should be consulted to determine the best type of floor for each situation. Flooring considerations include:

- Are the current floor materials/grout resistant to chemicals used in the area? Are they cleanable?
- How often is the floor wet? What chemicals are used? What temperatures are they exposed to?
- What kind of and how often is heavy equipment traffic (forklift, pallet jack, etc.) present? Are there safety concerns with the type of flooring (i.e., slip concerns on some monolithic floors without grit)?
- Will pallets be placed on the floor that may cause damage from nails or scraping?
- How much does equipment in the area vibrate and how often?
- How much does the equipment weigh and are special reinforcements needed?
- What kind and amount of maintenance is needed for the floor?

All vertical and horizontal joints, such as floor-wall junctions, coving, and pillars/beams must be sealed. These surfaces should drain freely and have no pockets, ledges, nooks, flat surfaces, or 90-degree angles. Columns wrapped in stainless steel should be sealed at the top and bottom; painted columns should also be sealed, and no flaking paint should be present.

Design and maintenance of non-production floors is also important to prevent harborage points for bacteria. Concrete surfaces should be free of pits, erosions, and voids. Floors should be solid, smooth, and sealed at wall junctions. Exterior walls should have an 18-inch inspection zone at the floor/wall junction designated and cleared from obstruction. This zone is often painted white.

✓ Drains

It is well-known that water drains "breathe," meaning aerosols can be created by moving water within a drainage system, which can rise out of drains and be carried by air currents to surrounding areas. Since pathogens can survive in drains, these water aerosols can carry pathogens up and out of drains and into the production environment; therefore, drains must be readily accessible for routine inspection, cleaning, sanitation, and environmental swabbing.

Individual drains should have a cover that does not require tools for removal; access to the drainpipe should not be permanently blocked. Removable baskets may be used to catch particulates to minimize wastewater solids loading. Round drains (versus square or rectangular) are preferred because they do not have corners or edges that can collect soil (See Figure 8).

Figure 8. Drains

The inside of the drain should be structurally sound with no rough edges or pinholes. If a two-piece drain is used, it should be continuously and smoothly welded. Trench or channel drains are not recommended due to increased surface area that must be cleaned, covers which are often difficult to remove, and multiple junctions which can collect debris or develop pinholes. Drains should be supported with a robust floor foundation to prevent settling. Where possible, cleanout access should be installed outside the processing area and floor cleanouts avoided whenever possible and as allowed by code. Please contact the correct local, state, and federal regulatory body to ensure your facility drain layout is being planned to code. In USDA dairy plants, there must be a drain (trapped) in the bottom floor of both dryer buildings and powder packaging rooms. The ones located in the floor foundation should be capable of being sealed and capped. In multi-level dryer buildings that are operated for multiple weeks or even months at a time, it's not practical to have trapped drains that are connected to the underground plant sewer system. Care needs to be taken that these are laid out properly to ensure drainage and dry out between the CIP intervals of the dryer and building. In no cases should drains in the upper levels of a dryer building remain connected to the underground system during processing. In new construction, drain placement and where drainage can occur needs to be considered. For example, drains should be placed away from frequently accessed components in the dryer such as fluid beds and sifters. Other considerations need to be given for wash down hose stations, their placement and use during dryer operations. For example, wash down stations in dryer operations should be configured to go directly to a drain and minimally used if possible, during production.

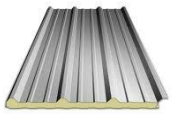
An accurate drain map that includes all drain line distances, pipe diameters, and drain locations is an invaluable tool when researching operational problems. The map should be updated with facility expansions. This map is also helpful to ensure drains remain accessible when laying out equipment and other materials throughout the room. Raw process and RTE process wastewater lines should be separated. All discharges from equipment in an area, such as from clean-in-place (CIP) skids and balance tanks, should be calculated and factored in the design to limit the potential for pooling. If using a wastewater treatment facility, chemical restrictions may change the amount of water used. All equipment sinks, and COP tanks discharge should be piped directly to a drain with an appropriate air-break or backflow prevention device instead of draining onto a floor.

Maintenance of drains and drainage systems is extremely important as biofilms can form in the drains if they are not cleaned and sanitized properly. Written drain cleaning program and procedures are essential documentation. In addition, as drain backups are an unexpected potential source of large-area contaminations, procedures around special cause cleaning, sanitizing, and controlling future contamination should also be established. Planned maintenance activities such as water jetting, snaking, pit pump-outs, and other drain repair work must have a "food safety construction plan" (See **Appendix C**) outlining control of aerosols, equipment used during the maintenance, foot and vehicle traffic, and the surrounding environment prior to beginning work.

✓ Walls, Ceilings, and Junctions

Walls, ceilings, and structural supports should be constructed to avoid any moisture or nutrient accumulations. Construction materials should be hard, non-porous, smooth, and able to withstand the environmental, cleaning, and sanitation conditions in the area. Suspended ceilings should be smooth, cleanable on both sides, and have a uniform height. ***Promptly correct any roof or water leaks with containment, cleaning, sanitizing, and identifying when and how the leak occurred.*** Environmental monitoring should be initiated and/or increased after any leak to gauge and monitor contamination risk and determine product disposition. Documentation of all actions taken, environmental test results, product decision as well as corrective and preventative actions need to be written.

Table 5. Examples of infrastructure options commonly found in food manufacturing facilities

Material	Typical Use	Pros	Cons
Glazed Cement Masonry Unit (CMU, or a block wall with a glaze)	Walls 	High structural integrity, impervious to a wide variety of chemicals	Expensive, difficult to replace, regrouting necessary (peeling, chipping possible)
Insulated Metal Panel (IMP)	Walls or ceiling 	Cheaper than glazed CMU, insulation properties, mid-range durability; can be used as a walk-on ceiling	Insulation is exposed if metal is damaged, floor to wall junctions can be challenging. Caulk must be replaced periodically due to significant panel flexing from wind shear or other building movement.
Fiberglass Reinforced Panel (FRP)	Walls or ceiling (whole panels or cut as part of a T-bar ceiling) 	Inexpensive, easy to install and replace	Backing wicks moisture, easily damaged; **not recommended**
Painted concrete, steel, etc.	Walls, ceiling, structural support	Easy to implement; durability dependent upon environmental conditions and paint type	Flaking paint could be a foreign material risk; various levels of maintenance required; can create niche harborage points
Stainless-steel filled with concrete or mounted against a wall	Walls, structural column support, silo/building interface	Stainless is cleanable and impervious to a variety of chemicals	Covering of wall or ceiling surface with stainless steel sheets creates harborages and is not recommended

Vertical surface-to-floor junctions should have a cove (rounded edge) and be free of pits, erosion, and voids. For tiled surfaces, grout should be maintained to prevent moisture from wicking behind the tiles. If stainless steel is used on walls or pillars, such as in a tank alcove or behind a COP tank, seals should be maintained.

Expansion joints in walls may be necessary for structural integrity and should be maintained with an appropriate sealant. Closed cell or encapsulated insulation should be used where possible in infrastructure and pipes. All insulation must be sealed at the ends to prevent moisture from being wicked. Junctions should be seal-welded where possible, threaded surfaces should be minimized, and all-thread rods should not be used. All utility lines and supports should be configured to prevent foreign material accumulation, be accessible and cleanable.

✓ Interior Space Design

Several factors should influence the design of interior spaces including overall traffic flow, equipment locations, and utility placement. Controlled flow of employees, contractors, and visitors through the facility should be established. To prevent cross-contamination, the sanitary transport of packaging materials, ingredients, and rework into RTE/high hygiene areas should be consciously designed as discussed in "Principle #2 Good Manufacturing Practices and Controlled Conditions" section. Methods for the sanitary removal of trash from high hygiene areas should be established and followed. Trash collection sites should be properly located, maintained, cleanable, and cleaned regularly. It may be necessary to design specific employee access and practices to avoid potential cross-contamination. In addition, this area should be monitored as a potential source of pathogen contamination that may be tracked throughout the facility.

There should be sufficient access to accomplish cleaning of building elements (columns, beams, bracings, etc.) and floor/wall interfaces. The equipment and facility layout should allow for access to overhead areas (ductwork, lights, etc.) for inspection and cleaning. Stationary equipment should be elevated sufficiently to allow cleaning and sanitizing underneath the equipment, and aisles should allow sufficient space for maintenance and sanitation access.

Remember

*Horizontal piping and conduits should **not** be installed above exposed product or processing equipment, because they could introduce foreign material hazards and may present cleaning and sanitizing challenges.*
Piping should be insulated to prevent condensation when its surface temperature is below the room's expected dew point.

✓ Cleaning and Sanitation Infrastructure

Automated cleaning systems, clean-in-place (CIP) and clean-out-of-place (COP) should be considered in facility design to ensure effective cleaning and sanitizing of equipment. Water temperature, flow, and pressure must meet specified requirements at the point of use to be effective. Final rinse systems are operated at city water pressure (generally 60–100 PSI) to limit the overspray and aerosol creation that is possible at higher water pressures. CIP skids should drain directly to a drain, not onto the floor. Be certain to leave a break for backflow prevention of at least 2X the pipe diameter. The backsplash behind COP tanks must be resistant to the chemicals used in the tank. Flooring material should be resistant to the moisture, high temperatures and chemical concentrations associated with CIP cleaners. For safety reasons cleaning chemicals should be stored and segregated based on compatibility. Methods for spill

contamination should be written with needed supplies in the proximity of chemical storage, especially chemical barrels, and spills should be cleaned up immediately. For personnel and food safety reasons, rooms should be designed with sufficient ventilation and air exchanges for chemical vapor and humidity control.

Frequent repairs of rooms dedicated for cleaning and sanitizing operations may be needed due to the infrastructure degradation because of chemical exposure. Caulking, grout, and other sealing materials are weakened by elevated temperatures and chemicals. To obtain good seals, repairs should be scheduled when the area is completely dry and proper cure time is available. CIP units and circuits require ongoing inspection and repair of leaks (lines, gaskets, and valves) to ensure proper in-place cleaning is achieved.

✓ Exterior of the Facility

The outside of the facility must be maintained so that it does not become a potential source of environmental contamination. Pathogens and other contaminants can enter a facility through damaged infrastructure, leaks, and be carried in by dust, animals, birds, or insect pests. Examples of items for consideration for exterior facility design are listed in Table 6.

Table 6. Exterior facility design considerations

Structural	Traffic patterns	Additional considerations
Roads/walkways/parking lot surfaces— smooth, intact, no standing water, water drainage away from building.	Employee entrance, break rooms, etc.	Vegetation control—nothing touching building, 18" minimum, vegetation on grounds chosen to not attract insects or rodents
Walls - solid, no cracks or voids, intact caulking from utility penetrations and between panels	Visitors, trucker, and construction contractors	Site security—fencing, adequate lighting
Roof—solid, flashing intact, canopies closed, no pooling of water	Controlled vendor delivery—uniforms, vending machines, chemicals, etc.	Pest control—no visible pests, no nests, insect-attractant lights away from building
Man & dock doors, windows, louvers, fans, vents sealed and locked	Accommodation for equipment that may go outside or into trucks/trailers	Garbage control—no loose trash on-site, adequate receptacles
Finished floor elevation higher than adjacent grades to prevent storm water ingress		On-site pallet and tractor-trailer control positioned to prevent unsanitary impact

Utilities

Utilities interact with food products in many ways and must not be overlooked as potential sources of contamination. The PMO[3] provides excellent guidance on the design needs and requirements of utilities setup and can be referenced for best practices.

✓ Potable Water

Potable water can be sourced from a municipal or private well location. Typical potable water setups contain a main backflow prevention device that should be inspected and documented at least annually. Additional point-of-use backflow prevention devices, or an air gap at least twice the diameter of the water supply inlet, should be set up to prevent cross-contamination of potable water supply with untreated or wastewater. A map to identify the locations of these devices in each processing facility is recommended. Boilers used for culinary steam production may be treated with chemicals to reduce water hardness, but only use chemicals approved by 21 CFR 173.310. Point-of-use filters should be used when water is added as an ingredient to the product or direct contact rinse water. Periodic microbiological and heavy-metal testing of water collected at various sample points throughout the facility should be conducted. Specific requirements are in place for water that comes in contact with Grade A pasteurized milk and/or milk products. This can be considered a best practice in any operation where water contacts the finished product or finished product contact surfaces (excluding during CIP). Such water is required to meet "pasteurized equivalent" standards as outlined in the PMO. The PMO, local, state, or federal regulations may drive additional requirements. A company's water testing program should be a written policy with all test results and corrective actions documented.

✓ Cooling Water

Cooling waters have been identified as a potential contaminant and need to be controlled. Recirculated water used for cooling should be tested at least semi-annually to ensure it meets internal microbiological standards. Freezing-point depressant chemicals (salt, glycol, etc.) must be either USP food grade or have Generally Recognized as Safe (GRAS) status unless systems meet specific design requirements set forth in the PMO. Reclaimed water from heat exchangers, evaporators, and membrane processes (Condensate of Whey or "COW water") may also be used for cooling in some applications. Controls must be in place to prevent cross-contamination, such as maintaining pressure differentials between the product and cooling water streams (i.e., higher pressure on the product side compared to the cooling water side) at all times.

Compressed Air and HVAC

✓ Compressed Air – Product Contact

Compressed air can also become a risk if it is not adequately designed for food manufacturing applications. The PMO and 3-A provide design standards for compressed air systems.[10] Compressed air for food contact surfaces or product shall utilize inline, point of use, HEPA filtration. This includes, but is not limited to, air-blows for lines, air incorporated in the manufacture of ice cream, baghouse pulsing systems, and airlock seals. Upstream of HEPA filtration on compressed air systems, an oil and water filtration/elimination system should be in place. Filtrations should also remove smaller particulate matter down to 0.01 micron at greater than or equal to 99.99% dioctyl phthalate (DOP) efficiency and microbial contamination down to 0.01 micron at least 99.9999% DOP efficiency with a sterile air filter.[11] This air will ideally have a dew point of -40^{o} F.

To mitigate the risk of aerosolizing environmental dust or other contaminants, compressed air drops in filling rooms or around exposed product should never be used while in production mode. It is strongly suggested to have a written program of periodic checks that are documented to ensure the air drops do not become a source of contamination.

✓ HVAC

It is important to reduce the risk of dust and contaminants migrating to higher product risk areas. Air pressure can be used to mitigate and control dust and contaminants. More details in "How to Control the Air" section. As a general guideline, room pressure is used to cause air to flow from high hygiene > RTE areas > raw areas (See Figure 9). A pressure gradient of 0.1 inch or 15 Pa may be sufficient. Air filtration must be in place to reduce potential microbial contamination. The micron size of filtration is determined by the microbiological sensitivity of the product manufactured in the area. If the product is sensitive to mold, HEPA filters may be required for quality reasons. In areas where products may not be exposed or are hot processed, MERV 14 filters may be adequate. Seven to ten air exchanges per hour are the minimum recommended; products sensitive to mold and areas considered sensitive may require significantly more (See Table 7 for additional guidance).

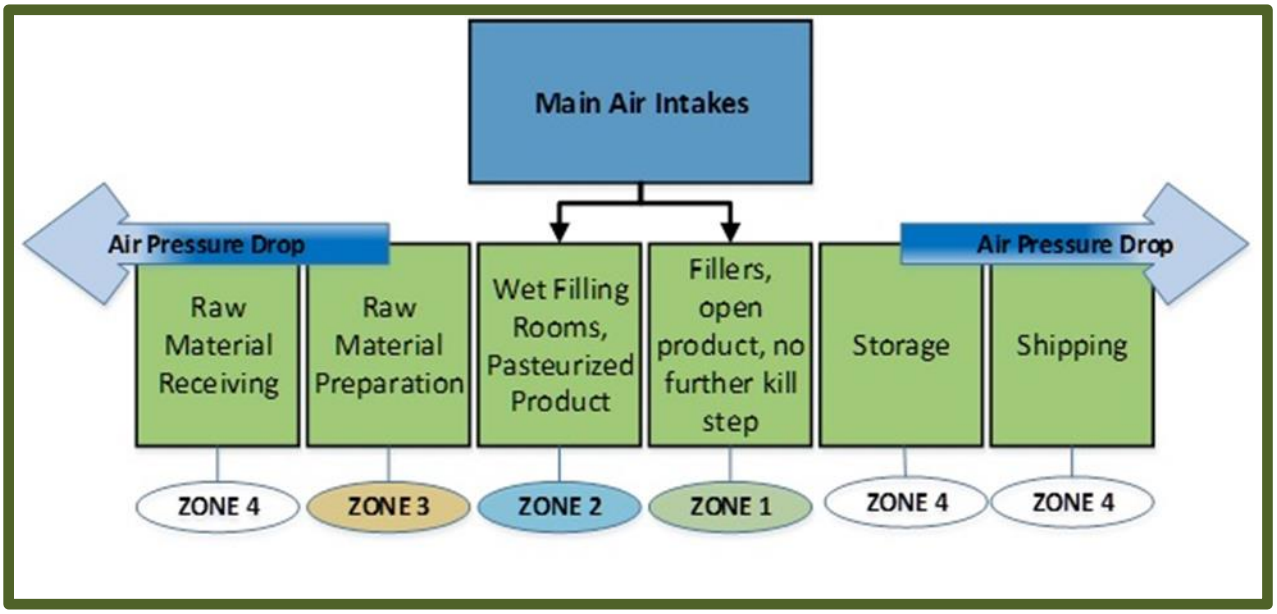


Figure 9. Zoning. Facilities should be zoned to prevent cross-contamination from raw to finished product. This figure includes airflow direction (controlled with room pressure) from high hygiene to general hygiene areas.

In some situations, dedicated HVAC/refrigeration systems may be needed to control specific zones:

- Dehumidification controls for high moisture areas (e.g., COP, batching/cooking areas) to reduce the potential for bacteria growth on surfaces or condensation formation. It is important to pipe these units in a sanitary manner directly to a drain.

- Portable HVAC/filtration units for areas with an increased likelihood of containing contaminants such as air from construction areas. These areas should be lower pressure than surrounding areas and the air should be vented or filtered.
- HVAC units may have a setting used to vent moist air to the outside during environmental sanitation cleanups. It is best practice to maintain positive air pressure in RTE areas during all phases of production and sanitation.

Table 7. Examples of air filter recommendations hygiene level

Class	Application	US ASRAE 52.2 (1999)	EU EN779 (2002)	BS 3928	Controlled Contaminant
ULPA Filter	Super Clean rooms			U17	> 0.12µm
				U16	
				U15	
HEPA Class	Clean Rooms	Merv 20	H14		> 0.3µm
		Merv 19	H13		
		Merv 18	H12		
		Merv 17	H11		
		Merv 16	H10		
Medium Class	Concerned Commercial and Industrial	Merv 15	F9		0.3 - 1.0µm
		Merv 14	F8		
		Merv 13	F7		
		Merv 12	F6		1.0 - 3.0µm
		Merv 11	F6		
		Merv 10	F5		
		Merv 9	F5		
Pre-Filter Class	Gross Filtration	Merv 8	G4		3-10µm
		Merv 7			
		Merv 6	G3		
		Merv 5			
		Merv 4	G2		> 10µm
		Merv 3			
		Merv 2			
		Merv 1	G1		

The amount of air exchanges in a room are also critical. Over pressurizing the room requires exhaust to balance room air and ensure adequate air exchange achieved. In High Hygiene areas the FDA specifies 20 to 25 air exchanges per hour. Where feasible the relative humidity should be maintained to best control fugitive dust and temperature below 78°F (26°C) in high hygiene zoned rooms with a rH<35%. Too low or high of humidity in dry powder packaging rooms allows fugitive dust to adhere to structures. Air pressure differentials from a clean area to a less clean area should be 0.03-0.05 inches of water to help reduce the introduction of contaminants. Mapping the air movement throughout the facility helps determine at risk locations. When mapping air flow, include intakes, exhausts, filter sizes, flow (laminar/turbulent), velocities (CFM), and pressure drops between buildings.

Controlling Air in Dry Dairy Operations

Controlling environmental pathogens in dry operations involves controlling factors they need for growth/survival such as food (milk powders) and water. Dust from milk powder is difficult to control, however efforts should be taken to minimize leaks and spills. In dry dairy processing environments controlling or restricting water use can reduce the ability for environmental pathogens to grow.

In powder operations where the operation/facility is meant to be kept dry it is important to consider placement of hose stations and CIP connections. Hose stations should be designed so that each unit has a main shut off in the event it leaks. Hoses can be removed while in operation and reinstalled when periodic cleaning is due. Quick disconnect on such hose station make this process more feasible. Removal of the hoses during normal operation prevents personnel from applying water to the environment when unwarranted. In dry areas where water use cannot be eliminated, the design of adequate draining becomes increasingly important. Drips pans may be necessary and routed to drains to ensure water is not introduced into areas it is not wanted. Placement of safety showers, eye wash stations, and hand wash sinks need consideration as well and any leaks must be corrected in a timely manner. Condensation from product or glycol lines can be addressed through proper routing through the facility or by adequate insulation. Insulation should be installed in a manner to ensure it is free of cracks and crevices, is wrapped with protective moisture barrier material, is inspected periodically for integrity, and is on a Master Sanitation schedule.

In addition to air used for drying, the overall air balance of the dryer building and its relation to adjacent spaces needs to be considered as illustrated in Figure 10. A simple air balance needs to be completed that considers both operating and non-operating dryer conditions. The example below shows that there is a difference in the air needed by the building HVAC system of 7,200 CFM between operating and non-operating states of the dryer. The dryer and HVAC should interface via the plant SCADA (Supervisory Control and Data Acquisition) system and the HVAC system should have the ability to control air flow based on the pressure setting of the dryer building. This will prevent excessive over pressure events to the dryer building and adjacent spaces.

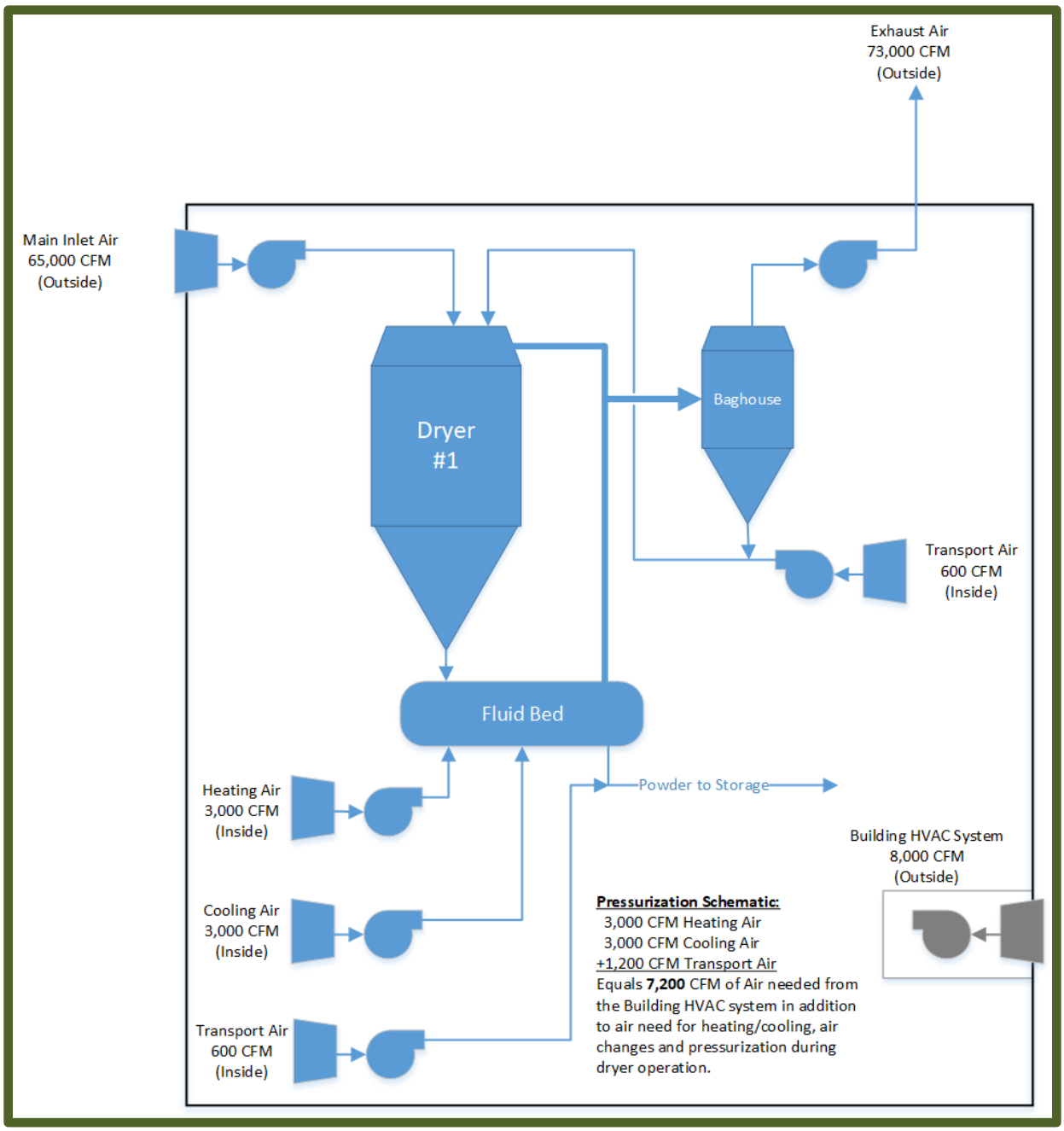


Figure 10. Dryer Air Flow Diagram

Dry Dairy HVAC Considerations

Special considerations for dryer buildings and powder handling areas are needed for food safe operation. Spray dryers and powder conveying systems, by design, move large amounts of air. In most instances this is a combination of external and internal air make-up. A pressurization and equipment schematic should be developed (See Figure 10) for the dryer and powder areas and are ideally managed in conjunction with other equipment in the dryer building. This would include how air is to be moved from space to space along with the major air needed for the dryer.

Generally, the main air inlet supply and exhaust pull air from the outside and exhaust to the outside having virtually no impact on the dryer building design. Internal or building HVAC make up and exhaust systems need to allow for all the operational components; this includes external drying/cooling systems and pneumatic conveyance uses, which can have quite large air volume needs and cause numerous problems if not accounted for properly. It is also critical to understand which components generate heat into the process space. If not properly vented these areas can become uncomfortably hot during operation.

Key considerations include:

- ✓ HVAC louvers should not direct hot or cold air directly on dryer or powder handling components. Differential cooling on the process equipment can cause unwanted condensation inside the vessels if the dew point of the product is reached.
- ✓ Spray dryers also have special vents on most drying chambers and baghouses that vent to the outside in the event of an explosion. Special care needs to be taken to inspect these areas when the dryer is not in operation. These areas also need to be heated to insure there is no temperature gradient that will cause powder buildup.
- ✓ Older facilities typically have multiple exhaust fans with few or no intake fans. In such cases, the rooms are under a negative air pressure and extra precautions must be taken since air flow cannot be controlled. Attention needs to be given to any window, door, crack, or crevice that may lead to an influx of unfiltered air.

Special Circumstances

While operating manufacturing facilities, special circumstances will arise. Special circumstances such as non-routine traffic (people), traffic patterns (room segregation, alternate routes, etc.), infrastructure and/or system breaches, or changed sanitation procedures have the potential to increase the risk for contamination. Several illness outbreaks have been attributed to construction which introduced pathogens into the plant environment. Recognizing and preparing for either planned or unplanned events is key to controlling food safety risks.

Refer to **Appendix G Hygienic Separation in Continuous Dairy Powder Systems** for guidance on how to control, monitor, and determine corrective actions by 1) analyzing an event in which a dairy powder produced during a continuous operation tested positive for a pathogen 2) determining reasonable and defendable hygienic separation points before and after the positive finding and 3) utilizing information and data to optimize the amount of non-contaminated powders that would otherwise be deemed necessary to discard while ensuring food safety risks are minimized.

Table 8. Types of special circumstances

Type of event	Examples
Planned	Non-emergency construction; a different pool of employees due to an expansion; changes in sanitation following purchase of new equipment; or a new formula or product being produced at a facility
Unplanned	Natural disasters, flooding, water leaks (drain backups, burst pipes, leaking roofs, fire sprinkler, etc.), and hygienic zone breaches

Planned events require preparations including the creation of a food safety construction plan (See **Appendix C**) which details rigorous procedures for construction projects. A good construction plan clearly communicates the step-by-step work to be done, gives a timeline of events, identifies who will perform mitigation steps, and when mitigation steps will be taken. A team composed of plant experts (such as Quality, Sanitation, Operations, Engineering) needs to be involved and contribute to the plan. The depth of a construction plan should be based on the location and type of work being done in the plant, as well as the history of the area.

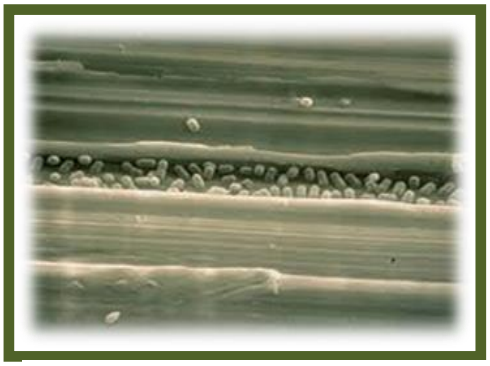
Unplanned events, like an infrastructure or system breach(See Special Considerations for Continuous Operations "Equipment and Infrastructure Breaches" section), are typically urgent and challenging because time, personnel, and material resources may be constrained. Once the event or circumstance is contained, an assessment of the products and environment affected must be immediately conducted. Investigational environmental pathogen sampling is important to assess the impact of the event on production areas, as well as determining if other areas were affected through traffic. The Grocery Manufacturers Association (GMA) *Lm* guidance document provides valuable information on dealing with roof issues, water leaks or drain backups.[12]

Equipment Design

Following sanitary design principles is critical to ensure cleanability and to eliminate harborage sites where microorganisms are protected from cleaning and sanitation. The equipment sanitary design checklist (**Appendix A**) can help identify areas of improvement on either new or existing equipment. Key principles of sanitary design for the dairy industry include:

- ✓ Microbiologically Cleanable
  - Equipment should be selected to eliminate the potential for survival of *Listeria* and other pathogens, as well as meet any regulations for the specific product. 3-A and PMO sanitary standards are a good starting point for dairy equipment, but they are most applicable to fluids and "inside the pipe" situations. It is important to verify that all production equipment is cleanable to a microbiological level and that it will not deteriorate after repeated cleaning cycles. (See Figure 11 & Figure 12)

Figure 11. Poor sanitary welds are not cleanable at a microbiological level



Amy C. Lee Wong/ University of Wisconsin

Figure 12. Scanning electron micrograph of *L. monocytogenes* growing on stainless steel

✓ Made of Compatible Materials

- Materials used to construct equipment must be compatible with the product, environmental conditions, cleaning methods, and chemicals. Most equipment in wash-down areas should be made of stainless steel or other corrosion-resistant, non-toxic, and non-absorbent material. Painted surfaces should be avoided. This applies to internal and external parts that may be exposed to product, cleaning chemicals, or moisture (Figure 13 & Figure 14). For example, anodized or coated aluminum should not be used with acidic products, high salt products, or when acid cleaners will be used. Similarly, some plastics deteriorate prematurely when exposed to chlorinated caustic cleaners.

Figure 13. Example of material incompatible with cleaning solution/ method

Figure 14. Example of compatible material covered with stainless steel

✓ Accessible for Inspection, Maintenance, Cleaning, and Sanitation

- Any inaccessible surfaces (product or non-product zone) should allow for rapid, tool-free disassembly. Fillers, pumps, valves, catch pans, guards, and other equipment should be easily disassembled for routine cleaning. Instead of bolts, fasten guards and in place catch pans with pins or slots that don't require tools for disassembly. If parts of the equipment cannot be visually inspected after cleaning, they are likely to be difficult to clean and could serve as harborage sites. (Figure 15 and Figure 16) All product contact surfaces should maintain a minimum 18" floor clearance to minimize potential for contamination to splash back from the floor. The outer perimeter of equipment should have a 12" clearance from the floor and 36" from walls and other large equipment to allow for cleaning access.

Figure 15. Splashguard requiring tool for disassembly and creating a catch point

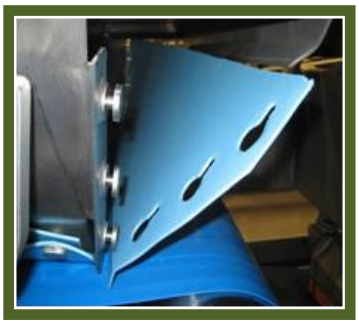


Figure 16. Splashguard with keyhole attachment that can be removed

Hard to inspect areas can sometimes be overlooked. It is recommended to have regular-inspections of the following special and/or hard to reach areas as part of the Master Sanitation schedule:

- Hot air inlet plenum and junctions where there are expansion joints, flashing or flexible connectors.
- Most dryers have insulation in the heating ducts and near the roof. Other components such as the main chamber, ducts, cyclones and baghouses are usually insulated by means of an air gap. In cases where there is no insulation or air gap, it is critical to control the room environments to prevent buildup of product.
- Any separated areas in the the dryer for "wet" versus "dry cleaning" such as baghouses, blanking plates, sifters, conveyance components, high pressure feed lines, etc.
- Main air inlet ducts that are tyically connected to the outside.
- Air handling coils for heating, cooling and dehumidification.
- Explosion venting and suppressing system(s).
- Fire deluge systems and connections.
- Duct draining and pitches, i.e. main inlet air duct need to draining to the chamber.

✓ Inspection of Expansion Joints

- Special consideration should be made for heat expansion when using metal to metal slip joints covered with a heavy gasket, or a heavy heat resistant material. These two methods accommodate the several inches required for main chamber, baghouse, cyclone, and duct expansion. Inspect joint gaskets, at minimum, after a main chamber wash or more frequently to ensure no damage. (Figure 17 & Figure 18)

Figure 17. Example of an exterior expansion joint that needs regular inspections

Figure 18. Example of an interior expansion joint that needs regular inspections

✓ Self-Draining Surfaces

- Product contact surfaces should be designed to drain freely and not accumulate product/cleaning solutions, minimizing the availability of water and nutrients to microbes. Product and CIP lines should not have dead-ends that allow liquid to collect.

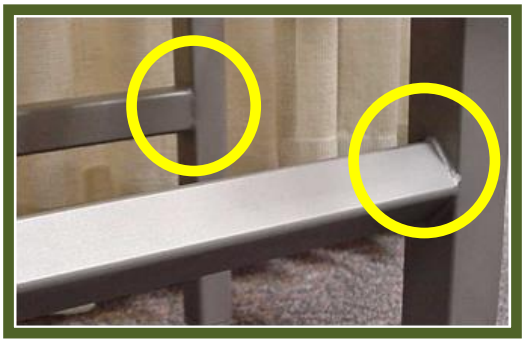


Figure 19. The square tubing on the left will accumulate soil on the flat horizontal surface. By rotating 90^0, or using round tubing, flat surfaces are minimized.

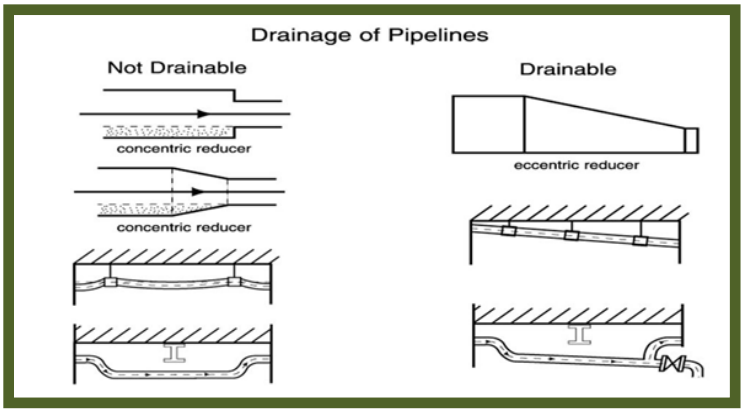


Figure 20. Non-drainable and drainable designs of

✓ Hollow Areas Hermetically Sealed

- Tubular framework, rollers, adjustable legs, and other hollow structures must not be penetrated in order to prevent soil and moisture from getting inside. It is often possible to replace a tubular structure with angle iron, which provides open access for cleaning and inspection. The integrity of double-walled vessels, such as tanks, silos, and mixers, should be monitored periodically for pinholes and small cracks. Mobile equipment (tables, stairs, ladders, and their wheels) should also be inspected and repaired where necessary.

Figure 21. Hollow square tubing not hermetically

Fig. 22. Examples of adjustable ball foot design – welded or gasket to seal and avoid debris infiltration

✓ No Niches

- Prevent accumulations of water, moisture, or soil by minimizing overlapping surfaces, seams, recesses, sandwich joints, and dead spots. Equipment should be built from single pieces of material whenever possible to minimize assembly with bolts, press-fits, or other fasteners. Avoid threaded parts including threaded legs.

Figure 23. Accumulation/niche created by reassembling the probe facing down instead of

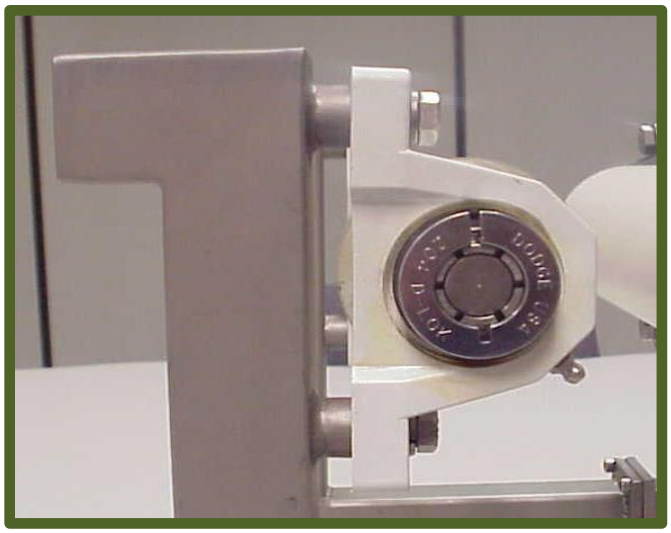


Figure 24. Minimize overlapping surfaces with spacers

✓ Newly Acquired Equipment

- When receiving new or used equipment, precautions must be taken to prevent introducing contamination. All equipment new to the facility must be cleaned and sanitized before it enters any production zone. Cleanliness and microbiological condition of the equipment should be confirmed by taking indicator and/or pathogen swabs. The equipment may need to be re-cleaned, sanitized, and checked before being placed into service. A best practice is to have a policy and SOP to handle new equipment entering the plant and commissioning of the equipment.
- Similar precautions should be taken when used or existing equipment is moved to different RTE areas.
- Used and/or repurposed equipment presents a greater risk because its history may be unknown and older designs tend to be less cleanable. Additional precautions are prudent.
- New stainless-steel equipment must be passivated (See **Glossary and Acronyms** section) for corrosion resistance and to enable cleaning.

Remember

It is important that equipment which was initially properly designed may become insanitary with wear. Additionally, repair parts, modifications, and maintenance techniques can compromise sanitary designs. Routine checks should be conducted in order to promptly identify and remedy issues.

✓ Other Considerations

- Non-product contact surfaces in close proximity to open product and surfaces which will be touched by operators (e.g., control panel buttons, valves, switches) should be designed using sanitary design principles as if they were product contact surfaces (See Principle #5 Environmental Pathogen Monitoring Figure 34 for Zone descriptions)
- Maintenance and safety enclosures (e.g., motor, drive, guards, electrical boxes, etc.) should not be located over open product. Motor-cooling or floor fans should not blow onto exposed product or direct product contact surfaces. Utility lines and maintenance enclosures should be at least 12 inches off the floor, not above open product, and of a cleanable design.
- Installations and remodels should take hygienic zoning into consideration, with special care not to mount structures that would be over product contacts surfaces.

Existing Equipment with Design Opportunities

Many facilities have older equipment that may not have been built using current sanitary design best practices. The equipment design checklists (found in **Appendix A, Appendix B**, and at usdairy.com/foodsafety), provide guidance on how to identify parts of older equipment that may be modified for easier cleaning and to eliminate niches. Examples include replacing the piano hinges common on older mixers with more sanitary ones and replacing hollow rollers on conveyors with solid ones. Routine inspections are required to ensure that the sanitary design of equipment is maintained as it ages or is modified. There are many examples where teamwork between maintenance, sanitation, operations, and engineering have identified opportunities to eliminate niches that were difficult to clean, inspect, and which could harbor pathogens. At a practical level, many upgrades may be justifiable when the cost of incremental time for disassembly and proper sanitation is considered as a recurring expense.

PRINCIPLE #4: EFFECTIVE CLEANING AND SANITATION PROCEDURES AND CONTROLS

Having a well-designed, effective cleaning and sanitizing program is an essential element of the full Pathogen Control Equation. Enhanced cleaning procedures have been proven to compensate for weaknesses in facility or equipment design until improvements can be implemented. Both routine and non-routine cleaning regimens are essential to remove bacteria and prevent bacteria from becoming persistent in the environment.

Routine cleaning is defined as the cleaning and sanitizing that is performed at the end of a pre-determined production cycle. It includes fixed and moveable items such as processing equipment, hand-held tools, product catch pans, scrapers, tubs, mats, carts, transfer hoses, etc. All of these can harbor bacteria if not cleaned routinely, and therefore must be identified and assigned for sanitation. A written process of practices to identify, tag, and store clean equipment should also be established.

Non-routine or periodic cleaning is defined as cleaning that is managed through the use of a written Master Sanitation Schedule (MSS). It may include floors, walls, drains, ceilings, other plant infrastructure, and deep dive cleaning of food contact and non-food contact equipment. The frequency of cleaning is determined by a risk assessment, including harborage potential, along with other environmental and/or regulatory factors.

Effective cleaning requires balancing these four critical variables:

- ✓ Chemical Concentration
- ✓ Mechanical /Manual Force or Abrasion
- ✓ Temperature
- ✓ Time

These variables are adjusted based on the soil type (Table 8), whether the product is cooked or uncooked, the surface type to be cleaned, and the cleaning method (manual or automated). For example, manual cleaning at lower temperatures and chemical concentration requires more force than cleaning with an automated system at higher temperatures and chemical concentration. Also, cleaning a cooked-on protein soil requires more mechanical action and chemical concentration than a non-cooked-on protein soil. Be aware that more chemicals (higher concentration) doesn't always mean greater effect. Your chemical supplier should be consulted to determine the appropriate range for each situation.

Understanding the product soil and its condition, (e.g. cooked-on or not) will help determine what is the proper chemical choice to clean the surface effectively. Chemical choices today vary significantly from a basic straight caustic offering to highly built products with added surfactants, emulsifiers, and wetting agents.

These cleaning chemicals interact with the product soil on a chemical and physical basis to allow removal during the rinse step. Work with your plant chemical supplier to make the best choice based on these factors.

Table 9. Common dairy soils

Soil	Cleaning Temperature	Cleaning Chemical
Butterfat	100–130 °F	Alkaline
Protein	120–150 °F	Alkaline*
Denatured Protein	140–170 °F	Alkaline*
Mineral (e.g., milkstone)	130–150 °F	Acid
Carbohydrate (e.g., lactose)	130–150 °F	Alkaline

*Recommend chlorine be added to boost cleaning efficacy

In the dairy industry typical cleaning methods that are required for effective cleaning are:

- ✓ 7-Step Manual Cleaning (There are specific approaches for wet vs. dry)
- ✓ CIP – Clean-In-Place
- ✓ COP – Clean-Out Of-Place

There are also combinations of these three methods that can result in effective cleaning. For example, prepping a tank for CIP cleaning requires manual hand cleaning of some parts such as a sample port. During the 7-Step cleaning process there are smaller parts placed within a COP tank for cleaning.

<u>Cleaning Wet Environments</u>

- ✓ 7- Step Manual Cleaning and Sanitation – Wet Environment

Cleaning and sanitation are most effective when the proper sanitation sequencing is followed to prevent potential cross-contamination within the environment during cleaning. A best practice many companies follow is to have a written sanitation standard procedure that covers the 7 steps of sanitation for everything that needs to be cleaned.

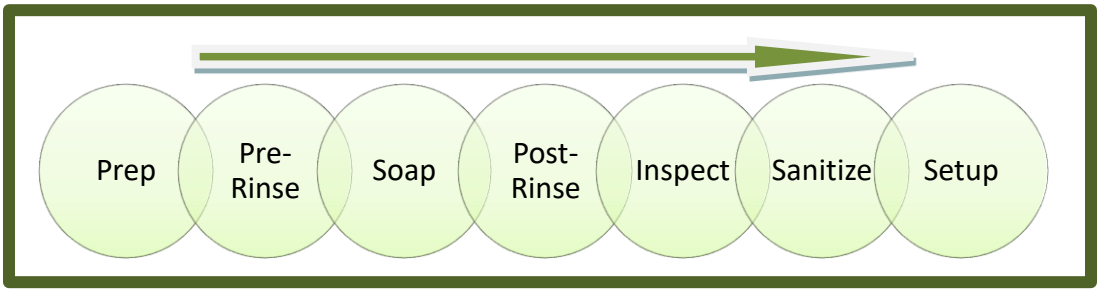


Figure 25. Seven Steps of Sanitation

1. Pre-Sanitation Preparation

   Remove all production supplies and waste, dry clean to remove as much product debris as possible. Do not use high-pressure water hoses or compressed air to remove solid food residue, because this may move debris around the facility as dust and aerosols which could contaminate other surfaces. Also, conduct any Lock Out Tag Out (LOTO) procedures to ensure personnel safety for the cleaning procedures.

2. Pre-Rinse

Using water at an appropriate temperature for the product soil, pre-rinse to remove as much soil as possible from the equipment and surrounding area. Water should be hot enough to melt fats, but it is important to note that temperatures above 130^{o} F can denature proteins and cause soils to adhere to surfaces. High-pressure water or compressed air is not recommended to avoid spreading contamination. High pressure can also drive soils deeper into equipment where removal is problematic. It is also known to damage bearings or electrical equipment. If drains must be handled due to blockage during this step, be sure that employees are trained to take the proper precautions, such as wearing gloves and smocks that are disposed of when done. If a COP is utilized for smaller parts, the parts should be gathered and placed in the COP tank during this step.

3. Soap Scrub

Apply an appropriate detergent to walls, floors, and equipment. Do not let detergents dry on surfaces. This application can be as simple as using a bucket and brush scrubbing or use of a foaming application to apply the detergent cleaner more effectively to walls, floors and then equipment. It is recommended that chemical titrations be performed during the foaming process to assure concentrations are within range. Be sure to tear down equipment parts to their simplest form. For example, gaskets, O-rings, and pipe fittings should be removed and disassembled. Using the proper color-coded cleaning tools (scrub pad, brush, etc.) is a best practice to minimize the chance of cross contamination during sanitation. Keep in mind that scrub pads are typically single use and brushes, and other tools need to be part of the cleaning plan and stored properly when not in use to also avoid cleaning tools becoming a vector for spreading pathogens. When using cleaning tools, it is important to apply mechanical action to remove all product soil. Mechanical action is especially important in breaking up potential biofilms, which will allow subsequent sanitizing to be effective. Cleaning the drains in RTE areas will take place at or near the end of this step. Drain cleaning should include dedicated cleaning equipment not used for any other cleaning tasks (typically black colored brushes, buckets, and PPE's). Dedicated personnel are also recommended, if possible, to help reduce the risk of cross-contamination of food processing equipment. If dedicated personnel are not available, personnel assigned to drain cleaning should change into clean uniform and PPE before working in any other areas of the plant.

Wet Sanitation Tips

- *An effective wet sanitation program starts with equipment that is engineered to be cleanable with good sanitary design principles.*
- *Employees should be routinely trained to SSOPs established for Routine and Periodic sanitation tasks.*
- *Cleaning procedures should be appropriate for soil type and compatible with equipment.*
- *Cleaning procedures should be initially **validated** (Is it the correct procedure for soil type?) for effectiveness. Procedures should be periodically revalidated. Cleanliness must be **verified** (visual inspection or testing to prove it removed soil/bacteria) after every sanitation cycle.*
- *Sanitation tools need to be managed to avoid spreading pathogens - scrub pads are typically single use, brushes and other tools should be cleaned and stored in a sanitary manner between uses.*

4. Post-Rinse

   Rinse away all chemical and remaining product residues with water from the top down. Certain soils may require a repeat of Steps 3 and 4 with an alternative type of detergent. Hose spraying of the floor should be minimized if required at any point in this step to prevent cross contamination of cleaned equipment.

5. Inspection

   Inspect and verify that there is no visible product residue to indicate the previous steps were effective. This typically includes the sanitor performing the cleaning and a leader to verify cleaning was satisfactory. Repeat Steps 3 and 4 if necessary. Inspection is best undertaken using strong illumination such as a flashlight.

6. Sanitize

   All steps prior to this step are focused on the removal of the organic soil from the equipment and room environment. The primary focus in “Step 6: Sanitize” is to eliminate microorganisms that may not have been removed during the prior cleaning steps. Sanitizing is only effective if equipment and other surfaces are clean and free of organic matter because organic matter can neutralize/deactivate, making it less effective. Sanitize equipment, walls, floors, equipment framework, etc. —starting from the bottom (floor level) and working upward— to ensure all surfaces are covered. Only EPA-registered sanitizers with documented, validated activity against pathogens should be used. It is a best practice, and may be required by regulation, that processing equipment that has been sanitized, but not used within the subsequent 4 hours, should be re-sanitized prior to starting up.

7. Reassemble and Setup

   Under sanitary conditions, wash and sanitize tools, hands, and gloves. Remove any pooled sanitizer and condensation. Bacteria need moisture to grow, so the production environment should be kept as dry as possible. Under certain circumstances it may be necessary to sanitize again after equipment assembly.

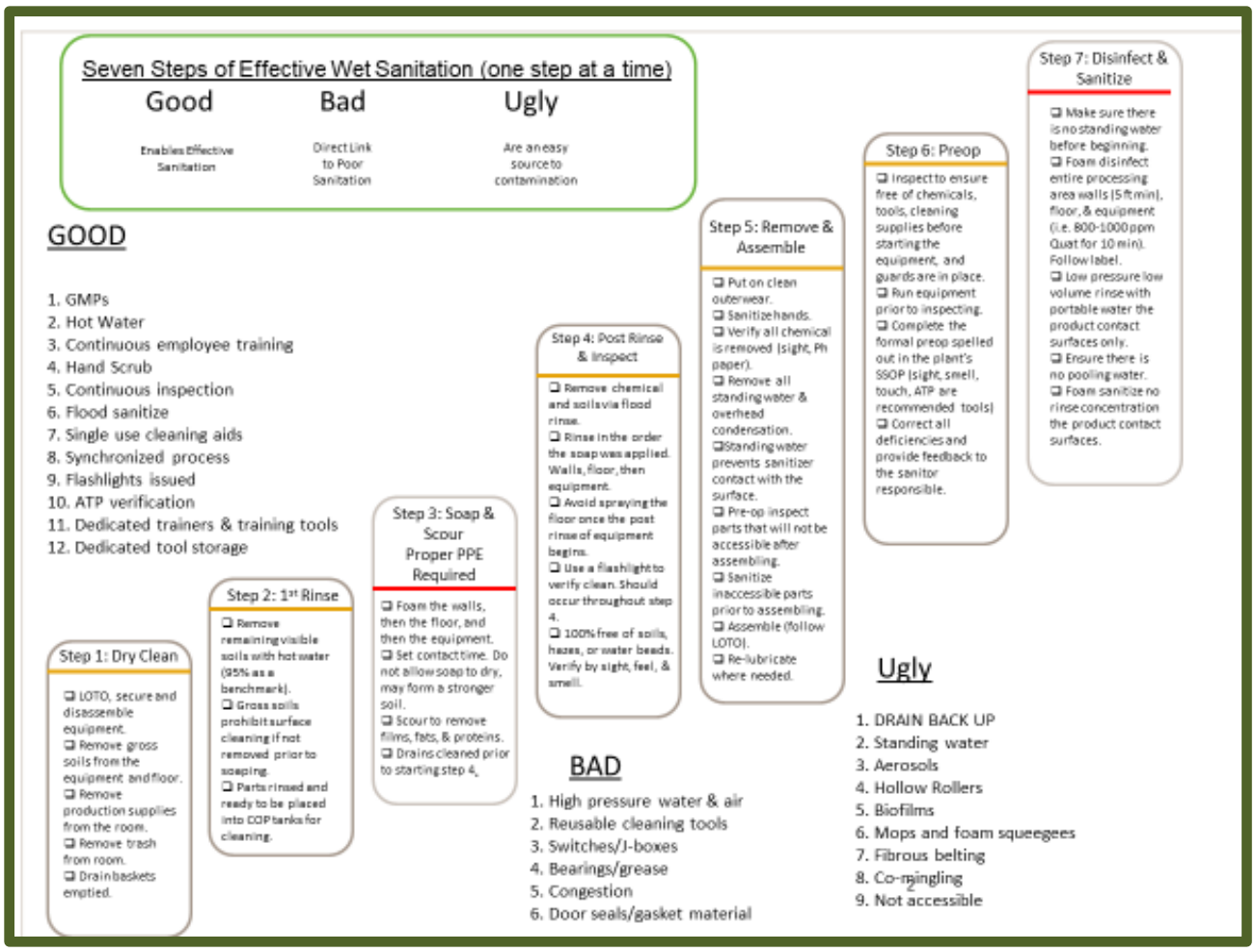


Figure 26. Seven steps of wet sanitation

✓ Clean-In-Place (CIP)

Clean-In-Place (CIP) is a common, routine cleaning regimen which can be highly automated and is used for enclosed surfaces such as pipelines, heat exchangers, cooling presses, vats, tanks, and cheese processors. CIP involves the circulation of cleaning solution through pipes at a documented and prescribed flow rate creating turbulent flow or through spray devices/balls for vessels and similar equipment. These systems use time, temperature, specific concentrated chemicals, and mechanical force to achieve maximum cleaning. Use of CIP systems requires that the equipment be of sanitary construction, with smooth, cleanable surfaces, and can be fully drained. As with manual cleaning, following proper sequencing, based on a sound program and system, is necessary to ensure that equipment is clean. CIP system circuit washes should be validated at the time of installation, and it is recommended that further on-going verification steps be performed at some frequency. This is to ensure that there are no changes to the circuit wash caused by the equipment or programming. It is recommended that chemical titrations are performed during the CIP wash to assure concentrations are within range; this information should be documented.

✓ Clean-Out-of-Place (COP)

A third cleaning system is clean-out-of-place (COP). With COP, parts that require manual cleaning are disassembled and submerged in a horizontal vessel which uses circulating detergent, heat, and agitation to remove product soil. Long pipe or small parts require different turbulent flow patterns within the COP tank. For example, the cleaning parts tank should have a cross flow of chemicals with the flow of chemicals being from end to end for any long pipes. COP tanks must be large enough so that parts are fully submerged and not crowded. Overloading a COP tank inhibits flow of cleaning solutions, rendering the process ineffective. All parts should be reassembled or properly stored at the end of the COP cycle (Figure 27 and 28). It is recommended that temperatures and chemical titrations are performed during the COP wash to ensure concentrations are within range and the results are documented.

Figure 27. Incorrect storage of parts in a COP tank. They should be stored in designated receptacles and/or areas.

Figure 28. Equipment must be fully submerged for appropriate cleaning.

✓ Sanitizing

Sanitizing can be done by utilizing either heat or chemical methods. Chemical sanitizer types include chlorine-based, iodine-based, quaternary ammonium compounds, and a variety of acids including peracetic acid. These types of sanitizers can be categorized as rinse-required, or no-rinse required. Label instructions should be followed to ensure efficacy and prevent unapproved chemical contact with food. Caution must be exercised to avoid recontamination of equipment after it has been sanitized.

It is important to sanitize only clean equipment as excess food soil will make sanitizers ineffective. Sanitizer solutions must be tested to verify that the label defined concentration is consistently present. Too little sanitizer is unacceptable, but too much can also have diminished efficacy, may result in surface residues. For floors, walls, and drains, sanitizer with residual properties should be used. Check with your chemical supplier for guidance on the appropriate products to use in each situation.

Heat sanitization should be controlled to ensure it is adequate to kill the target organisms while being mindful that excessive heat can damage equipment. Heat sanitizing using dry steam or hot water is only effective when appropriate temperatures can be maintained throughout the equipment being sanitized for

the appropriate amount of time. Heat sanitizing procedures should be verified for each piece of equipment and surface. For verification purposes, thermocouples with a recording device are recommended during heating applications.

✓ Sanitation Effectiveness Monitoring - Wet

Written monitoring, corrective actions, and documentation activities are crucial for verification of the effectiveness of the facility's cleaning and sanitation program. Key elements of pre-operational monitoring and verification include smell, touch, and visual inspection of equipment; ATP swabbing and clean equipment swabbing for indicator organisms (See Introduction: Indicator Testing and It's Role in Controlling Pathogens Section). Visual inspection and ATP swabbing provide immediate actionable feedback, while culture-based swab results are used to verify microbial removal and sanitizing effectiveness. The results of these monitoring activities should be tracked and trended to verify program effectiveness and to determine the need for additional training or sanitation standard operating procedure (SSOP) changes. This will also aid in the identification of equipment design/integrity issues. For cleaning processes which utilize CIP or COP, temperature charts, cycle charts, and concentration checks should be monitored by trained personnel.

✓ Special Cause Cleaning – Wet Wash Environment

There are occasions due to construction, specific activities in the plant, positive environmental swab results, or other issues, when it becomes necessary to perform deep or special cause cleaning. During special cause cleaning, equipment is disassembled for cleaning beyond what is routine, and enhanced sanitizing procedures/chemicals are used.

When a special cause situation arises, the plant location and surrounding area should be isolated to prevent unnecessary access until the special-cause cleaning can be performed. For example, if there is potential for cross-contamination of product due to adjacent traffic, the area should be roped-off or restricted until special cause cleaning is completed. Additional floor mitigation sanitizer barriers may be necessary to prevent potential spread to other areas of the production plant. If there are adjacent lines, it may also be necessary to put temporary walls in place to prevent cross-contamination. During the cleaning process, employees should take necessary precautions to prevent cross-contamination. The employees performing the cleaning should not return to their normal production tasks until steps such as a uniform change, footwear changes, showers, handwashing, and tool decontamination occur.

During special cause cleaning or periodic deep cleaning, equipment should be disassembled to expose internal surfaces. Any overlapping parts are disassembled to expose all surface and bolted/fastened parts are separated. If the equipment is complex, the equipment manufacturer may be consulted to support the teardown. After removal of any soil and subsequent deep cleaning, different sanitizing methods should be considered based on access to surfaces, presence of electronic components and motors, and other factors.

Sanitizers should only be used in accordance with their EPA registered and approved label instructions. Some options are:

- A sanitizer with oxidizing capability, such as chlorine dioxide or peracetic acid.
- Alcohol wipes for electrical boxes or control panels that must remain dry.
- Chlorine dioxide gas may be used if the area can be safely contained.
- Steaming by shrouding the equipment and injecting live steam to ensure the coldest spot reaches 160^{o}F for 30 minutes minimum.

The last two methods are useful in more extreme situations and can be effective for complex equipment with poor access to all surfaces. After the deep cleaning is completed and the equipment is reassembled, the entire area, including floors and any nearby drains, should be sanitized prior to returning to production. A swabbing regimen should be put into place to confirm that the cleaning was successful, and that the area no longer poses a contamination risk. All actions should be documented as well as verification that the corrective and preventive actions are effective.

Cleaning Dry Environments

A key rule in dry dairy production areas is that "dry needs to stay dry." Plants that process dry dairy products and powders frequently have some wet processing, so it is important to maintain a high level of hygiene in wet areas and clear separation to keep moisture out of the dry areas. Traffic from wet to dry should be controlled with transition areas that have some form of dry floor mitigation. *Listeria* species and *Salmonella* can survive for prolonged periods but do not grow in dry (low water activity) environments. Most dairy powders are hygroscopic and will absorb moisture from the environment. Another key rule in dry dairy is to keep the product in the pipe/process, the less product that builds up the easier it is to clean. If the dairy powder is allowed to accumulate, it likely will find niches that enable survival and growth of *Listeria, Salmonella,* or other microbial contaminants. Cleaning plans should include preventing powder accumulation, proper air circulation, and humidity control. Relative humidity that is either too high or too low allows particles to stick to surfaces. Relative humidity should be no greater than 35% in a powder packaging area.

In dry areas, cleaning is commonly carried out using High Efficiency Particulate Arrestance (HEPA) filter vacuums, brushes, brooms, or other means to dislodge and remove soil. In addition, it is important to continually clean areas during production to avoid build-up of product or soil. It is important to clean product build-up with proper procedures to avoid further aerosolizing the powder, which can move it around the plant. Cleaning utensils should be kept clean and stored in a manner that prevents

Dry Sanitation Tips

- *Cleaning tools, brushes, brooms, dust pans and vacuums, etc. should be part of a master sanitation plan and environmental monitoring plan.* ***Do not let them become a source of contamination.***
- *Fast drying alcohol sanitizer, with or without quaternary ammonia, is commonly used in dry processing areas. Note: Some sensitive products do not allow the use of quaternary ammonia in processing areas*
- *Chlorine dioxide gas can be used to sanitize difficult to reach dry equipment*. Trained personnel and proper personnel safety is critical

contamination and moisture build-up. Utensils should be monitored for wear and replaced as needed. Vacuums and dry-cleaning utensils should be part of the environmental monitoring program. Alcohol-based sanitizers can be used to sanitize dry product contact surfaces, due to their fast-drying nature. If periodic wet cleaning is done anywhere in the dry processing plant, all product and packaging material should be removed from the area, and dry processing equipment not being cleaned should be isolated to ensure it stays dry. The area should be completely dry prior to resuming dry processing or packaging.

✓ 7-Step Manual Cleaning and Sanitation – Dry Environment

Cleaning and sanitation are most effective when the proper sanitation sequencing is followed to prevent potential cross-contamination within the environment during cleaning. Product contact surfaces may require additional cleaning, such as dry wiping or alcohol/quaternary ammonia wipes. If any parts are wet cleaned, ensure they are completely dry before reassembly. Many companies follow a seven-step dry clean process:

1. Pre-Sanitation Preparation
   Prepare environment and equipment for cleaning, prior to beginning cleaning procedures, and purge powder storage and packaging equipment. Cover exposed product contact surfaces (fill heads, de-aeration probes, etc.) with new/sanitary plastic to prevent contamination during the cleaning process. Ensure all packaging materials are removed from the area and garbage cans are emptied. Do not use compressed air to remove food residue, because this may move debris around the facility since dust could contaminate additional surfaces and/or embed the powder deeper into equipment.

2. Secure, Dismantle, & Inspect Equipment
   Safely access equipment for cleaning and inspection. Lock Out/Tag Out (LOTO) equipment based on manufacturer and/or organization requirements. Gather necessary tools that are clean and in good condition, for cleaning as described in the SSOP for that equipment or area. Next, dismantle equipment to cleaning configurations based on manufacturer specifications and the SSOP. Dismantling should allow for access to difficult to reach areas where product and soil have accumulated. Inspect the environment and equipment to identify heavily soiled areas that will require targeted detailed cleaning. Ensure parts and components are handled in a sanitary manner during cleaning. They should be stored on sanitary racks, mats, or hangers.

3. Pre-Clean
   Remove the majority of soil from equipment and the environment. Use a systemic approach of top to bottom cleaning so debris is most effectively removed. Overhead lines, equipment and building structures should be cleaned first followed by walls and equipment moving down. Brushes, scrapers, scrub pads and vacuums (specialized attachments available) should be used to loosen and remove soil. The tools should be designated for product contact surface and non-product contact surfaces and items like wipes and scrub pads should be single use. If vacuums are used, it is recommended they are dedicated to specific rooms (avoid centralized vacuums if possible) and are cleaned and maintained regularly to avoid them becoming a source of contamination. Once material has collected on the floor, sweep, or vacuum and discard it.

4. Detail Cleaning
   Spot clean identified heavily soiled areas using targeted methods. Apply mechanical action with scrapers, brushes, scrub pads or wipes to remove residual product. Isopropyl alcohol may also be used to help remove soil. It is recommended that the wipes and scrub pads should only be used once then discarded. If available, clean crevasses using specialized tools. The goal is to keep dry areas dry, but in some situations the application of water-based cleaners may be used for stubborn soils. If possible, any wet cleaning should be done in a separate and appropriate area. If this is not possible, then it should be done in a limited and controlled manner to ensure enough dry time and sanitizing after cleaning. Water application should be documented, and increased verification methods should be used to confirm no microorganisms remain. Once all other cleaning is complete, remove plastic from product contact surfaces and clean. Sweep, vacuum and discard any material remaining on the floor.

5. Final Cleaning
   Clean from the top down and in the direction from the room towards the equipment using the designated tools. Finish cleaning the product contact surfaces and then clean the floors, framework, and equipment again. Product contact surfaces may require additional cleaning, such as dry wiping or alcohol/quaternary ammonia wipes. If any parts are wet cleaned, ensure they are completely dry before reassembly.

6. Sanitation Inspections
   Inspect equipment and the environment for cleaning effectiveness and confirm equipment and the environment are free of soil by sight, feel and smell (change gloves if soil found). Good GMP's should be followed during inspections to avoid cross-contamination. Appropriate lighting (flashlights, head lamps, etc.) should be used to allow for proper visual inspection. LOTO procedures should still be in place at the beginning of this step. Reassemble guards and other parts that were removed for cleaning. Once fully assembled, start conveyors, and run at least one full cycle and again check for any visible new soil deposits. If soil is found, cleaning should be repeated.

7. Final Inspection and Documentation
   The responsible person for signing off on the sanitation's effectiveness should visually inspect everything again to ensure that the cleaning was satisfactory. In addition, it is recommended that ATP tests be used following each cleaning for rapid verification of effective cleaning of equipment and environment. When using ATP tests in dry environments it is important to establish acceptable baselines because dry cleaning is not likely to remove all the organic material on the equipment surface. Complete any post cleaning inspection forms and document any corrective actions. Validate cleaning effectiveness through microbiological swabbing of the area and equipment prior to any sanitizing activities.

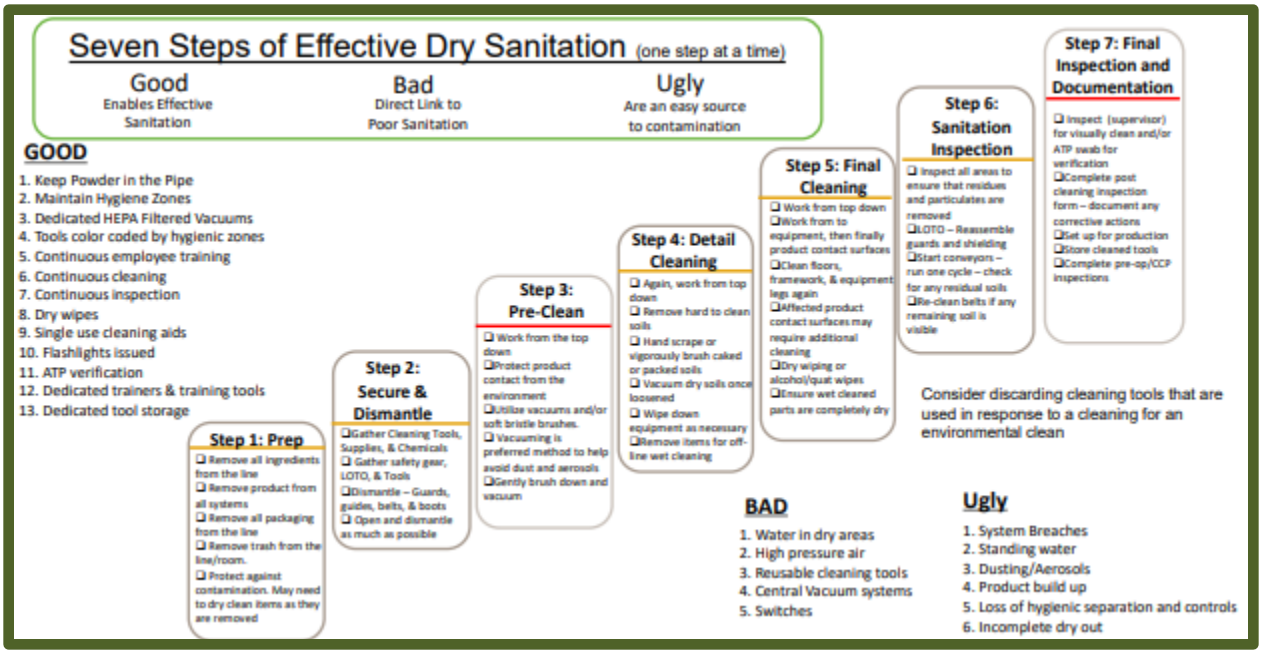


Figure 29. Seven steps of dry sanitation

✓ Sanitizing

Once the surfaces are verified as clean, the sanitizing process should begin if required by the SSOP. In a dry environment this can be achieved by using either alcohol wipes and/or by spraying the area with alcohol; both will quickly evaporate. The use of sanitizers or sanitizing wipes is not always regularly done in dry environments. In some instances, the use of sanitizer and sanitizing wipes is avoided to keep moisture in dry production areas to an absolute minimum. If sanitizer is used it should be applied in a top-down application method ensuring all surfaces are covered.

✓ Dry Cleaning Tool Considerations

Dedicated cleaning tools in critical and high care zones may need a separate color code system from the rest of the facility. Dedicated vacuums in each dry zone of the plant are a best practice: i.e., a separate HEPA filtered vacuum for dryer room, powder storage room, and packaging room. The use of “hot-boxes” to store regularly used items and vacuums in dry zones helps control pathogen cross-contamination. Cycling “hot boxes” on and off for periods of time at 130^{o}F is common.

Figure 30. Dedicated HEPA filtered vacuum cleaners.

Figure 31. Overhead pipe exterior cleaning tools.

Figure 32. Product contact brushes stored in blue bags after cleaning until next use

Figure 33. Vacuum attachments designated by shape rather than by color

✓ Sanitation Effectiveness Monitoring - Dry

Similar to wet sanitation effectiveness monitoring, documented monitoring programs and corrective actions are crucial for verification of the effectiveness of the facility's cleaning and sanitation program. Key elements of pre-operational monitoring include smell, touch, and visual inspection of equipment, and clean equipment swabbing for indicator organisms (See Introduction: Indicator Testing and It's Role in Controlling Pathogens Section). Visual inspection provides immediate actionable feedback, while culture-based swab results are used to verify microbial removal and sanitizing effectiveness. Visual inspection should be used to establish expectations for results, remembering that the limitations of dry cleaning – eliminating the use of water – may mean that equipment and environments may not appear "shiny." Micro results will help validate the dry-cleaning expectations. ATP swabbing may not be an option in dry cleaning applications due to 1) the desire to not introduce water into the environment, and 2) dry cleaning may not completely remove all organic material which could result in positive readings for ATP. An ATP testing protocol for dry cleaned only areas may be used to monitor cleaning effectiveness if baseline results for ATP readings can be established. The use of ATP swabs and wet micro swabs may necessitate a controlled modified dry clean with an alcohol wipe if the introduction of even a small amount of moisture is a concern. The results of these monitoring activities should be tracked and trended to verify program effectiveness and to determine the need for additional training or sanitation standard operating procedure (SSOP) changes. This will also aid in the identification of equipment design/integrity issues. Whenever moisture is introduced into the environment or on equipment of dry clean only areas, it is suggested to monitor the equipment and/or area to ensure the proper steps are taken to achieve a complete dry out.

✓ Special Cause Cleaning and Deep Cleaning in Dry Environments

Normal daily cleaning of Dry Clean Only areas – such as bagging/packaging rooms, sifter rooms, storage bin areas, anything post dryer and the dryer tower - should involve only dry-cleaning practices and procedures. This would include taking a continuous sanitation, 24 hour-7-day, approach to keep all product in the pipes and not found in the environment. Also, dry cleaning should follow a top-down approach utilizing the seven steps of dry cleaning using dry towels, brushes, and vacuums to collect and remove all product from the environment. A best practice after a special cause cleaning is to conduct a "Source of Contamination" evaluation. Simply put, this means having people stationed to see what equipment becomes dirty/dusty first after the clean-up. Whichever equipment is soiled first is your primary source of contamination and fixing it should be prioritized. This can be repeated and each time you will fix your worst leaks.

A modified or alternative wet clean may be necessary to remove soil from hard to clean areas, to be a mitigation for a microbial concern, or as a preventative step for any breaks into the closed system post-dryer. A modified or alternative wet clean would include the use of alcohol or alcohol/quaternary solution to clean and sanitize/treat the area in question but should occur ONLY after an effective dry clean has been performed to remove as much product as possible.

NOTE

Evaporation of any liquids but especially those containing water will potentially change the relative humidity in the room, depending upon air handling efficiency. This could lead to condensation forming at another point in the system.

Great care must be taken to not introduce unnecessary water/moisture into the dry environment. Special efforts should be made to ensure product and water do not mix and leave behind any residues that may serve as nutrients for pathogens of concern. After wiping surfaces with the alcohol solution, the surfaces and area should be completely dried out before exposure to product.

A controlled wet clean may be necessary to remove hard to clean areas as well, but it is not preferred. A controlled wet clean would include a localized spraying of conventional cleaning chemical or sanitizing solutions, followed by scrubbing, wiping and controlled rinsing, as necessary. The objective is to contain the introduced moisture to a small area where it can be controlled and removed from the environment without introducing excess water into the surrounding environment. Again, it is critical to first conduct a thorough dry clean to remove as much product as possible before attempting a controlled wet clean. Controlled wet cleans should be closely monitored to ensure containment and ensure complete dry out afterwards. Any area that gets wet will need to be wet cleaned to ensure complete removal of any wetted soils, therefore containment, inspection, and dry out are critical. NOTE: The same evaporation and potential condensation concerns apply as mentioned for modified wet clean. Use of alcohol following a controlled wet clean can help promote evaporation of water during the dry out.

Sometimes it becomes necessary to conduct a wet clean in a specific dry area or of the entire dry clean only plant, due to microbiological concerns, equipment, or structure failure/moisture introduction, or as a planned Deep Dive for periodic equipment tear down and/or clean break establishment. The same principles will apply as outlined for the controlled wet clean. Efforts should be made to contain and minimize water introduction, but again, any area that gets wet will require a complete wet clean. Therefore, a commitment must be made to conduct a complete wet clean following the seven steps of wet cleaning, and then ensuring a complete drying out of all equipment and the environment prior to beginning production. The first step of wet cleaning is dry cleaning, and it is critical to conduct a complete dry clean to remove as much product as possible prior to introducing any water through the cleaning process – even if the area had already been wetted in by other modes of water introduction. The dry out process should be verified by visual inspections and monitoring relative humidity throughout the process and facility. A complete wet clean in a dry clean only area will require tear down inspections and deep cleaning of equipment and structure to ensure no wetted product or excess moisture is left behind.

Similar to wet sanitation requirements, during special cause cleaning or periodic deep cleaning, equipment should be disassembled to expose internal surfaces. Any overlapping parts are disassembled to expose all surfaces and bolted and/or fastened parts are separated. If the equipment is complex, the equipment manufacturer may be consulted to support the teardown. After removal of any soil and subsequent deep cleaning, different sanitizing methods should be considered based on access to surfaces, presence of electronic components and motors, and other factors.

Some options are:

- Alcohol wipes are used for electrical boxes or control panels to limit water.
- Chlorine dioxide gas may be used, in extremely tough areas to mitigate, if the area can be safely contained.
- Dry steaming can be used to spot treat when other mitigation tools have not fully solved the issue but be cautious of condensation and water in the area.

Master Sanitation Schedule

A Master Sanitation Schedule (MSS) is a documented system for managing and tracking non-routine cleaning and sanitizing tasks. These can be areas of the plant (both infrastructure and equipment) that are not typically cleaned after each use or production cycle. Because these tasks are non-routine, it is important to have a comprehensive list and set cleaning frequency based on pathogen risk, cleaning history, and proximity to exposed product. Master Sanitation tasks can be categorized as Periodic Infrastructure Cleaning (PIC) or Periodic Equipment Cleaning (PEC).

PIC Examples

- ✓ Walls
- ✓ Floors
- ✓ Ceilings
- ✓ HVAC ductwork
- ✓ Overhead equipment (hoists, beams)
- ✓ Pallet jacks
- ✓ Forklifts
- ✓ Floor scrubbers
- ✓ Ladders/Steps
- ✓ Electrical Cabinets
- ✓ Overheads
- ✓ Lights
- ✓ Conduit
- ✓ Coolers/Refrigeration Units
- ✓ Dry Storage/Case Packing Areas

PEC Examples

- ✓ Conveyors
- ✓ Dryers
- ✓ Chillers
- ✓ Heat exchangers
- ✓ Scales
- ✓ Wear strips
- ✓ Pumps
- ✓ Valves
- ✓ Spray devices
- ✓ Gaskets
- ✓ Guards
- ✓ Chains/Sprockets
- ✓ Check-balls/Valves
- ✓ Catch Pans
- ✓ CIP System Components

Each task on the MSS should have an associated SSOP and should be assigned to trained personnel. Each task area should also be inspected periodically before and after cleaning to ensure that the frequency is appropriate, and that the task is being properly completed. The MSS program should be re-evaluated when process, new equipment or structural changes are made to the plant. A plants MSS PEC and PIC tasks listing is never 100% complete. They should be constantly reviewed and updated in conjunction with new or on-going PEMP investigations, and other outage findings, with adjustments made to task listing and frequency of cleaning.

PRINCIPLE #5: PATHOGEN ENVIRONMENTAL MONITORING

A robust environmental monitoring plan designed to verify the effectiveness of pathogen control programs is an important component of any food safety plan. Top management commitment and involvement in the design and execution of this plan is critical, and should include regular reviews of environmental results, trends, corrective actions, and a drive for continuous improvement. A successful written plan also depends on detailed planning, proper resourcing, definition of roles, and empowerment of the responsible personnel.

A good Pathogen Environmental Monitoring Program (PEMP) has various components that work together:

Facility-Specific Risk Assessment

Pathogen Monitoring Plan

- Target microorganisms
- Where to sample
- When to sample
- How often and how many samples
- Sampling and sample transport
- Selection of testing laboratories
- Evaluation of results and trending
- Response to results and trending

<u>Facility-Specific Risk Assessment</u>

In order to identify areas of vulnerability, each facility must collect relevant background information and perform a facility-specific evaluation. This will aid in determining the number, location, and frequency of sample collection and provide a valid risk-based foundation for the program. A 24-month plant historical review of environmental testing results is ideal when creating or updating a PEMP program because it will include seasonal environmental changes, production volume/mix changes, personnel vacations, holidays, and other cyclical factors which impact the plant environment. Facility assessment considerations include:

- Product exposure to the processing environment after pasteurization but prior to packaging.
- Human handling of product prior to packaging
- Traffic flows and human interactions with products and equipment
- Physical separation of raw and RTE
- Extended processing time and its impact
- Equipment and facility design challenges

According to FDA, "It is recommended that your environmental monitoring procedures use a risk-based approach in which you establish strategies for environmental monitoring (e.g. environmental sampling, sampling sites and frequency, test procedures, and corrective actions) based on both the characteristics of your RTE food products and the processing methods used to produce those products. In general, the greater the risk that a RTE food could become contaminated with a pathogen and support growth of the organism, the greater the frequency of environmental sampling and testing[7]" It is generally accepted that the use of indicator organisms for target pathogens of concern is part of a robust PEMP plan.

<u>Developing a Pathogen Monitoring Program</u>

- ✓ What to Test For
  - Wet Processing Areas

    Listeria species are a broad group of indicator microorganisms which, when detected, signal that conditions are also favorable for the pathogen *L. monocytogenes (Lm)* to grow or survive. The goal of a Listeria Environmental Monitoring Program (LEMP) is to aggressively look for, find, and eradicate conditions that can support pathogens including all *Listeria* species from the processing environment, ensuring the absence of *Lm*. A program based on detection of *Listeria* species is broader than one monitoring for *Lm* specifically because *Listeria* species will be found much more frequently in the environment. Another advantage of *Listeria* species monitoring is the time for results. Environmental swab test results for bacteria species are typically available much faster than tests that confirm the identification of *Lm*. Faster results will enable a more rapid response and intervention actions, if required. It is considered a best practice to monitor for the presence of *Listeria* species. Further testing to determine which species of *Listeria* has been detected when a positive *Listeria* species is found can be valuable to gain more knowledge of the environment.

  - Dry Processing Areas

    Enterobacteriaceae (EB) testing
    - EB can be used to detect a change in sanitary condition, such as introduction of moisture in a dry area.
    - Sampling is typically done in controlled production areas such as critical and/or high hygiene zones.
    - Typically, the target level is <100 cfu/swab and the action level are >1000 cfu/swab.
      - Target levels are determined by swab location (proximity to product) and product risk level.

    Salmonella
    - It is known to survive in low water activity foods (<0.85 Aw).
    - Historically, *Salmonella* ssp. has been associated with milk powders.
    - Any detected requires immediate corrective actions.

Cronobacter sakazakii

- *C. sakazakii (*formerly known as *Enterobacter sakazakii)* is an opportunistic and devastating pathogen in premature and term infants, the elderly and other immune compromised people and elderly nursing home residents as stated in CDC website: https://www.cdc.gov/cronobacter/index.html
- FDA requires *C. sakazakii* testing for infant formula manufacturers per 21CFR106.55. Similar to *Salmonella*, *C. sakazakii* is able to survive in low-moisture foods, like powdered infant formula, for exceptionally long periods of time.
- Any detected requires immediate corrective actions https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048694.htm

✓ Where to Sample

The goal of an effective PEMP is to aggressively seek and find any target pathogens present in a facility so that they can be eliminated. It should be expected to find these organisms on occasion in the plant environment. Product contact surfaces, processing rooms, and areas adjacent to processing areas are referred to in a series of successively larger "zone" rings where "Zone 1" is a product contact surface, and "Zone 4" might include a floor in a warehouse. The objective of the zone designations is two-fold: 1) developing a mindset of taking actions to prevent pathogen travel through adjacent zones to product contact surfaces, and 2) establishing a common set of terms for discussions among practitioners. Zones are defined based on the proximity to the product and potential risk of contamination[13] (Figure 34). Zone designations are generally fixed, but could be dynamic depending on the facilities layout, personnel activity, or equipment conditions.

There is an important difference between "zones" and "sampling sites or locations." Swab sampling "sites" are the specific physical location of the sample (e.g., shaft of motor #43, handrail on blender deck, left guide on product conveyor), which must be recorded with each sample. For example, your sampling plan for monitoring Zone 2 on a particular manufacturing line would contain a list of all specific sampling sites that are non-food contact surfaces immediately adjacent to Zone 1. The Zone 3 list would contain sampling sites further from Zone 1 and adjacent to Zone 2, and so on (See Table 10).

REMEMBER

Raw Areas

- *Covered by basic GMPs.*
- *If raw areas are swabbed, it should be done only after sanitation to evaluate cleaning effectiveness.*
- *Environmental Monitoring activities focus on hygienic junctions with other hygienic zones.*

Examples:

Milk Receiving
Milk Storage
Milk HTST Room
Raw Ingredient areas

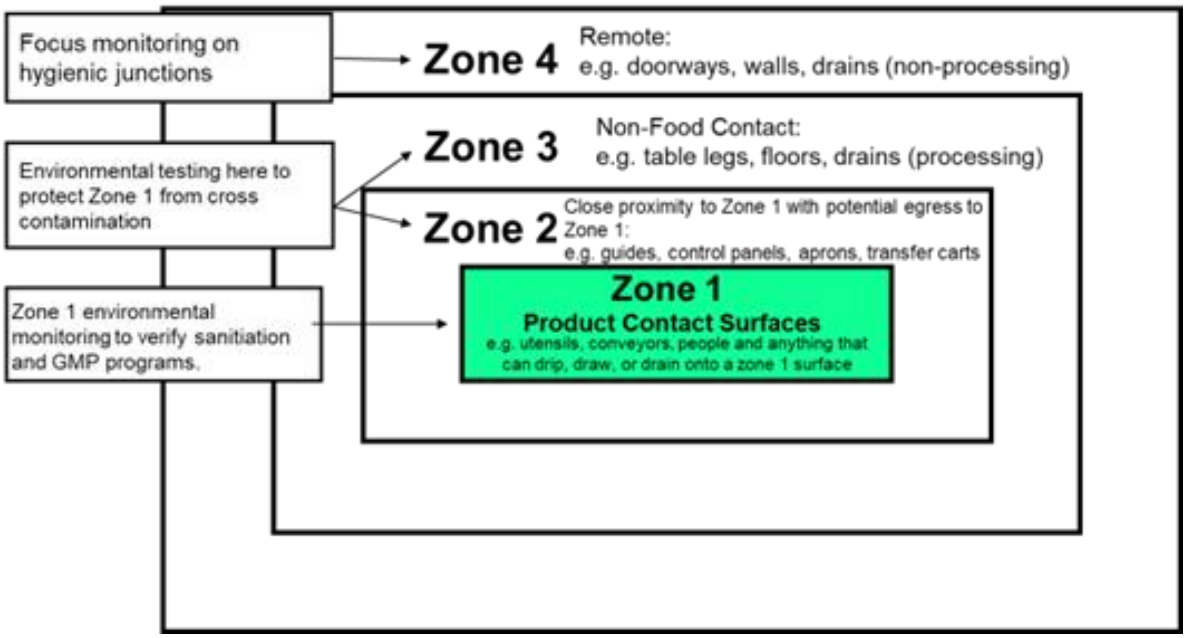


Figure 34. Environmental Monitoring Zones

Table 10. Additional information on zones and sampling

	Description	Examples
Zone 1	Product contact surfaces – direct and indirect (includes anything that can drip, drain, draw, or diffuse onto product contact surfaces or into product)	Filling heads, hoppers, scrapers, utensils, packaging equipment surfaces, product contact conveyors, brine
Zone 2	Non-product contact surfaces near Zone 1 which, if contaminated, could reasonably contaminate product contact surfaces through normal operations	Sites near Zone 1 which might include: items above exposed product, package guides, equipment legs, framework, motor housings, tank lids, control panels, scrap carts, conveyors, HVAC vents, air filters, floor mats at packaging
Zone 3	Other locations within RTE or High Hygiene processing areas. Remote chance of contaminating product or product contact surfaces under normal practices without mechanical or human intervention	RTE or High Hygiene processing room floors, walls, surfaces, wall/floor junctions, cleaning tools (brooms, squeegees), floor scrubbers, forklifts, floor drains, ceiling drainpipes, wash stations, ingredient storage areas, transition rooms, etc.
Zone 4	Areas outside of RTE or high hygiene processing rooms	Warehouses, laboratory, lockers, break rooms, compactor areas, offices, maintenance shops

(Adapted from ICMSF 2002)

A sampling plan should be dynamic and robust, incorporating static, rotating, and random sites with planned sample sizes that take into consideration risks such as raw/RTE crossover, facility/equipment age and condition, history, and product type. Sampling Plan/Considerations regarding testing locations include:

- Zone 1
  - Target the appropriate pathogen or indicator bacteria based on risk assessment (e.g., *Listeria monocytogenes* = *Listeria spp. or Salmonella*) *Enterobacteriaceae* (EB) indicates evidence of previous moisture and cleanliness and can be used to assess a Zone 1 prior to doing *Salmonella* testing.
  - Obtain an environmental understanding of the RTE production line areas prior to implementing Zone 1 testing by having a good data set of Zones 2 & 3 to study and review. The review of the Zone 2 & 3 data should indicate environmental control of the affected RTE production line area(s).
  - Verify effectiveness of your control programs, such as GMPs (See **Principle #2 Good Manufacturing Practices and Controlled Conditions**) and sanitation (See **Principle #4 Effective Cleaning & Sanitation Procedures and Controls**), against target pathogens.
  - Each company will need to design a plan appropriate for their own situation, based on the risks presented by their plant characteristics and processing conditions, to develop their Zone 1 testing program. Testing for and finding Listeria species on a Food Contact Surface (FCS) does not establish the presence of *L monocytogenes* on the FCS or in product, but appropriate and aggressive corrective actions need to be taken and documented. Consider developing a program where the data is continually reviewed to drive actions (e.g., if a production line's Zone 3 data indicate increased activity one should consider holding product when testing Zone 1 sites).
  - More information on Zone 1 monitoring can be found in the FDA's Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry, Draft Guidance[7]. You should involve an internal or external Food Safety Expert to develop your Zone 1 monitoring program to determine which specific sites to sample and how product will be controlled pending sampling results from routine and non-routine sampling of zone 1. As the new FDA Listeria control guidance describes, only test for Listeria species in zone 1 (not Lm).
- Zone 2 & 3
  - Robust and routine sampling of Zones 2 and 3, for Listeria species and Salmonella, obtains an early indication of target pathogens and identification of harborage sites, helps prevent Zone 1 cross-contamination, ensures corrective actions have eliminated target pathogens from harborage sites, and verifies the effectiveness of your control programs for the target pathogens.
- Zone 4
  - Zone 4 sampling should take place less frequently and is used to determine whether transient microorganisms are present that may pose an eventual risk to the RTE areas, or for investigational purposes. Sampling non-production and transition areas (Zone 4) may also help to assess the effectiveness of sanitation and GMP controls.
  - Areas historically associated with Listeria species presence (e.g., hollow rollers on conveyors, gasket material around doors, hollow support structures, grease inside bearings, slicers, dicers, drip pans, condensate, and drains) should be preferentially included in the plan for wet processing areas.
  - Areas historically associated with *Salmonella* and/or *C. sakazakii* detection (e.g., floor/wall joints, sifter tailings, vacuums, dust collector, air intake cabinets/filters, floor sweepings, etc.) should be preferentially included in the plan for dry processing areas.

- Focus on the most critical areas of the plant such as where water may accumulate. It is recommended to include the area between the final kill step and final packaging if product is exposed to the environment.
- Sample at interfaces, transition areas, and barriers between raw areas and RTE areas to verify the effectiveness of separation efforts.
- Sample collection personnel should have the freedom to sample additional sites based on observations. (e.g., an area in dry processing that shows evidence of moisture intrusion).
- Special project/construction environmental sampling is recommended during the length of the project to detect if any areas of disturbance introduce pathogens. Preventable large scale pathogen contamination events that resulted in illnesses and deaths were associated with construction projects or other ingress issues from outside the factory. For example, Peanut Corporation of America sold *Salmonella* contaminated peanut products, resulting in 9 deaths and over 700 illnesses. The source of the *Salmonella* is thought to be most likely from roof leaks onto raw peanuts during storage.
- A cross-functional food safety team with knowledge of the plant's programs, processes, and practices should be used to develop a list of sampling sites. A site map identifying facility layout, traffic flow and hygienic zoning areas should help drive site selection.

✓ When to Sample

Routine environmental sampling is performed during production, at least 3-4 hours into the production cycle. Extended runs may warrant sampling later in the run, starting at least halfway between sanitation cycles. This timing is recommended because harborage sites may not be identifiable immediately after cleaning and sanitation. Pathogens established in a niche may work their way out with vibration and moisture as equipment is operated. Some samples can only be collected safely when equipment is not running, these samples can be collected at the end of production before cleaning or any other time when the equipment is idle and can be safely accessed.

Routine sampling should be conducted on a set frequency (e.g., daily, weekly, bi-weekly) based on individual facility conditions, circumstances, and history. Timing should rotate to ensure situations are monitored across all days, shifts, plant areas, and zones. Varying timing to represent the entire production schedule and to capture events that only occur periodically will help in investigating any issues. Some Zone 4 sites may only be sampled monthly or quarterly.

For non-routine, investigational, or special events swabbing, timing and number of samples is determined by the specific circumstance. Sample when conditions are not typical, such as during audits, tours, construction, etc. Always sample when a drain backup or roof leak occurs especially in traffic pattern areas. Additionally, a process should exist for swabbing all

REMEMBER

Routine Sampling

- *Should be conducted on a set frequency (e.g., daily, weekly, bi-weekly)*
- *Rotate the timing of when swabs are taken across all days, shifts, plat areas and zones.*
- *Make investigative swabs part of routine sampling.*
- *Aggressively look for potential microbial harborage points or niches*

new incoming equipment prior to use, and pre- and post-swabbing for construction.
Beyond routine sampling sites, it is also a good practice to perform some random sampling/testing as a further check that the facility's pathogen control programs are working as intended.

✓ How Often and How Many Samples

The number of samples collected will differ by zone, the risk to exposed product, and the complexity of the production system. The overall number of samples taken each week is facility- and product-specific. Considerations include, but are not limited to:

- Generally, it is recommended that a minimum of 5 samples be collected for Food Contact Surface (FCS) and non-FCS per line for small facilities. Facility size and layout as well as history will determine sampling numbers. For more details refer to FDA's Control of *Listeria* monocytogenes in Ready-To-Eat Foods: Guidance for Industry, *Draft Guidance*[7].
- Process conditions: degree of RTE product exposure to the plant environment, human handling prior to packaging, product temperature at packaging (hot fill vs. cold fill).
- Product risk assessment: does the product support survival or growth of pathogens?
- Condition of the processing facility: floors, overheads, wall conditions, age, product flow, etc.
- Sanitary condition of processing equipment: welds, cracks, pitted, material, easily cleaned, etc.
- Industry historical data and recent outbreaks: industry environmental monitoring norms, recent product or ingredient concerns, inherent risk profile of product type or equipment, etc.
- Other factors: distribution conditions, shelf life, intended use, target distribution channel, if product is for higher risk consumers (young, old, pregnant, immunocompromised)
- Flexibility: plan should accommodate routine as well as investigational, validation, and verification objectives.

Remember

It is important to recognize that swabbing requires abrasive/firm rubbing to enhance the chances of finding areas where biofilms may have been established.

✓ Sampling-Swabs and Media

- Trained plant personnel should collect samples aseptically using hygienic handling practices.
- Individuals sampling should proceed from "clean" areas to lower hygiene areas to avoid cross-contamination of the facility. This means Zone 1 product contact surface (PCS) swabs are taken before non-PCS swabs and RTE area swabs before non-RTE areas.
- Sterile sponges are effective for sampling large areas (e.g., 12 x 12 inches and larger) and smaller "swabs" may be used for small or difficult-to-access areas. Sponges and swabs must be moistened with an appropriate buffer solution. If residual cleaners or sanitizers may be present on sample sites, a buffer containing a neutralizing agent must be used. Consult with your testing laboratory or technical expert regarding the choice of buffer solution.

NOTE

Zone 1 areas are also often called either Food Contact Surface (FCS) and/or Product Contact Surface (PCS). These are interchangeable terms.

- A separate sponge or swab should be used for each distinct site. For sponges, sample as large an area as reasonably possible using firm rubbing/abrasion to enhance the chances of finding organisms where biofilms may have become established.
- For long pipelines or inaccessible assemblies, such an enclosed tank, rinsing with a buffer solution and then testing the rinse solution (rinsate) is an acceptable practice.
- In Dry Dairy operations sterile dry wipes may be used to collect samples to not introduce any moisture into the area. Work with your testing lab for proper handling of each sample collection type.
- Compositing samples to reduce testing costs should be considered only in mature PEMP programs where positive results are rare. Compositing can cause delayed follow-up and/or confusion when conducting corrective action. Up to five separate sponges may be combined into one "composite sample" for testing. Do not composite swabs from different zones. Sample compositing should not be done during an investigation following a positive swab. In the event of a suspect result on a composite, each site must be treated as suspect and individual corrective actions taken. Consult with your testing laboratory regarding appropriate compositing protocols.

✓ Sample Transport

- Swab samples should be held and transported refrigerated. Ideally, swabs are tested within 48 hours after being taken, it is recommended the time does not exceed 72 hours.

✓ Selection of Testing Laboratories

It is important that your testing laboratory is accredited and reliable for the desired tests. It is recommended that the laboratory be accredited to ISO 17025 or have a management system to address the key components of an accredited laboratory:

- Staff competency and documented training.
- Test methods documented and based on accepted standards.
- Equipment fit for purpose and appropriately calibrated.
- Documented QA program including proficiency testing.
- Internal audits of lab operations.
- Internal environmental monitoring to help evaluate if conditions are impacting client results.

The laboratory should be experienced in testing of environmental monitoring samples for pathogens and should use only test methods that are recognized or accredited for product or environmental testing. These methods are described in the FDA Bacteriological Analytical Manual, ISO methods, or validated through recognized validation bodies, such as AOAC.

<u>Evaluation of Results and Trending</u>

Results should be reviewed as soon as practical after receipt. It is recommended that a facility map be used to indicate where sample sites are located and to indicate where positive results occur. Mapping gives a visual depiction of the sites in relation to exposed product equipment, traffic routes, and convergence areas and may lead to identifying patterns not otherwise apparent (See Figure 35). Indicate sampling time to

identify shift, before/after sanitation, etc. A food safety team should monitor and review PEMP data on a regular basis, looking for trends or patterns (See Figure 36).

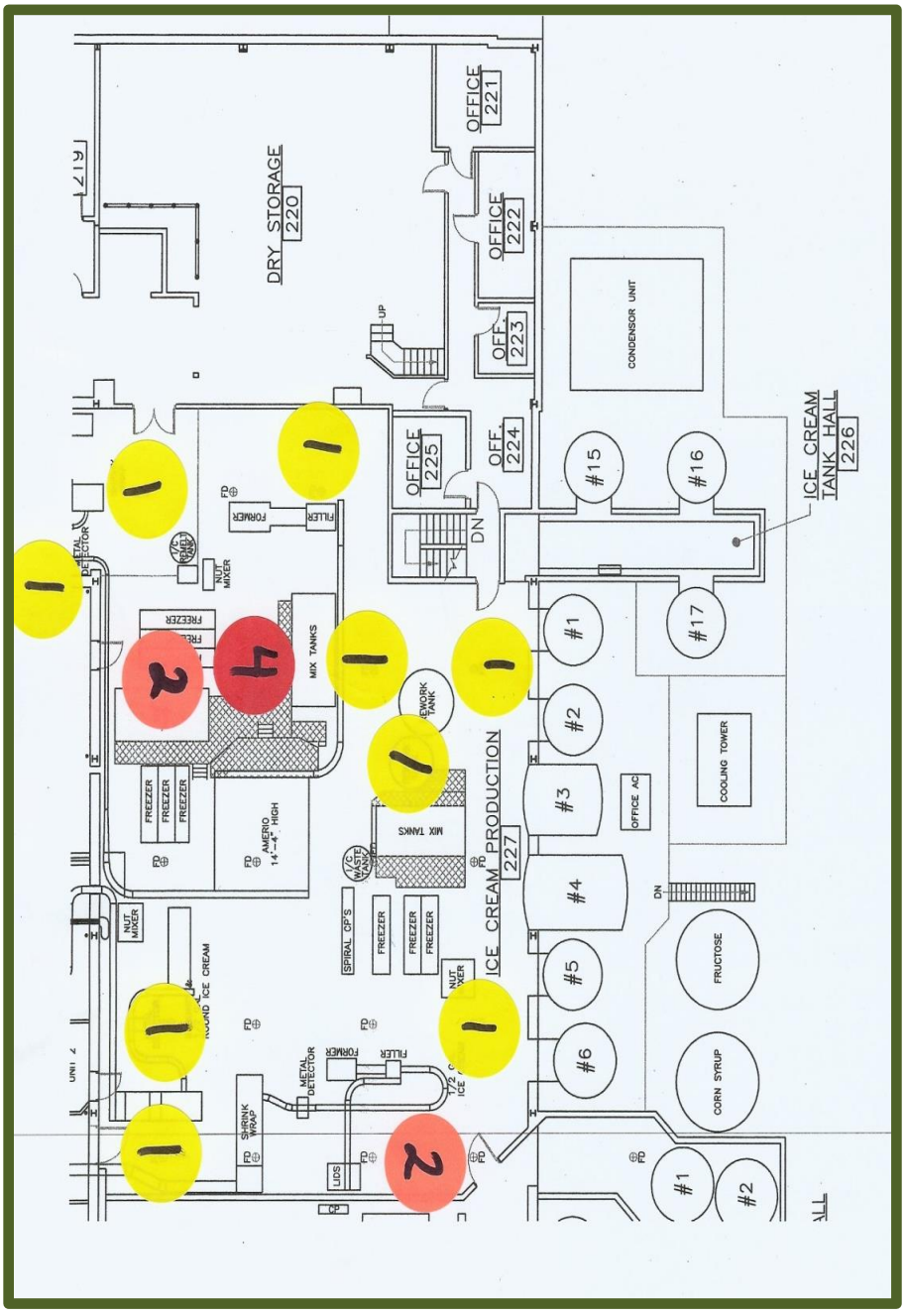


Figure 35. Example map format for tracking and trending

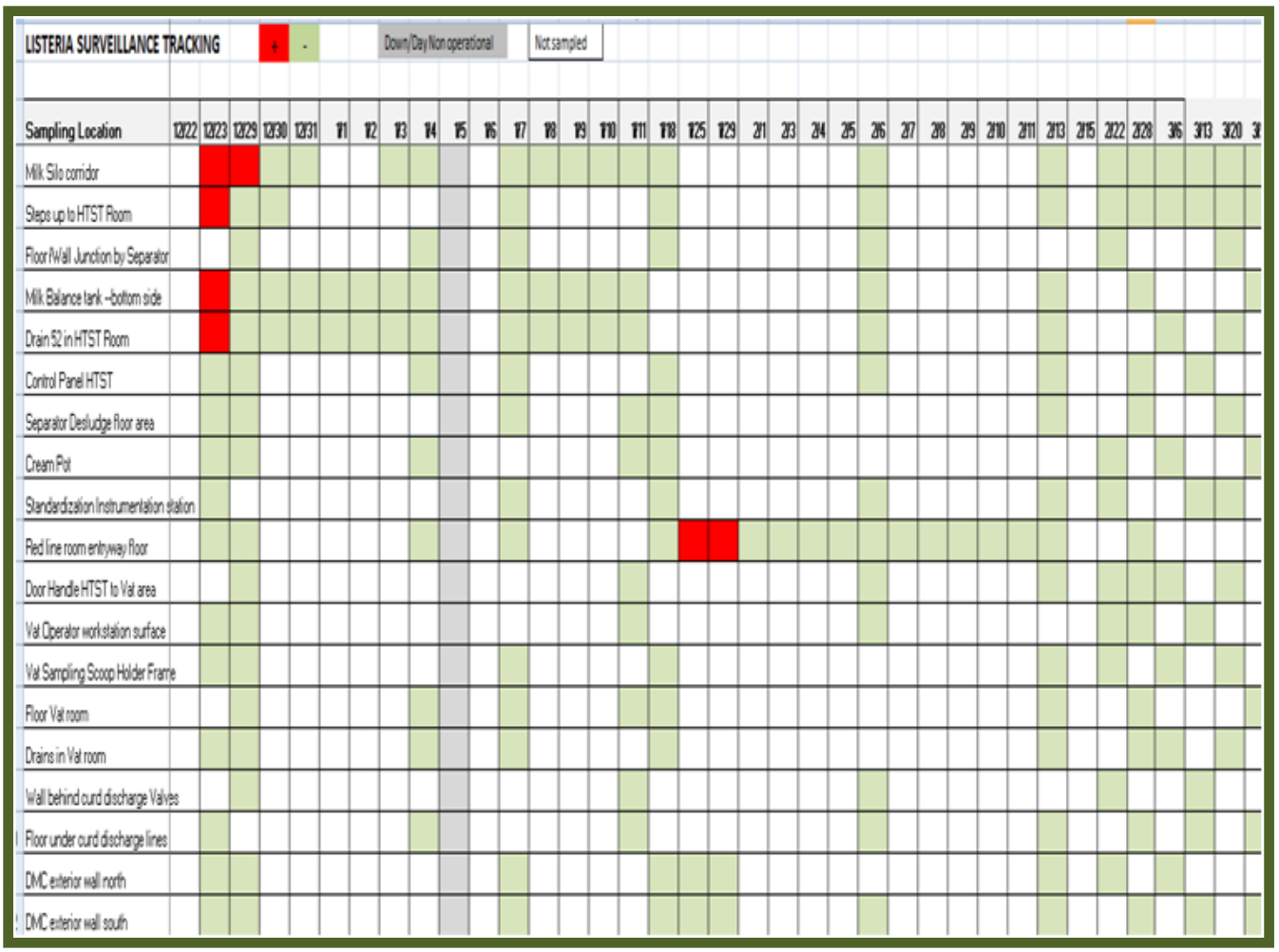


Figure 36. Example spreadsheet format for tracking and trending

Case Study 1—Eliminating a Growth Niche

During routine sampling in a processing room, a floor sample under a conveyor and near a metal detector came back with a presumptive positive for *Listeria* spp. during operation.

The food safety team immediately conducted investigational swabs on nearby sections of the floor, on equipment framework, legs, guards, and bearings/shafts. Investigational swabs were taken after cleaning and during operations.

All post-cleaning swabs came back negative with the exception of one near a bearing housing (See Figure 37). During operation, other sites adjacent to the bearing housing were also positive.

Figure 37. Sandwich area formed by the bearing housing and framework where *Listeria* spp. had established a niche and the framework had rusted.

Maintenance disassembled the bearing housing and noticed rust on the housing and the framework. They changed the housing and asked sanitation to clean and sanitize (quaternary ammonium) the framework. To verify the effectiveness of their actions, the new housing and the sanitized framework were sampled for *Listeria* species. The results were negative for the new housing but there was a presumptive positive result for the framework.

Maintenance removed the housing and used a different type of sanitizer (alcohol-based). An individual swab still came back presumptive for *Listeria* species.

At that time, maintenance decided to remove all the rust on the framework by buffing and sanitizing it. Following these actions, the results were negative for *Listeria* species on all surfaces adjacent to the housing including the floor. The area was monitored and sampled through multiple rounds of cleaning to build confidence the issue was mitigated.

This case study highlights the importance of vectoring to identify a niche and the importance of verifying the effectiveness of the actions taken.

Response to Results and Corrective Actions

A corrective action response is required for all environmental positive pathogen findings (presumptive and/or confirmed) and out of specification indicators. Additional testing of identified indicator or pathogen species, for example *Listeria innocua* (non-pathogenic) or *Listeria monocytogenes,* to determine sub-types (e.g., using genetic fingerprinting or genome sequencing methods) can provide useful information for tracking unique organisms and determining route cause and/or harborage sites. Response to a positive result requires a company or plant to:

- ✓ Isolate and limit traffic in/around the area. Resample areas represented by the positive sample.
- ✓ Conduct a thorough investigation/risk analysis of area.
- ✓ Complete vector swabbing at the first opportunity, before cleaning, if possible, to better determine the contamination source and prevent the potential spread of the organism to other areas.
- ✓ Implement intensified cleaning and sanitizing, possibly including equipment disassembly.
- ✓ Intensified sampling and testing to confirm the effectiveness of corrective actions.
- ✓ Determine root cause and implement long-term corrective actions for the root and contributing causes. In the event a long-term corrective action must be delayed, mitigation steps/temporary actions must be taken to prevent spreading and/or contaminating product/product contact surfaces.
- ✓ Determine if finished product testing is warranted based on proximity of positive result to an FCS and/or to exposed finished product.
- ✓ Document all findings, corrective actions, and risk assessment rationales.
- ✓ Ensure senior-level food safety/quality directors and executives are kept informed of identified problems and resources needed to resolve them.
- ✓ Further details on Zone 1 mitigation and corrective action steps can be found in FDA's Control of *Listeria* monocytogenes in Ready-To-Eat Foods: Guidance for Industry, *Draft Guidance*[7].

The immediate response to a positive is to resample the area or equipment extensively to identify the specific source site. If a composite sample was tested (it is not recommended) then all individual composited sites must be investigated. If possible, limit access to this area to prevent unintentionally transferring the pathogen to other areas of the facility. It is possible that equipment may have to be disassembled to be fully inspected and cleaned. Then thoroughly clean and sanitize the affected area. When cleaning the area, verify that the standard procedures are adequate for the equipment/area to be cleaned. Mechanical action (scrubbing) is necessary for the removal of biofilms.

Complete a vector analysis of the area to determine how the organism may have been introduced and if it may have spread but be careful not to spread any potential contamination. Look up, down, and in all directions (360 degrees) for potential sources.

Remember

***Corrective actions** should always include re-swabbing of the area under similar conditions to verify that remediation efforts have been successful. Each facility should establish a required number of consecutive negative results before considering the area "clean." This number is often 3 but may vary based on the zone and general environment. If the zone has multiple traffic patterns, re-swabbing should be conducted based on a complete cycle of traffic or processing. It is critical to document all investigations and corrective actions as well as follow-up testing.*

The investigation should include a review for leaks, crevices, metal joints (welded and bolted), broken or loose tile, hollow areas, air handling units, and air flow. Include both stationery and transient equipment in the investigation. Be sure to include traffic patterns in the area, as they are a potential source as well as a risk of tracking the organism to additional areas. The analysis should include inspections using your senses (sight, smell, touch) as well as a regimen of investigational swabs to assist in locating the source. Follow-up sampling is performed after cleaning (see sidebar).

Special Considerations

- ✓ **If repeated positive pathogen or indicator results** are encountered within an RTE area, close to or in Zone 1, for which the cause has not been identified, **it is strongly recommended that the facility cease production**, identify causes, and take corrective actions before resuming production.
- ✓ When a test reveals the presence of *Lm or Salmonella* in a product, the product is considered adulterated and must be withheld from commerce. If any part of the production lot has already been shipped, it must be recalled, and a report filed through the FDA Reportable Food Registry.
- ✓ The above conditions may indicate a loss of control and the facility should engage internal or external food safety professionals to lead and facilitate troubleshooting and corrective actions.
- ✓ Cheese brines directly contact product and should be considered Zone 1. *Listeria* can survive in the cold, salty conditions of cheese brines, so they deserve special attention. Brines and brining equipment should be clean and in sanitary condition. The brine itself should be considered an ingredient, not just a processing aid, and must be sourced and handled accordingly. Refer to **Appendix H Brine Systems Food Safety Best Practices** for the food safety elements of a brine system program, with an emphasis on microbiological controls.
- ✓ Shelves, boards, and other surfaces that are used to age or drain unpackaged cheeses and other dairy products are considered Zone 1 and should be maintained in a sanitary fashion.
- ✓ When brines, aging shelves, boards, and other direct product-contact surfaces are tested for an indicator such as *Listeria* species, company management should have a clear understanding of the product implication in the event of a positive test result. Possibly implicated product should be held until negative results are received.
- ✓ Sifter Tailings in dry dairy operations may be considered similar to finished product when tested for indicators or pathogens. The company management should have a clear understanding of the product implication in the event of a positive test result.

Program Verification and Documentation

Verification of the PEMP should be a routine process involving the review of all program elements, results, corrective actions, and documentation. It includes visual observation of the program execution to ensure that all required steps are performed properly and completely. Verification of the PEMP may include activities applicable to the overall program or to a specific line/area. Items to be reviewed include:

- ✓ Review sampling techniques and methodology
- ✓ Does the monitoring program include the appropriate numbers of samples, appropriate site locations, and correct timing of sampling?
- ✓ Is the proper sampling procedure being followed and correct locations being sampled?
- ✓ Are samples handled and delivered to the lab in an appropriate manner?
- ✓ Are the correct (analytical methods) methods being used? Are they followed correctly?

- ✓ Are all personnel taking and handling samples trained in correct protocols?

- ✓ Review records and results
  - Are documents, records, and reported results (including required review/signoffs) accurate and complete?
  - Are there documents, records of response for all findings and corrective actions?
  - Have periodic reviews of results identified any trends or repeat issues?
  - Were corrective actions implemented and followed?
  - Do records show that the corrective actions effectively re-established control?
  - Are the appropriate management personnel aware of results and corrective actions?
- ✓ Identify modifications to the sampling plan in response to
  - Results/trends/repeat issues.
  - Special circumstances.
  - Changes to product, process, equipment, and/or plant environment.
  - Industry history.

SWAB-A-THON

A valuable verification/validation activity that many companies have adopted is to conduct a "swab-a-thon" on a periodic basis (once or twice annually). This is a deep dive swabbing event (100+ swabs depending on size of facility) that is above and beyond the base program sampling to look even harder for the presence of pathogens in the processing environment.

Records of sampling maps, plans, results, and corrective actions should be maintained. These are valuable when evaluating the effectiveness of the plan and enable valid reviews for improvement. As with all records, they should be dated, signed, and traceable to the facility and processing line.

During the verification, additional sampling may be conducted at additional and/or different sites to demonstrate that routine sampling has been effective. Finished product testing may also be used. Other activities may include engaging an outside expert, consultant, or reviewing published materials.

Case Study 2—Environmental Contamination Leading to Presumptive Positives

The facility receives different natural cheeses and other microbiologically sensitive material to make process cheese. Blending and packaging takes place in a high hygiene room where the product is cold packed. The packing line is wet cleaned daily. Because the product is cold packed and exposed during packaging, the pathogen environmental monitoring program includes Zones 1, 2, 3, and 4 sampling for *Listeria* species during operation (minimum 4 hours after the beginning of production). When Zone 1 surfaces are sampled, all product is held pending negative results.

One of the Zone 3 samples, a floor sample from the packing room, was presumptive positive for *Listeria* species. Corrective action was taken by cleaning with foam and scrubbing the entire floor followed by application of peroxyacetic acid sanitizer. Follow-up swabs were all negative (three consecutive sets) for *Listeria* species.

Then, about a month later, another floor result was presumptive positive for *Listeria* species. Similar corrective actions were taken, and investigational swabs revealed an additional Zone 3 positive for *Listeria* species. All investigational Zone 2 results were negative. After the corrective actions, the first two sets of follow-up results were negative; however, on the third set, one swab was presumptive positive for *Listeria* species, which led to more investigational swabs. Some Zone 3 investigational swabs taken during operation came back presumptive positive for *Listeria* species. All *Listeria* species environmental samples taken after cleaning, but before operation, were negative.

When mapping the results and observing production, the food safety team noticed that water was dripping onto the floor and across a piece of peripheral equipment before draining near exposed product. The sanitation team had minimal access to clean under the peripheral equipment and the epoxy floor showed some damage in that area.

For preventive actions, the team installed a temporary barrier during production preventing water from dripping onto the floor and performed periodic sanitizing of the floor with a peroxyacetic sanitizer during operation (note: alkaline peroxide powder would also be an option that would help keep the area dry). Following the implementation of these preventive measures, all environmental *Listeria* species samples were negative.

For corrective actions, maintenance fixed the leak, sealed the peripheral equipment with the floor, and resurfaced the floor.

What To Do If Targeted Pathogen(s)/Indicators Are Never Detected?

If you are not finding your target pathogen, are you looking hard enough?

It is unlikely that an effective PEMP in a dairy facility would never yield positive results. If your target pathogen(s) are never detected, then the sampling program should be revisited. Potential reasons for not detecting pathogens include:

- ✓ The sampling and/or testing procedures may not be rigorous or sensitive enough.
    - Ensure likely harborage points have been identified and sampled.
    - Ensure sampling times and frequencies are selected to detect the pathogen when most likely to be present.

  Ensure sampling procedures are followed and size of area sampled is adequate.
- ✓ Failure to neutralize residual sanitizer in sampled areas.
- ✓ Faulty detection methods or low technician competency.
- ✓ Manipulation of sampling or testing to obtain negative results.

Best practices for maintaining a robust pathogen environmental monitoring program:

- ✓ Ensure the pathogen environmental monitoring program (PEMP) evolves with changes in plant design, installation of new equipment, changes in traffic patterns, etc. Add or delete sites (when necessary), rotate sites within high-risk areas, and include investigational swabs during routine testing.
- ✓ Incentivize and verify that employees conducting swabbing are trained and maintain a mentality of seeking out potential points of risk (i.e., always maintain a "seek and destroy approach" vs. just swabbing to complete a task). The goal is to find cross-contamination risks rather than generating repeat negative results every swabbing event.
- ✓ Confirm that the method of analysis and swabbing tools are suited for the target and optimized to find contamination (pick-up, recovery, and detection). Stay current with new methodologies and techniques to maintain a robust program.
- ✓ Re-evaluate PEMP risk assessment – are the target organisms of risk to the process environment and product still the right ones or have things changed and there are now new risks to consider?

Case Study 3—Environmental Contamination of a Brine System

A specialty cheese manufacturer was notified that a random regulatory test had identified *Lm* in product sampled at retail. The product was still within shelf life and was obtained as unopened containers. Further sampling at the manufacturer's stock cooler identified additional packages with *Lm*-positive tests. A full product recall was initiated. The manufacturer had several very good controls in place and appeared to be very conscientious in their sanitation procedures.

Investigation and Observation

After extensive investigational swabbing, *Lm* was identified in a small crack in the ceiling above the open brine pit. An isolate from the crack had the same genetic fingerprint as the *Lm* isolated from the contaminated cheese. The crack could only be seen from a ladder above the brine area. The ceiling was reportedly cleaned every day after packing cheese. The brine was tested, and it showed presence of the same *Lm* identified in product and the crack. Additionally, one spot on the floor below the brine tank had a positive with the same isolate from the product, the ceiling crack, and the brine.

A thorough review of the environmental monitoring program identified overhead areas as the problem, including the ceiling in the RTE room, and it was added to the routine monitoring plan. It was also discovered that during sanitation, the ceiling was being washed using a high-pressure water hose, with spray/drips falling into the uncovered brine. This was identified as the probable source of the *Lm* contamination. The brine also splashed onto the floor sometimes and likely contaminated the floor.

Corrective Actions and Preventive Actions

- ✓ Recalled the product.
- ✓ Identified an infrastructure breach—the ceiling crack (which regular inspections would have identified) as a critical breach since it was over open brine. The owner immediately instituted regular inspections of overhead areas.
- ✓ Workers were provided with proper cleaning brushes and mops for the ceiling and overhead areas and use of high-pressure water hoses was prohibited. Furthermore, the pressure was turned down on all cleaning hoses. A long-lasting sanitizer is now used after cleaning the overhead areas.
- ✓ A new preventive measure of covering the brine during sanitation was instituted to prevent contamination with cleaning fluids or splashing from non-food contact areas.

Case Study 4—Environmental Monitoring Investigation in a Dry Dairy Operation

In a drying facility a significant full wet wash of the system that required a bag change was performed and then dry heated, as required by the Sanitation SOP. They had a typical start-up, were on schedule, and completed zone 3 swabs with all swabs results being negative. Three consecutive system purges (pushing new production material through a system in order to remove contaminants from piping and vessels) were conducted. All purge samples and the following finished product (at 1500g sample) were tested for Salmonella and were confirmed negative. Lastly, the facility performed a sifter tailings test(25 g). Their findings were negative on day 1 and 2. However, on day three and four the sifter tailings test resulted in presumptive positive for Salmonella with the same serotype on both samples.

Follow-up swabs were conducted for another 9 consecutive days obtaining only negative results. They performed 100 swabs on the floor, forklifts, drip marks, tote cart, compressed air for boot, bin vent sock and other equipment. The entire system was washed and sanitized from the conveying line, in the dryer room, to the receiver and boot, in the tailing room. All this was done to establish a clean break. The problem was not resolved, and the source was not yet found.

On day ten, the team recognized they had failed to investigate upstream of the conveying line, from the sifter tailings to the dryer room. They had only vectored downstream in the dry room. They then performed 30 swabs in the dryer room around the sifter tailings. The test results presented positive, with the same serotype as day three and four.

The room was clean, dry, and had strict hygiene controls in effect. The one object that stood out was the hose flex connector for the top of the sifter tailing receiver bin. It appeared dirty on the inside, and there were signs of moisture on the ferrule. After the discovery, the area was immediately quarantined.

The day following swabbing of flex connector hose, the system was dismantled, the flex hose was replaced, and the entire system was cleaned and sanitized. When the test results came back, the exterior and the interior both were positive with the same serotype.

The facility then determined the cause of the positive tailing came from the flex hose, not the dyer system. The problem occurred when the hose became contaminated from the major washes and did not dry appropriately before putting back into use.

<u>Corrective Actions and Preventive Actions</u>

- ✓ The facility replaced the flex hose, as part of the GMPs, to ensure it maintains a cleanable surface.
- ✓ A new type of hose and clamp installed allowed for ease of cleaning.
- ✓ The facility created a plan for follow-up swabbing until consecutive days were negative.
- ✓ They did not consider the area clean until the follow-up samples were negative.
- ✓ They implemented routine swabbing of this area.

PUTTING IT ALL TOGETHER

The control of select pathogens in dairy manufacturing environments is possible. When using food safety best practices in an organized and integrated approach, control is understood and actively managed. This approach is symbolized by the Pathogen Control Equation.

This document is intended to provide the reader with educational materials and recommended approaches organized in sections that correspond to the Pathogen Control Equation.

It is the experience of seasoned dairy industry food safety practitioners that:

> *Proactive work in each of the equation elements will advance overall dairy plant pathogen control.*

AND

> *The equation serves as a simple tool to organize thoughts and actions should a pathogen challenge occur.*

In essence, the Pathogen Control Equation can lead the food safety expert in determining what is important, where to focus resources, and how to create an integrated plan for remediation.

Food safety professionals using this knowledge and striving for continuous improvement will continue successfully advancing food safety performance for the communities they serve.

Thank you for sharing the dairy industry's commitment to protecting consumers and advancing food safety performance every day.

SPECIAL CONSIDERATIONS FOR CONTINUOUS OPERATIONS

EQUIPMENT AND INFRASTRUCTURE BREACHES

A Breach is any exposure, planned or unplanned, of the dry dairy processing system or controlled hygiene area that poses a risk of contamination. Any disruption to the normal operations of the manufacturing process could be a breach and should be considered for breach control protocols. Whether a breach was planned or unplanned, they increase the risk, at a varying degree, to the product zone within the closed system.

Breaches may range from routine planned activities to major unplanned and nonroutine events. Small breaches are as simple as opening an access door to manually collect a sample from a product stream, whereas dealing with a system plug up is a more invasive and higher risk breach that may still be considered routine if it occurs frequently. Routine breaches, whether low or high risk, should involve normal utensils and personnel doing their job and following SOPs that have been developed to ensure hygienic performance of these activities to prevent cross-contamination. SOPs for routine activities can be used for the basis of emergency responses to major unplanned or non-routine events.

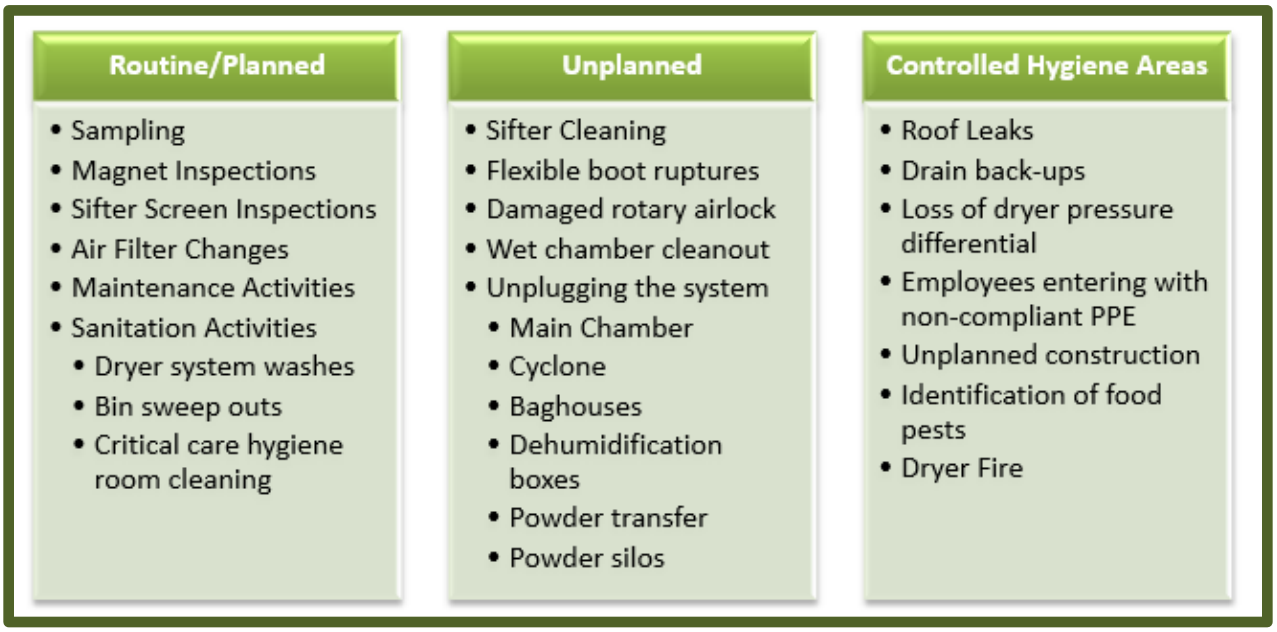


Figure 38. Examples of Breaches

It is always of upmost importance to protect the product contact zone and surfaces. This becomes even more important and difficult in dry dairy processing due to the inability to wet clean and sanitize as a mitigation step. Therefore, we stress that the post-dryer powder processing equipment be maintained as a “closed system”, always striving to keep all product within the system and keep the surrounding environment out of the system. Leaks and breaches are the two most common failures of the closed system.

Routine/Planned Breach Considerations and Opportunities to Reduce

Routine breaches are necessary activities that must be performed at a set frequency to maintain process control in sensitive areas. Breaches should be minimized when possible and when necessary to conduct, there are defined best practices to ensure product safety is protected. An example of a procedure defining best practices for entry into a powder system is listed in Appendix F. To reduce the number and risk of breaches the following should be considered:

- ✓ Testing and Sampling
  Leverage historical data to determine value and frequency of testing.
  - Has all sampling been reviewed for purpose and value?
  - Can the frequency of sampling be extended to reduce system breaches?
- ✓ Sampling Methods
  - Can an auto sampling device be utilized to eliminate system openings?
  - Is opening the system required to pull a sample?
- ✓ Magnet Checks
  Consider the balance between magnet check effectiveness to determine equipment issues and the risk of breaching the system.
- ✓ Sifter Screen Inspections
  Are sifter screen inspections needed during production?
  - Can sifter screen inspections be coordinated with preventive maintenance or other shutdowns?
  - Can the sifter screen be inspected without removing it?
- ✓ Maintenance Activities
  Maintenance should be trained to work in sensitive areas and be aware of the risk of system breaches.
  - Do they have proper PPE that adheres to safety requirements and protects the system from contamination?
  - Proper tool sanitation programs or dedicated tools to sensitive areas should be followed.
  - The maintenance team utilizes “work permits” to remind and document specific mitigation practices followed when breaching the system.
  - The maintenance team works with operations to plan, and when possible, group work, to minimize system stoppages and breaches
- ✓ Sanitation – Powder Areas
  Allow enough time for dry-out after warm-up of chamber and transport system after CIP and verify the system is dry as a pre-operational check.
- ✓ SOP
  Basic policy and procedural steps should be defined for routine breaches to ensure the activities are performed as safely as possible with minimal impact to the enclosed system.
  - Prepare all tools and sanitation supplies in advance, ensure they are clean and dry before use; tools should be dedicated to the task.
  - Employees must wear appropriate sanitation PPE including gloves, protective sleeves and even fully body protective suits as appropriate.

- Special care needs to be taken to clean the area before opening, keep it sanitary during the activity and fully clean/dry when complete.
- Ensure all employees conducting the activity are fully trained on the expectations and take special care and time it will take to do the task safely.

✓ Unplanned Breaches Considerations

During instances of unplanned major breaches to equipment or normally controlled production areas, extreme care should be taken when transferring equipment in and out of the production environment. This may require monitoring of forklift traffic, putting up caution tape to better control traffic patterns, and implementing corrective actions. Specific breach and/or invasive maintenance procedures should be developed to prevent cross-contamination from such events. Consideration should be given to the risks associated with the product and the best subsequent cleaning activities to control any adverse effects from maintenance activity. It is important that pre-operational inspections are used for the rooms, equipment, and up-stream and down-stream processes after any major breach event to ensure adequate cleaning was conducted to prevent cross-contamination upon start-up. In addition, post start-up inspections are recommended to ensure that the process is properly sealed to avoid contamination of the environment. Written documentation of these types of activities is recommended.

When recovering from a major breach situation it is important to follow good sanitation procedures. More info is available in **Principle #4 Effective Cleaning and Sanitation Practices**. Also, maintenance and sanitation tools, including vacuums, used to clean after a breach situation may require disposal or special treatment prior to reuse.

✓ Controlled Hygiene Area – Breach Recovery Actions

It is important to have a documented plan and process to follow if a breach occurs. These plans often describe communication, the team to assemble and actions that may need to be taken.

- Notify QA manager and Production manager and assemble cross functional team.
  - Identify potentially affected product.
  - Discuss the plan to clean and sanitize the area affected and how to document the corrective action.
  - Discuss how to coordinate extra environmental monitoring swabs during and after the event.
- Quality (typically QA manager)
  - Determine product holds and the appropriate disposition of affected product.
  - Maintain the adverse event action plan and schedule follow-up meetings until all actions are closed out.
  - PEMP team pulls appropriate swabs.
    - Identify additional areas to be swabbed beyond planned sites and during additional corrective actions.
    - PEMP monitoring results are documented and tracked

- Sanitation
    - Thorough cleaning of affected areas
    - Documentation of cleaning
    - Issue corrective actions until area is shown to be clean

✓ Product Disposition after Dryer Breach – Considerations for Disposition

While unplanned dryer system events can happen at any time, and by definition cannot be planned for, there are proactive plans that can be put in place to make the production facility more prepared. Because dryer systems may not be capable of being fully wet washed, it is more difficult to bracket and create a clean sanitation break after a breach event. It is critical for the operations team to have a clearly defined risk assessment of breaches to the dryer system.

Possible things to consider for a disposition plan may include:

- Develop a procedure for alerting the key individuals when there is a system breach!
- A documented procedure to identify, and possibly hold, all affected product and any product that was produced immediately around the time of the breach.
- Defined approach to reviewing production and maintenance records, as well as sanitation records to understand if the breach has been resolved appropriately.
- Building a timeline that illustrates the events before, during, and after the breach.

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 manufacturer 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:

- In October 2019, after some discussion about continuous improvement in our dryer process, our Food Safety Team decided to start tracking dryer system breaches. An electronic form was created with easy access for the dryer operator to record each time the system was breached.
- Data collected was classified into Reason for Breach, Person performing the breach, Location of Breach, time, and date.
- The form allows for comments about the breach to help gather additional information.
- 19 areas were identified where a breach could occur in the system.
- 10 routine causes of a breach were identified.

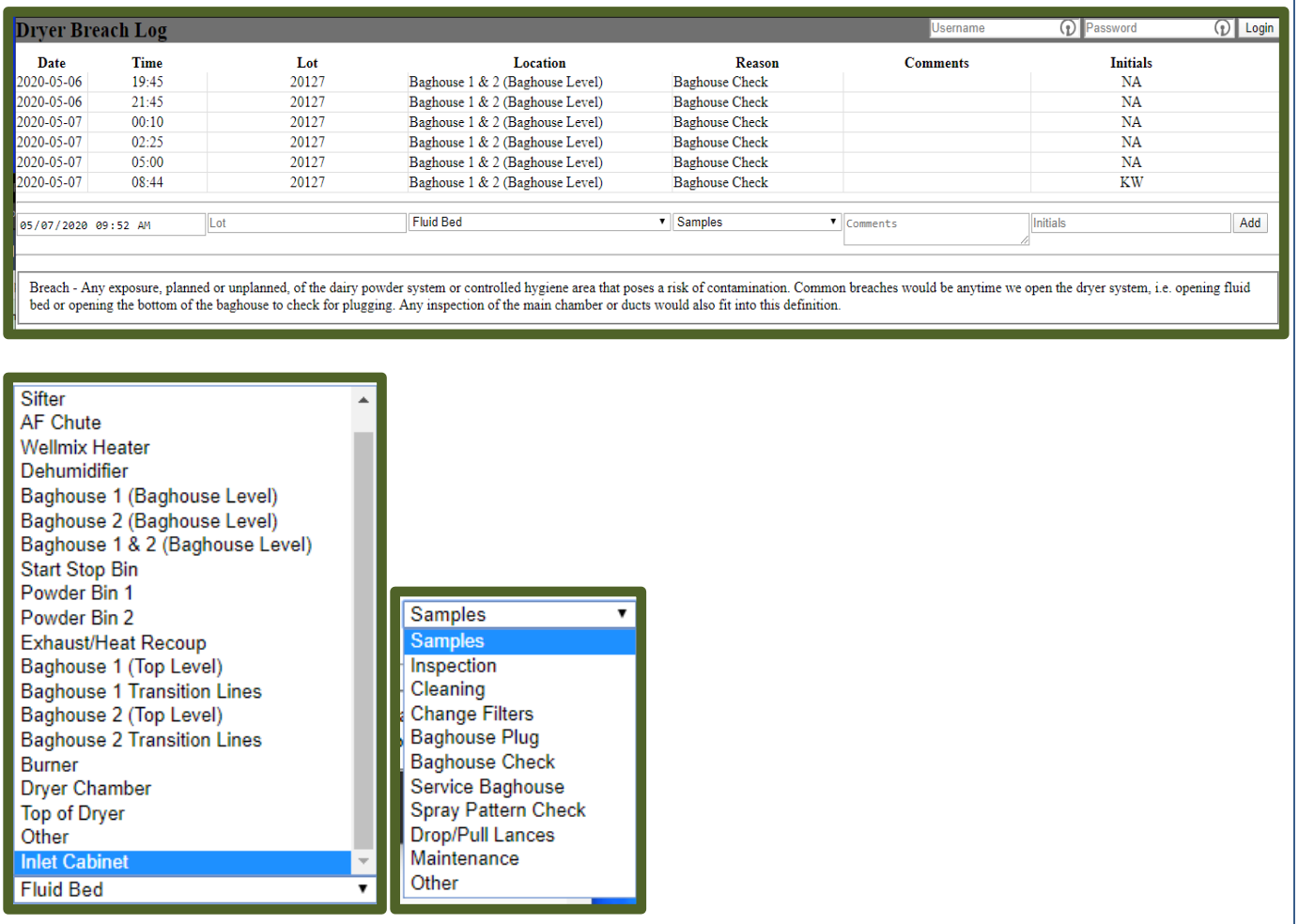


Figure 39. Example of dryer breach log to remind operators what they are looking for.

Initial Findings:

For the month of October, the information in the electronic forms and operator logbooks was reviewed to establish a baseline of the number breaches. A weekly summary using a data analysis tool, Power BI in this case, was created and published each Monday. Starting in November, Operations Management worked with dryer operators to reduce system breaches. Breaches per week were communicated to the operators along with the overall goal of tracking breaches of dryer system to enable the company to improve dryer operation and set goals to reduce the number of breaches.

Communication:

- What can the operators tell us?
- Supervisors discuss with operators why we are recording all breaches.
- Supervisors discuss with operators the need to reduce checks.

Action Steps That Reduced Baghouse Checks:

- Understand why Baghouse checks were occurring.
    - Operators may need more training.
    - Capital projects needed to improve the operation and reduce checks.
- Leverage tools to reduce baghouse checks.
    - Cameras, Sensors, etc.
    - Humidity Control

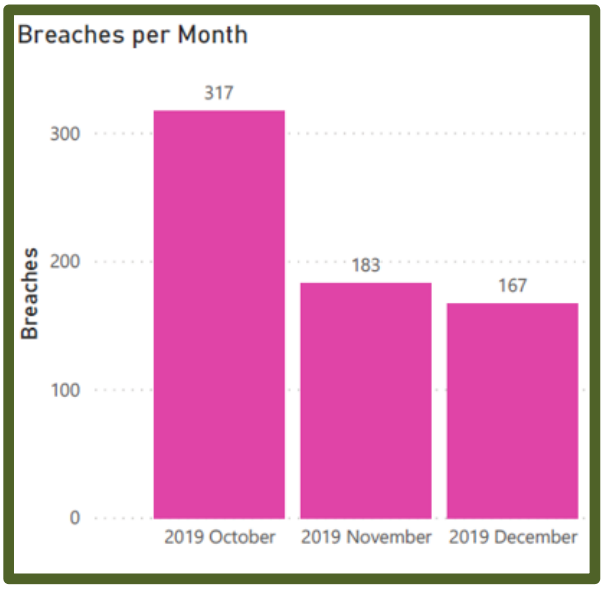


Figure 40. System breach tracking

What The Data Showed Us:

In this example the October data was used as the baseline to measure any improvement.

- Baghouse checks were the major contributor to the breaches. This led to an increased focus to drive a reduction.
- A 40% reduction in breaches was realized after the first month of data collection due to the action steps implemented.

DRYER SYSTEM PURGES – HOW AND WHY

Following the detection of a pathogen in finished product, the drying system should be thoroughly cleaned and sanitized. This will give the system a recognized “clean break.” After cleaning and sanitizing, a system purge, along with intensified testing, may be used to help create lot separation. A purge cycle consists of the start-up of the system, drying of a minimal amount of product, and system shutdown. Multiple start up and shut down cycles may be conducted to complete the purge process depending on the situation, as well as the size, complexity, and hours of operation of the dryer and packaging system. The goals of the purge are to knock loose any buildup where there may be contamination, to detect any modes of ingress of contamination into the closed system, and to verify that the system is under good microbiological control. If successful, the purge and testing process will further verify that the breaks in the system (hygienic and clean) have been successful.

This section focuses on the use of a system purge as part of the establishment of a hygienic break following the detection of a pathogen in finished product, but it is important to note that a purge may be used in other situations as well, such as:

- ✓ Following a routine complete or partial system clean
- ✓ During a product changeover for allergen separation
- ✓ Following a repair or modification of the dryer system
- ✓ Following an extraneous matter event

A purge may include the complete drying system or part of the system depending on the situation. A complete system purge includes start-up, drying of product, and shutdown of the entire drying system copying a complete production run. A complete system purge is intended to flush out all components of a dryer system, including the following:

- ✓ Dryer main chamber
- ✓ Fluid bed
- ✓ Cyclones
- ✓ Bag houses
- ✓ Conveying lines
- ✓ Sifters
- ✓ Packaging lines including nuisance dust collectors
- ✓ Autosamplers

A partial system purge may be used if there is a known issue downstream in the process, such as a known point source of contamination due to new equipment being added into the system or current equipment being repaired. This type of purge may include one or more of the system components listed above for a complete system purge.

The number of system purge cycles and product volumes may be adjusted depending on the situation. For example, a routine startup of a basic dryer system may only require one purge cycle, while a purge following a pathogen detection may require multiple cycles. Also, a more complicated system design may necessitate additional purge cycles, such as:

- ✓ A tower dryer, multistage dryer, or belt dryer
- ✓ A single pass or wet agglomeration system
- ✓ A complex powder storage system and/or multiple silo
- ✓ Additional blended ingredients
- ✓ Multiple packaging lines

A risk assessment should be completed prior to any system purge activities to help determine the type of purge needed, the number of cycles, the product volume to be produced, and the samples needed for testing.

Following are examples of different types of system purges:

- ✓ For the routine startup of a box dryer producing 2,000 lbs. of powder per hour feeding directly from the end of the dryer to the packaging line hopper 1 purge cycle with sampling at the beginning, middle and end of the first pallet for the organism(s) of interest may be appropriate. Side-streams from the process such as sifter tailings or nuisance dust from the packaging lines can also be tested.

Following a *Salmonella* detection in finished product 5 purge cycles with a minimum of 7 samples per cycle may be appropriate. The samples should be tested for *Salmonella* (375 grams), as well as any other qualitative and quantitative tests that would add value, such as Standard Plate Count, coliforms and Enterobacteriaceae. Side-streams from the process such as sifter tailings or nuisance dust from the packaging lines can also be tested.

GLOSSARY AND ACRONYMS

3-A Sanitary Standards – Standards from 3-A, a non-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries.

Aseptic Technique – Ensuring samples collected for microbiological testing are not contaminated by the sample collector.

AOAC – An organization that develops official analytical testing methods.

ATP – Adenosine triphosphate, swabbing method used to verify proper cleaning has occurred. Detects the presence of organic matter or bacteria.

Biofilm – A protective layer shielding the pathogen from destruction by routine cleaning and sanitizing chemicals.

CAPA – Corrective Action, Preventive Action.

CCP – Critical Control Point, a process step at which control can be applied, which is essential to eliminating a product safety hazard or reducing it to an acceptable level.

CIP – Clean-In-Place, a cleaning method that circulates cleaning solutions and water, used for pipelines, large tanks.

COP – Clean-Out-of-Place, equipment is dismantled and cleaned in a central washing area, normally a COP tank with temperature controls and agitation of cleaning solution.

COW Water – Condensate of Whey, water that is extracted from dairy products. Often used for heat recovery or as a cooling media.

EMP – Environmental Monitoring Program.

Food Safety Construction Plan – A plan that identifies timelines and roles/responsibilities for specific actions during planned downtime activities.

Food Safety Plan – A plan to describe handling, processing, preparation, and storage of food to prevent foodborne illnesses.

GMA – Grocery Manufacturers Association, a trade group based in Arlington, VA.

GMP – Good Manufacturing Practices, best practices employed by food manufacturers to ensure sanitary handling of food and food environments.

Grade A – Dairy products produced under sanitary conditions sufficient to qualify for fluid consumption.

HACCP – Hazard Analysis and Critical Control Points, a systematic approach to the identification, evaluation, and control of food safety hazards.

Harborage – A place of refuge or safety for microorganisms where they can grow and/or remain dormant/hidden until conditions for growth occur.

HEPA – High Efficiency Particulate Arrestance, air filtration capable of removing 99.97% of 0.3 micron–size particles.

Hot box- A cabinet that is used to store dry cleaning equipment, such as brushes and vacuums, which is held at 130F or higher to minimize and eliminate potential pathogen growth.

HVAC – Heating Ventilating and Air Conditioning.

LEMP – *Listeria* Environmental Monitoring Program.

Listeria monocytogenes – Facultative anaerobic bacterium causing listeriosis.

***Listeria* species** – Genus of bacteria that currently contains 10+ species including *L. monocytogenes*. Gram-positive, rod-shaped, facultative anaerobe, and non-spore forming.

Listeriosis – A bacterial infection most commonly caused by *L. monocytogenes.* It normally affects the immunocompromised, pregnant women, newborns, and elderly. It is characterized by fever, meningitis, encephalitis, and fetal death.

Low water activity- Water in food which is not bound to food molecules can support the growth of bacteria, yeasts, and molds (fungi). The term water activity (A_w) refers to this unbound water and associated energy state in a closed system at equilibrium. In general, food with low water activity prevents the growth of microorganisms because organism-specific requirements for growth are not met. NOTE: The water activity of a food is not equivalent to its moisture content most commonly determined on a weight/weight basis.

MERV – Minimum Efficiency Rating Value, an air filtration rating scale used to describe filter efficiency and capability.

MSS – Master Sanitation Schedule, a documented system for managing and tracking non-routine cleaning tasks.

NACMCF – National Advisory Committee on Microbiological Criteria for Foods, provides impartial, scientific advice to food safety authorities and industry.

Passivation – The process of chemically creating a corrosion-resistant barrier on stainless steel. Prevents or retards degradation which could result in the inability to properly clean the surface.

PC – Preventive Control, risk-based, reasonably appropriate procedures, practices, and processes that significantly minimize or prevent hazards.

PCS – Product Contact Surface.

PEC – Periodic Equipment Cleaning, a portion of an overall Master Sanitation Schedule dealing with equipment that is not routinely cleaned after each use.

PEMP – Pathogen Environmental Monitoring Program, plan designed to verify effectiveness of all pathogen control programs.

Persistent Microorganism – Organism which has become established in an environment's niches and cannot be removed through normal sanitation; special cleaning and sanitizing are required for removal.

PIC – Periodic Infrastructure Cleaning, the portion of an overall Master Sanitation Schedule that deals specifically with floors, walls, ceilings, and other infrastructure elements.

PMO – Pasteurized Milk Ordinance, the collection of minimum public health standards governing all aspects of Grade "A" milk and milk products. Includes standards for sanitation, equipment, farms and processing facilities, processing, transportation, storage, testing, and labeling of Grade "A" milk and milk products.

Presumptive Positive – A test indicating a positive result which has not been confirmed by additional specific methods.

Raw – Dairy products or other ingredients that have not been pasteurized or undergone other treatment to reduce microbial load.

Refrigeration – An environment with temperatures at or below 45° F and above freezing.

RTE – Ready-to-eat, a food that is designed to be consumed with no consumer cooking step.

SOP – Standard Operating Procedure.

Spore forming - a form assumed by some bacteria that makes it resistant to heat, drying, and chemicals.

SSOP – Sanitation Standard Operating Procedure.

Transient microorganism – An organism brought into a plant which is removed during normal sanitation.

USP – U.S. Pharmacopeia Convention, scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide.

Vectoring – The process of inspecting and swabbing locations in all directions around a location that has tested positive for a pathogen or indicator bacteria. It is also referred to as a 360-degree review.

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Additional Resources:

- FDA—Memorandum of Information (M-I-86-17): Preliminary Status Report on FDA's Dairy Product Safety Initiatives Recommended Guidelines for Controlling Environmental Contamination in Dairy Plants
- FDA 2008—Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen-Ready-To-Eat Foods, Draft Guidance.
- FDA 2015- Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples
- https://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467056.pdf
- Corlett, D.A. and Stier, R.F. 1991. Risk assessment within the HACCP system. Food control. 2:71-72
- Online resources, check sheets, and tools provided by The Innovation Center for U.S. Dairy can be found at www.usdairy.com/foodsafety

Appendix A—Sanitary Design Checklist *

Electronic versions available at www.usdairy.com/foodsafety

	Dairy Products -- Outside of the Pipe			Review Date:			
	Sanitary Design Checklist			Review Completed By:			
				Review Location:			
				Review Description:			
#	Description		S	M	U	NA	Comments
PRINCIPLE #1 - MICROBIOLIGICALLY CLEANABLE							
1.1	Equipment is designed & constructed to be maintained in a cleanable condition.						
1.2	Surfaces can be cleaned to visually clean standard and meet pre-op inspection requirements.						
1.3	Representative surfaces can be monitored prior to start up for allergen residue or microbiological activity.						
1.4	Construction of equipment meet the GMP definition of "easily cleanable".						
1.5	A HACCP based product risk assessment was completed during the design phase to understand risks associated with the product type.						
1.6	Method of cleaning needed for the product risk was incorporated into the chosen design of the equipment.						
1.7	Equipment design meets efficiency requirements in equipment specifications.						
1.8	Equipment has no apparent flaws that will fail over its life and make it uncleanable.						
			100	out of	100		
PRINCIPLE #2 - MADE OF COMPATIBLE MATERIALS							
			S	M	U	NA	Deficiency
2.1	Product Contact Surfaces are made with materials which are corrosion resistant, non-toxic, and non-absorbent and approved as an acceptable product contact surface by regulatory agencies.						
2.2	Composites & plastics used will remain intact without changes in shape, structure & function through cleaning & sanitation protocols. These should be easily removed and replaced as needed.						
2.3	Plated, painted & coated surfaces are not used for food contact surfaces or for process equipment surfaces directly above the product zone areas.						
2.4	Coatings and plating if used on non contact areas away from product zones, must be designed to remain intact throughout life of equipment.						
2.5	Cloth back belts are not used.						
2.6	Materials not permitted for use include wood, enamelware, uncoated aluminum, un-coated anodized aluminum.						
2.7	Metals used are compatible with one another.						
2.8	Seals and O-rings should be chosen to be compatible with the products and cleaners used on line.						
2.9	Materials used in construction are compatible with the product, the environmental conditions they will be exposed to, as well as the cleaning methods & chemicals						
			90	out of	90		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #3 - ACCESSIBLE FOR INSPECTION, MAINTENANCE, & CLEANING/SANITATION							
			S	M	U	NA	Deficiency
3.1	All surfaces in the product zone are readily accessible for cleaning and inspection						
3.2	Product zone components with inaccessible surfaces shall allow for tool free equipment disassembly (compliant with local personnel safety laws).						
3.3	Where access or disassembly is not possible, the entire assembled unit is cleanable using techniques that assure cleaning to address product risks.						
3.4	Parts remain attached or are hung on the equipment for easy cleaning & to prevent damage or loss. Separate parts carts are supplied as an alternative.						
3.5	Machinery and chain guards slope away from product zones and are easily removed (compliant with local personnel safety						
3.6	Product catch pans or drip pans are easily removable (compliant with local personnel safety laws) for clean-up so that they are not lost or separated from the equipment.						
3.7	All belting is easily removable or the belt tension is removed easily without tools so the surfaces underneath can be cleaned.						
3.8	All surfaces in non-product zone shall be readily accessible for cleaning and inspection.						
3.9	Installation for product contact areas and conveyor travel paths will maintain at minimum a 18" floor clearance.						
3.91	Equipment design provides a 12 inch clearance to the floor to allow for cleaning and inspection.						
3.92	Equipment is located 30 inches from overhead structures and 36 inches from the nearest stationary object.						
3.93	All air, vacuum, & product hoses, & their assemblies, on the equipment are easily removable for cleaning.						
3.94	All air, vacuum, & product hoses are transparent or opaque, & the interior surfaces meet product contact surface guidelines.						
3.95	All utility (electric, air, vacuum) lines should be separated (not bundled) or enclosed in smooth conduit or dust free enclosures to avoid soiling and / or allow for cleaning.						
			140	out of	140		
PRINCIPLE #4 - NO LIQUID COLLECTION							
			S	M	U	NA	Deficiency
4.1	All surfaces should be designed to eliminate product collection or water pooling (if water is used during cleaning & be self-draining).						
4.2	Materials used in construction shall be non-absorbent						
4.3	Round framework is used for horizontal members wherever possible.						
4.4	Where square or rectangular tube is used, the flat surface is turned 45 degrees to horizontal where possible.						
4.5	All open surface areas are made of sufficient strength to prevent warpage & subsequent pooling of water.						
4.6	Moisture does not drip, drain, or draw into product zone areas.						
			70	out of	70		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #5 - HOLLOW AREAS HERMETICALLY SEALED							
			S	M	U	NA	Deficiency
5.1	All rotating members, such as drive sprockets or belt pulleys, are to be solid or filled with dye and fully sealed with continuous welds.						
5.2	All stationary hollow tube construction, such as frame members or blade spacers, are fully sealed with continuous welds to prevent interior contamination.						
5.3	There are no fastener penetrations into hollow tube construction.						
5.4	Threaded leg adjustments (for equipment) are internal and do not penetrate the tube frame members.						
5.5	Name plates & tags are minimized. When attached, plates & tags are continuously welded. Rivets or screw attached plates (often sealed with caulk) are absent.						
5.6	Void areas do not exist that would allow infestation activity to gain and maintain harborage and growth.						
			150	out of	150		
PRINCIPLE #6 - NO NICHES							
			S	M	U	NA	Deficiency
6.1	Equipment is designed to prevent the ingress, survival & multiplication of microorganisms, insect activity or allergens in void or niche areas.						
6.2	There are no lap joints. Examples include standing off flanged bearings versus mounting directly to side of a conveyor.						
6.3	Seals and O-rings will be designed to minimize product contact.						
6.4	All surfaces near the product contact zone areas are designed as if they were product contact zone areas.						
6.5	Piano hinges, knurling, braided covers, exposed threads, and socket head cap screws are not approved designs.						
6.6	Belt scrapers do not have lap joints and are removed without tools.						
6.7	Belts supports are constructed from single pieces of material.						
6.8	Product zones and adjacent zones are free of open seams, recess, inside threads, rivets, etc.						
6.9	All surfaces should be designed to eliminate water pooling & be self-draining.						
6.1	No dead ends or spaces are permitted. All equipment areas are accessible for cleaning & treatment to enable removal of allergen residues, microbiological activity or evidence of insects.						
6.11	Fasteners are not used in or above the product zone.						
6.12	Fasteners which may be a product contact surface must utilize the ACME 60º stub thread						
6.13	If fasteners are necessary, they do not have exposed threads and have a positive locking method to prevent falling- or vibrating-off.						
			150	out of	150		

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

PRINCIPLE #7 - SANITARY OPERATIONAL PERFORMANCE							
			S	M	U	NA	Deficiency
7.1	Buttons on control panels are easily cleaned & sanitized during operations.						
7.2	All compressed air used for blowing on the product or contact surfaces is filtered to a minimum of a 0.3 micron level and dried to prevent the formation of moisture in the piping system.						
7.3	No bearings are present in product contact zone areas.						
7.4	Separation between product contact & non-product contact areas prevents cross contamination during operations.						
7.5	All surfaces near the product contact zone areas are designed as if they were product contact zone areas.						
7.6	Product contact surfaces are made to prevent build-up of product residue during operations.						
7.7	Shafts passing through a product zone shall have a air gap to prevent product contamination						
			100	out of	100		
PRINCIPLE #8 - HYGIENIC DESIGN OF MAINTENANCE ENCLOSURES							
			S	M	U	NA	Deficiency
8.1	Drives, chain guards, electrical control boxes, and bearings are not located over open product zones.						
8.2	Control and junction boxes are fastened to the frame in a manner consistent with the sanitary design principles.						
8.3	Utility supply lines & pipes are separated to prevent catch points and to allow for cleaning.						
8.4	Utility lines are 12 inches off of the floor and cleanable .						
8.5	Conduit & supply lines are not routed above product contact areas.						
8.6	Maintenance enclosures in direct wash down areas must be able to be exposed to water and chemicals used in cleaning & sanitation (securing with a plastic bag is not acceptable).						
			50	out of	50		
PRINCIPLE #9 - HYGIENIC COMPATIBILITY WITH OTHER SYSTEMS							
			S	M	U	NA	Deficiency
9.1	Exhaust systems have welded seams with adequate access for cleaning and inspection.						
9.2	Vertical duct sections have a drain (e.g., to the floor) to prevent drainage from going back into the equipment.						
9.3	Separate exhausts are supplied for raw and RTE product zones.						
9.4	C.I.P systems are designed, installed & validated (using a recognized third party), in sections of ductwork that are not easily cleaned through access openings.						
9.5	Equipment is designed to meet criteria of waste water infrastructure capability to assure no backups of drainage lines result under normal operations.						
			50	out of	50		

PRINCIPLE #10 - Sanitation Integrated Into Facility Design							
			S	M	U	NA	Deficiency
10.1	Water temperature, flow and pressure meets specified requirements at point of use						
10.2	Cleanup hoses are stored outside of process areas when not in use.						
10.3	Rinse systems are operated at city water pressure to limit overspray and creation of aerosols.						
10.4	Hand washing and sanitizing sinks (hands free) are provided in transition areas.						
10.5	Hurdles are installed (foot baths, doorway foamers, boot washers) at locations as required to maintain zones of control.						
10.6	Cleaning systems (e.g., COP, CIP, equipment washers) are provided to facilitate proper cleaning and sanitizing of equipment based on sanitation needs.						
			0	**/**	**100**		

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Appendix B—Dairy Facility Design Checklist *

Electronic versions available at www.usdairy.com/foodsafety

	Dairy Facility Design Checklist				Review Date:		
					Review Completed By:		
					Review Location:		
					Review Description:		
#	Description		S	M	U	NA	Comments
PRINCIPLE #1 - Distinct Hygienic Zones Established In The Facility							
1.1	Facility is divided into hygienic zones and facility drawings accurately reflect hygienic zones						
1.2	Active control barriers prevent uncontrolled movement between RTE / high hygiene and non-RTE / lower hygiene areas.						
1.3	Transition areas with hurdles exist between raw and RTE areas or from lower to higher hygiene areas.						
1.5	Restrooms are located outside of from RTE / high hygiene areas						
1.6	Separate equipment and tool storage areas exist for RTE/ high hygiene versus non-RTE / lower hygiene areas.						
1.7	Separate QA labs exist for RTE / high hygiene and non-RTE / lower hygiene areas						
1.9	Space is provided for clean equipment storage						
1.91	Soiled laundry collection locations are established						
1.92	Trash collection is properly located, and locations are cleanable and maintainable						
1.94	Color codes (e.g., garments, helmets) are used to identify hygiene areas						
			0	**/**	**120**		
PRINCIPLE #2 - Personnel & Material Flows Controlled to Reduce Hazards							
			S	M	U	NA	Deficiency
2.1	Movement of employees, contractors, and other visitors through the facility is predetermined and controlled						
2.2	Systems are in place for sanitary transportation of packaging materials and ingredients into RTE / high hygiene areas to minimize cross contamination						
2.4	Systems are in place for sanitary transportation of rework into RTE / high hygiene areas						
2.5	Systems are in place for sanitary removal of trash from RTE / high hygiene areas						
			0	**/**	**100**		
PRINCIPLE #3 - Water Accumulation Controlled Inside Facility							
			S	M	U	NA	Deficiency
3.1	Floor design and drainage systems prevent standing water and wet floors						
3.2	All floor joints and cracks are sealed						
3.3	Wall and curb surfaces drain freely without pockets, ledges and nooks						
3.4	Areas above ceilings do not accumulate water						
3.5	Equipment wastewater discharges are piped directly to drains						
3.6	Drain pans are sloped to be free draining						
			0	**/**	**100**		

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PRINCIPLE #4 - Room Air Flow and Room Air Quality Controlled							
			S	M	U	NA	Deficiency
4.1	Room temperature meets process requirements						
4.2	Controls are in place to prevent condensation						
4.3	All rooms have their pressures controlled to ensure the airflow will be from clean to less clean areas						
4.4	Critical process air is adequately filtered to protect micro sensitivity of the product based on quality and pathogen control risks.						
4.5	Makeup air is sufficient to maintain specified clean areas positive to adjacent rooms.						
4.6	Air handling system components for RTE / high hygiene areas meet the 10 Principles of Equipment Sanitary Design						
4.7	Provision is made to capture high concentrations of heat, moisture and particulates at the source						
4.8	HVAC/refrigeration system components are located to avoid risks of product contamination through air flow or condensation.						
4.9	HVAC/refrigeration systems are dedicated appropriately to specific control zones to prevent cross-contamination						
			0	**/**	**100**		
PRINCIPLE #5 - Site Elements Facilitate Sanitary Conditions							
			S	M	U	NA	Deficiency
5.1	Driveways, parking lots and pedestrian walkways are paved and drain to prevent standing water						
5.2	Landscaping and grounds are designed to minimize attraction and harborage of insects and rodents						
5.3	Adequate trash receptacles in pedestrian traffic areas are provided						
5.4	Insect attractant lighting is positioned to draw insects away from the building						
5.5	Grading provides positive drainage away from building						
5.6	Finished floor elevation is higher than adjacent grades to prevent storm water ingress into building						
5.7	External operations (e.g., trailer cleaning, bulk storage, trash and waste management) are designed and positioned to prevent unsanitary impact on the facility						
5.8	Storm water system is properly designed and maintained to prevent standing water on the site with retention basins.						
5.9	A minimum of 18" of asphalt, gravel or concrete borders are present on all exterior sides of the facility						
			0	**/**	**100**		

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PRINCIPLE #6 - Building Envelope Facilitates Sanitary Conditions							
			S	M	U	NA	Deficiency
6.1	Building envelope (i.e., shell, skin) is constructed of materials that are solid, impervious, and free of cracks and voids						
6.2	Roof flashing systems prevent harborage of insects, birds and rodents and roof is sloped and drains freely.						
6.3	Canopies are totally closed						
6.4	All louvers, fans, vents and openings have insect screens and vents prevent pigeon harborage.						
6.5	Doors are impervious, fully weather stripped and fit well						
6.6	All door and window sills are firmly anchored to the slabs and set in full beds of sealant						
6.7	All voids associated with utility penetrations (e.g., electrical weather heads, gas mains, sprinkler risers) are sealed.						
6.8	Concrete wall panels are caulked from roof to footing						
6.9	Dock doors have a dock seal or shelter and are weather stripped and rodent proofed.						
			0	**/**	**100**		
PRINCIPLE #7 - Interior Spatial Design Promotes Sanitation							
			S	M	U	NA	Deficiency
7.1	Aisles are sufficiently spacious for maintenance, sanitation to access with equipment and materials movement						
7.2	There is sufficient access to clean building elements (e.g., columns, beams, bracing) and wall / floor interfaces.						
7.3	Stationary equipment is elevated sufficiently to allow cleaning and sanitation underneath the equipment						
7.4	The equipment and facility layout allows access to overhead areas (ductwork, lights, etc.) for inspection and cleaning.						
7.5	There is an interior perimeter inspection zone of 18 inches to allow for inspection and cleaning.						
			0	**/**	**80**		
PRINCIPLE #8 - Building Components and Construction Facilitate Sanitary Conditions							
			S	M	U	NA	Deficiency
8.1	Suspended ceilings are smooth, cleanable (both sides) and at a uniform height						
8.2	All vertical surface to floor junctions have a cove and surfaces that are free of pits, erosion and voids						
8.3	Concrete surfaces are free of pits, erosions and voids, solid and smooth						
8.4	All vertical and horizontal wall joints are sealed appropriately						
8.5	Closed cell or encapsulated insulation is used						
8.6	Horizontal structural members have no flat surfaces where dust or soil could accumulate.						
8.7	All-thread rods are not used and other threaded surfaces are minimized						
8.8	Expansion joints are adequate to avoid irregular cracking in floors and are limited to the extent possible						
8.9	Bases of drains are supported with a robust foundation to prevent settling						
8.91	Items attached directly to a building surface such as electric conduit, water lines, have at a minimum 1 inch standoff from wall surface.						
8.92	Floors are constructed to prevent harborage, impervious, easily cleanable and resistant to wear and corrosion						

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PRINCIPLE #9 - HYGIENIC COMPATIBILITY WITH OTHER SYSTEMS							
			S	M	U	NA	Deficiency
9.1	Exhaust systems have welded seams with adequate access for cleaning and inspection.						
9.2	Vertical duct sections have a drain (e.g., to the floor) to prevent drainage from going back into the equipment.						
9.3	Separate exhausts are supplied for raw and RTE product zones.						
9.4	C.I.P systems are designed, installed & validated (using a recognized third party), in sections of ductwork that are not easily cleaned through access openings.						
9.5	Equipment is designed to meet criteria of waste water infrastructure capability to assure no backups of drainage lines result under normal operations.						
			50	out of	50		
PRINCIPLE #10 - VALIDATED CLEANING & SANITIZING PROTOCOLS			S	M	U	NA	Deficiency
10.1	Cleaning & sanitizing are considered in the design process.						
10.2	Cleaning protocols must be safe, practical, effective and efficient						
10.3	Cleaning and sanitation protocols are have been developed by the manufacturer, validated by a third party, and provided in a training manual that is easily read and understood by cleaning and sanitation employees.						
10.4	Equipment design and materials are capable of withstanding standard clean-up procedures. Equipment materials have been reviewed with the MSDS for the cleaning and sanitizing chemicals to assure compatibility.						
10.5	All belts should withstand heating to 160ºF for up to 30 minutes.						
			50	out of	50		

* Dairy specific checklist built on earlier work by AMI and other individual experts

S = Satisfactory, M = Marginal, U = Unsatisfactory, NA = Not Applicable

Appendix C—Food Safety Construction Plan SOP and Checklist Example

1.0 PURPOSE

1.1. Analyze the nature of the project to determine the risk level.

1.2. Identify steps required to manage construction and maintenance activities and maintain a sanitary plant environment during construction projects.

1.3. Establish a Food Safety Construction Plan (FSCP) outlining steps to ensure proper management of construction and maintenance activities and verification of sanitary conditions prior to resumption of operations.

1.4. Define key roles responsible for specific activities within the project scope.

2.0 SCOPE

2.1. This policy applies to the removal, installation, or modification of equipment or infrastructure components that could negatively impact food safety.

2.1.1. Temporary equipment or infrastructure will also require a construction plan, depending upon use and conditions.

2.1.2. Medium- and high-risk projects require a Food Safety Construction Plan to be developed by the project manager and approved by the plant/distribution center quality manager and corporate quality before construction activities begin.

2.2. All projects will be reviewed to assess Food Safety risk and intervention requirements prior to implementation.

2.2.1. Physical, chemical, and microbiological hazards should be considered.

2.2.2. Considerations of how a project will affect the entire plant, particularly air, water, and traffic routes, will be considered.

3.0 DEFINITIONS

3.1. Low-risk projects can be controlled through preventive or general maintenance processes. See matrix in Reference 6.1 for categories.

3.1.1. This encompasses projects or activities where precautionary safety processes exist and/or there is a proven history of success.

3.1.2. Special-Cause Cleanup requirements should typically suffice.

3.1.3. Examples of projects in ready-to-eat (RTE) production areas (no environmental history).

3.1.3.1. Normal preventive maintenance.

3.1.3.2. Modification of an equipment guard requiring welding.

3.1.3.3. Installation of electrical conduit during downtime.

3.1.4. Examples of projects outside of RTE areas.

3.1.4.1. Normal preventive maintenance.

3.1.4.2. Removal of ammonia lines.

3.1.4.3. Maintenance work done in palletizing.

3.2. Medium-risk projects can be controlled through specific intervention and controls to prevent contamination.

3.2.1. This encompasses activities in or near production environments where enhanced monitoring has not revealed any microbiological issues. Depending upon circumstances, this may include both pathogen swab data as well as indicator organism (yeast/mold, coliform, APC) results.

3.2.2. Work zones must be defined and segregated.

3.2.3. Examples in RTE environments.

3.2.3.1. Installation of a new line in an isolated production room where no soil or outside elements will be exposed.

3.2.3.2. Installation of shred scale platform.

3.2.4. Examples of projects outside of RTE areas.

3.2.4.1. Installation of new auto palletizing equipment in warehouse.

3.2.4.2. Shipping floor repair.

3.3. High-risk projects must be controlled through special intervention and controls to prevent contamination.

3.3.1. This encompasses activities in areas where microbiological issues are known to exist, or the potential risk of product contamination (safety or quality related) is elevated. Examples include:

3.3.1.1. Any time soil is exposed/broken (drain repair/installation, bollard installation, etc.).

3.3.1.2. When any production area (including Zone 4) is exposed to the outside environment (roof projects, infrastructure repair).

3.3.1.3. When air circulation is shared between construction zones and production and/or storage areas and dust generation or moisture migration is a concern.

3.3.2. The length of the project should also be taken into consideration, with longer projects being a higher risk because temporary structures are often more difficult to maintain effectively. Work zones must be defined and isolated from the rest of the facility.

3.4. An enhanced environmental monitoring scheme must be developed and deployed by the plant quality manager or designee.

3.5. Negative pressure within the construction site should be established whenever possible.

4.0 PROCEDURE

BEFORE CONSTRUCTION

4.1. The project manager will submit a written FSCP to the plant/distribution center quality manager and corporate quality for medium and high-risk projects outlining controls and safeguards that will be implemented before, during, and after construction activities (Form 6.1).

4.1.1. An enhanced environmental monitoring scheme will be deployed to assess microbiological risk in the site, surrounding areas, and traffic routes prior to initiating the project.

4.1.1.1. Monitoring will incorporate Zone 2, 3, and 4 locations as well as potential traffic routes and vectors (carts, pallets, etc.).

4.1.1.2. Swabs of incoming equipment are required.

4.1.1.2.1. Equipment swabs should be taken at the plant upon arrival if the equipment is sequestered in the facility, until favorable results are obtained.

4.1.1.2.2. Swabs may also be taken at the manufacturer on incoming RTE and non-wash-down equipment if shipping and storage conditions limit exposure to the outside environment.

4.1.1.2.3. New construction areas or areas that will undergo substantial reconstruction activities do not need to be swabbed upon arrival, because extensive cleaning and validation will be performed before startup.

4.1.2. Potential problems should be identified and addressed by a cross-functional team and integrated into the Food Safety Construction Plan. Team members minimally include QA/sanitation, production leadership, and maintenance.

4.1.3. Additional precautions will be taken if microbiological activity is identified.

4.2. It is the responsibility of the project manager to review the food safety construction plan with plant leaders, incorporating feedback from sanitation, operations, maintenance, and other plant or corporate functions. Plant/distribution center quality manager and corporate quality will then review and approve each plan.

4.3. Impact on customer ordering and scheduling will be accessed and communicated prior to initiating the project.

PRE-CONSTRUCTION

4.4. All contractor personnel will be trained on plant Good Manufacturing Practices before beginning work. A record of trained personnel will be maintained. It is permissible to train the owner or designee of the contractors and have them train their personnel.

4.5. Equipment will be assessed to evaluate and remediate any food safety risks of design or condition.

4.5.1. Product will not be released until receipt of acceptable results.

4.5.2. All equipment defined as high-risk should have a construction plan associated with any work performed.

4.6. Traffic patterns for supplies, construction materials, waste, lunchroom, and toilet facilities must be established and clearly identified. The project manager will ensure traffic routes are dedicated, appropriately cleaned and sanitized, and adhered to.

4.7. Steps will be taken to prevent accumulation of humidity, dust, fumes, vapors, or gases from construction sites. The condition of the site must not cause condensation on temporary walls or adjacent areas.

4.8. Exhausts from the construction site will be blocked from other plant areas.

4.8.1. Air quality (indicator organism) and appropriate air pressure should be monitored by the QA department as outlined in the FSCP.

4.8.2. Negative pressure within the construction site should be established whenever possible. This is required for high-risk projects.

4.9. Storage of idle equipment, contractor supplies, or other items should be minimized; if necessary, covered and neatly stored off the ground.

4.10. Equipment and tools will be cleaned and sanitized prior to entry into the facility. Swabs should be taken of non-plant equipment that may be a vector (forklift, wheelbarrow, etc.) within plants, and special precautions should be taken to minimize areas affected.

4.10.1. External tools and equipment will be swabbed after sanitizing (and after the sanitizer has dried).

4.10.2. Clean, sanitize, and swab traffic pattern of equipment coming in if the equipment is brought in to clean and sanitize.

4.11. Durable dust and watertight partitions will be provided at all construction sites to prevent migration of contaminants such as dust, filth, debris, and moisture from the construction site to non-construction areas. Doors to areas with exposed product will be provided with seals and will be self-closing.

4.11.1. Plastic or Visqueen can be punctured and is not considered a durable alternative in production environments.

4.11.1.1. Long-term (>2 weeks) projects located in a functioning Zone 3 should have a temporary solid-structure wall (IMP, etc.) when possible. Wood should be avoided whenever possible.

4.11.1.2. Zone 3 projects of less than 2 weeks should have triple-layer plastic with metal studs or a solid-structure wall with triple-layer plastic.

4.11.1.3. Long-term projects located in Zone 4 should have a wall type that takes into consideration the length of the project, the type/amount of traffic, and the type of work being done in the area.

4.11.2. Equipment that cannot be removed from the construction site will be thoroughly covered during pre-construction and construction activities.

4.11.2.1. Double layers of plastic will be used. Tape will be adhered to the plastic overwrap, not to the equipment, where possible.

4.12. Any tape residue must be removed prior to resumption of production. Reaction plans will be developed by the project manager and outlined in the FSCP to address potential breaches or changes to the plan.

DURING CONSTRUCTION

4.13. Production areas must be maintained in a sanitary condition to ensure products are manufactured in a Good Manufacturing Practice (GMP) compliant environment. During construction (demolition, installation, remodeling, etc.) steps will be taken to ensure that contaminants are kept out of the production environment. Equipment and handling devices that move between the construction site and various locations in the facility (e.g., scissor lifts, welders, supply carts, pallets) will only enter process and storage areas if they are cleaned and sanitized prior to entry.

4.13.1. Devices dedicated to construction activities should not enter manufacturing areas during production periods.

4.13.2. Wheels should be cleaned and sanitized on a routine basis throughout the project. This should be done at a minimum of each shift but maybe more often depending upon the project.

4.14. All plant doors and entrances must:

4.14.1. Remain closed when they are not in use.

4.14.2. Form an adequate seal when closed.

4.14.3. Not be left propped open unattended.

4.14.4. Be repaired immediately if damaged.

4.15. All partners and contractors will wear appropriate clean clothing, hair restraints, and footwear as defined in the contractor briefing document when entering production areas.

4.15.1. Projects may require extra PPE to be worn by partners or leaders while on the construction site as defined in the FSCP.

4.15.2. Contractors must put on new GMP PPE when entering or re-entering the facility.

4.16. Special projects may have a non-GMP area in the plant due to special construction activities. In these circumstances, GMP apparel is still required when going through the plant when not in these construction areas. Examples may include:

4.16.1. Roof work.

4.16.2. Drain work (non-GMP area inside of construction vestibule).

4.17. The site must be free of standing water.

4.17.1. Adequate exterior drainage or grading must be provided.

4.17.2. Wet-vacs are not preferred but may be used if they are equipped with a HEPA filter. The use of a vacuum to remove water or other debris must be approved by the quality manager or the project manager.

4.17.3. The filter must be routinely visually inspected and secured.

4.17.4. Wet-vacs used in high-risk projects must be cleaned, sanitized, and swabbed before being used again.

4.18. Water hoses will not be used to clean the floor or equipment when product or packaging material is exposed due to the formation of aerosols. Cleaning will be coordinated with plant sanitation and production staff.

4.19. Waste materials and rubbish will be removed from the construction site on a minimum daily basis.

4.19.1. All waste containers taken through the plant must be covered and adhere to a designated traffic route. All garbage and debris will be removed prior to closing the space.

4.19.2. Materials associated with microbiological issues will be subject to special handling precautions prior to and during removal.

4.20. Reaction plans will be developed by the project manager and outlined in the FSCP to address any unanticipated breaches or changes to the plan.

POST-CONSTRUCTION

4.21. After the temporary partition is dismantled, all construction materials will be removed, and the entire area cleaned and sanitized without disrupting existing operations.

4.21.1. The partition should be cleaned and sanitized before being removed from the area.

4.21.2. Waste should be double bagged when removed from the facility, especially for high-risk projects.

4.21.3. Special-cause cleanup will be documented where applicable.

4.22. HVAC ductwork that was subjected to or exposed to construction activities will be thoroughly cleaned and sanitized.

4.22.1. New, refurbished, or modified ductwork will be cleaned and sanitized by a qualified contractor.

4.22.2. Proper pressure and air balance must be verified prior to any manufacturing activities.

PRIOR TO STARTUP

4.23. Prior to startup, the sanitary condition of the site and all equipment must be verified. This will be documented through a checklist specific to each project and encompass the following elements:

4.23.1. The manufacturing department, equipment, and support areas will be thoroughly inspected for sanitary operating conditions. Findings will be documented, and subsequent corrective actions noted.

4.23.2. The manufacturing area and all equipment will be subject to a full cleanup and a deep sanitizing treatment appropriate for the area as determined in the plan and verified at the conclusion of construction activities.

4.23.3. Effectiveness of cleanup and sanitary condition will be verified by bioluminescence and microbiological monitoring.

4.23.4. An enhanced pathogen monitoring scheme will be conducted in the post-construction area and surrounding locations. Zones 2 to 4 will be monitored.

4.23.5. Air quality will be measured and verified.

4.23.6. HVAC ductwork subject to construction will be monitored for positive pressure and yeast & mold at enhanced frequencies.

4.23.6.1. Abnormalities will prompt immediate corrective action and product evaluation where appropriate.

4.23.6.2. Frequencies may be modified depending on findings if approved by the plant quality manager and corporate quality.

4.24. The plant quality manager and corporate quality will provide approval to resume manufacturing activities after completion of the project.

4.25. Any questionable issue(s) will be forwarded to corporate quality and operations management for further evaluation.

SPECIAL CIRCUMSTANCES

4.26. Projects involving water line modification: Water quality will be confirmed to meet chemical and microbiological criteria.

5.0 DOCUMENTATION

5.1. A list of trained contractors will be maintained; non-conforming contractors will be identified and documented to prompt subsequent action.

5.2. The construction site plan and related documentation will be readily available.

5.3. Special-cause cleanup documentation following construction will be available where applicable.

6.0 FORMS

6.1. Construction Form Checklist

CONSTRUCTION PLAN CHECKLIST (Example)

Tailored to each Circumstance

PROJECT **SUBMISSION DATE:**

PLANT: **IMPLEMENTATION DATES:**

DEPARTMENT: **PROJECT MANAGER:**

DESCRIPTION OF CHANGE:

Project resources, including contractors:

Key assumptions:

CONSIDERATIONS

BEFORE CONSTRUCTION

- Environmental Assessment—Highlight or bold the risk level that most closely matches the project. The risk level defaults to the highest category unless otherwise explained below.

	High risk	**Medium risk**	**Low risk**
Pathogen/pest history	History in room within the past 6 months	History before an effective mitigation effort or no history in past 6 months	No history in past 6 months
Location in plant	RTE with exposed product or cultured dairy post-pasteurization	RTE or raw with good isolation throughout project; Zone 4 with limited isolation	Zone 4 with good isolation
Type of work	Exposed soil, exposure to outside elements, shared air circulation with production, long term project (>2 weeks)	Risks controlled through specific, but limited, intervention measures	Proven history of success for similar projects, small precautionary processes sufficient

PROJECT RISK: High ☐ Medium ☐ Low ☐

COMMENTS ABOUT RISK: _____

_____

_____

Italicized items should be modified/changed for each project. List who is responsible for each action on the construction plan. "Typical requirements" are basic minimum requirements for each section that should be modified to meet the specific needs of the project.

- Scheduling implications
  - *Will production be running in the room?*
  - *Will aspects of the construction (cleaning/traffic) affect other parts of the plant?*
  - *What is the timeline of the project, start to finish?*

PRE-CONSTRUCTION

- Contractor Training—**Typical Requirements**
  - Basic contractor training will take place when they arrive at the plant on a per contractor basis.
  - The training will consist of a GMP and traffic pattern review as well as safety and security requirements.
  - Contractors will adhere to all standard plant contractor procedures and wear appropriate gear including hair nets/beard nets, hard hats, ear plugs, safety glasses, shoe covers, and smocks at all times during the work.
  - All parts, equipment, and tools brought into this area will be clean and thoroughly sanitized prior to entry into the plant.
    - No visible dirt will be allowed on any parts, tools, and equipment entering this area.
    - Tools with wheels (forklifts, wheelbarrows, scissors lifts, etc.) should be sanitized when brought in and swabbed once dry.
    - Once tools and equipment are in the plant, they should remain inside, if possible. Tools/equipment will have to be cleaned/sanitized upon reentry into the plant.
  - Access to any area beyond the construction/work areas without prior consent is not allowed.
  - Contractor should work with plant to ensure that plant access clothing and accessories, as well as cleaning and sanitation chemicals, are present in sufficient quantities at all times.
  - Establish requirements for break room/restroom use and GMPs required for this project.

- Isolate Site
  - Short term projects (<3 days)–triple-layer plastic with wood or metal studs:
    - Metal studs should be used if the area will have wet-cleaning routinely done in area.
    - Absorbent pads/dikes should be used as necessary to divert water away or contain within a construction site.
    - Ensure there is a good seal along the wall/floor.
    - If production is not running in the area, Zone 1 areas should be protected with plastic, but containment may not be necessary (depending upon project).
  - Long-term projects (>2 weeks)—IMP wall or plywood containment with at least double layers of plastic inside and a single layer outside.
  - Isolation of any production areas from construction sites—may include covering equipment with plastic, removing non-essential equipment from area, HVAC considerations.

- Traffic Plan
  - Include a map with mitigation steps.
  - Identify construction traffic route.
  - Partner traffic route (if applicable).
  - Trash traffic.
  - Equipment traffic route, including staging and/or cleaning areas.
  - Include current or added mitigation steps (footbaths, foamers, sanitizer stations, etc.).

- Dust and Fume Control
  - Isolate HVAC in construction site from production areas.
  - Cleanup mode should be used when possible.
  - Establishing negative pressure in the construction area is necessary if dust, soil, outside environment exposure, and/or environmental history is present.

- Reaction Plan**—Typical Requirements**
  - Plant QA and/or project manager is responsible for adherence to the plan with cooperation from all team members.
  - Any significant deviations to the plan will be reviewed with corporate quality for concurrence prior to action/reaction.
    - If due to time or urgency, the plant can make the call, but corporate quality must be notified to review actions as soon as possible.
    - Any environmental deviations will be reported to members of the corporate quality department.

DURING CONSTRUCTION

- Condition of Site and Surrounding Area**—Typical Requirements**
  - Plant employees and/or leadership will monitor the construction area for compliance.
  - Sanitation employees will monitor sanitizer stations, footbaths, etc.

- Partner and Contractor GMP Compliance
  - Contractor requirements for going in/out construction site.
  - Special GMP apparel needed for plant employees/leaders in construction area.

- Traffic Flow
  - Contractor traffic flow.
  - Trash traffic flow.
  - Traffic patterns will be cleaned and sanitized on a routine basis.

- Site Integrity (breaches)—**Typical Requirements**
  - Any breach from the construction areas will be dealt with by the quality manager and could include contractor removal from site or cost penalties for increased sanitation and/or food safety inspection.
  - Any breaches in temporary walls will be repaired, reported to the quality manager or designee, and addressed with a special-cause cleanup.

- Waste Removal—**Typical Requirements**
  - Any waste generated will be tightly controlled with double-layer plastic bags as soon as generated; the bags will be tied and removed from the operations area to the waste handling area as required.
  - Bags will be spritzed with sanitizer before being removed from the construction site.

- Environmental Monitoring—**Typical Requirements**
  - Air monitoring (yeast/mold, air velocity) should be conducted during the construction project.
  - Pathogen swabs (*Listeria ssp*., *Salmonella* ssp.) should be conducted during and after the construction. Minimum areas to be included are traffic patterns and just outside of the construction area.

POST-CONSTRUCTION

- Material Removal**—Typical Requirements**
  - All waste and construction materials will be removed from the site.
  - They will all be placed in plastic bags and sealed when passed through plant areas.
  - Temporary walls/floors should be cleaned/sanitized before being removed from the construction site. Plastic will be put in bags before being discarded.
  - Contractor tools will be removed from the area after completion of work.

- HVAC Cleaning/Balance
  - HVAC in the construction area should be cleaned and sanitized if dust is generated from construction activities.

PRIOR TO STARTUP—**Typical Requirements**

- Cleaning/Sanitation Plan
  - System flush and deep clean—documented special cause cleanup.
  - Traffic patterns will be included in special cause cleanup.

- Verification
  - Inspection—visual inspection will be performed following sanitation.
  - Swabbing
    - Equipment swabs (ATP, APC, coliform) will be conducted following special cause cleanup.
    - Air monitoring (yeast/mold, air velocity) will be conducted for several weeks following the construction project.
    - Pathogen swabs (*Listeria* ssp., *Salmonella* ssp. depending on project) will be conducted during and after the construction. Minimum areas to be included are traffic patterns and the construction site.

APPROVAL: _____

Appendix D—Autosampler Reliability Calculator

This calculator is designed to determine if the number of aliquots being pulled during the production of the batch are sufficient to detect Salmonella if it is present at 1% in the batch when a sample volume of x grams is tested for the batch. The yellow highlighted parts of the calculator can be manipulated, and the reliability calculation will update accordingly.

Explanation of items needed for the reliability calculation:

1. Size of the batch / load in: kg
    a. Enter the total volume of the batch that will be tested at x grams.
    b. Amount is to be entered in kilograms.
2. Number of aliquots : n
    a. Enter the number of aliquots that are taken during the production of the total volume of the batch.
    b. The spreadsheet will auto-calculate the number of seconds between aliquots.
3. Quantity per aliquot: g
    a. This number is only used to determine the total volume of product that will be collected over the total number of aliquots in #2.
    b. Total sampled is auto-calculated based on the number of aliquots and the size of each aliquot.
4. Volume analyzed for S on Volume sampled : g
    a. Enter the total volume that will be analyzed based on the total volume of production.
    b. This number is used to calculate the “Size of analyzed individual sample in : g” which is then used in the reliability calculation.
5. Time to produce 1 batch : h
    a. Enter the time it takes to make the total volume of the batch.
    b. This number is used to calculate the number of seconds between aliquots.

Example:

For a grab autosampler, with regular aliquot sampling intervals

Please fill in the cells with an *

Number of salmonella :	n	100,000			
Relative volume of contaminated part :	%	1		0.01	0.99
Conversion of the sample from g to kg :	kg	0.001			
Size of analysed individual sample in :	g	2.50			
Size of the batch / load in :	kg	4,000 *			
Number of aliquots :	n	300 *	1 aliquot every	6	sec
Quantity per aliquot in (only used to calc total sampled) :	g	15 ⇨	total sampled	4.500	kg
Volume analysed for S on Volume sampled :	g	750 *			
Time to produce 1 batch :	h	0.5 *			

5

95.1 % **Reliability that the tested sample detects the presence of Salmonella in the production batch**

In this example, there is a 4,000 kg batch produced in total. The auto-sampler is set to take a sample 300 times during the total batch of 4,000 kg. Based on testing the batch at 750 grams, the 300 aliquots are sufficient to detect a Salmonella if it is present in the total batch. If you change the number of aliquots, you can see that 300 is the minimum needed to attain 95% reliability that the presence of Salmonella will be detected. Note: all 750 grams of the sample are enriched to ensure the 95% reliability is achieved.

The reliability calculation is mainly focused on the number of aliquots sampled during the production batch. Once the total amount and sample amount are set the aliquot can be changed to determine the reliability of detecting a defect in the total production batch.

The actual functioning Reliability Calculator can be downloaded from this website: usdairy.com/foodsafety

Appendix E—Pathogen Test Sample Size for the Intended Final Consumer

Knowing if there is a lethal step for *Salmonella* ssp. between the time test samples are collected and product consumed is important for a decision on appropriate sample size for enrichment and testing for Salmonella. FDA BAM has three different categories of sample size and testing based on the immune and health status of the intended final consumer and whether or not any lethal process is completed between sampling and consumption. The address of the website for this information is: https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063335.htm

The three categories are:

Food Category I: Foods that will not receive a process step lethal to *Salmonella* ssp. between sampling and consumption and are intended for consumption by the aged, infirmed, or infants.

Food Category II: Foods that would not go through a process step lethal to *Salmonella* ssp. between sampling and consumption (and not intended for the aged, infirmed or infants).

Food Category III: Foods that would normally go through a process step lethal to *Salmonella* ssp. between sampling and consumption.

As an example, for Food Category I a 3 ton per hour drier producing a heat sensitive dried powder for a dry blended infant formula would produce 30 tons or 30 pallets of 25kg bags or 30-2,200lb bulk bags in a ten-hour run. With no further lethal process step, this product would be tested as Food Category I. From the samples collected and composited across the production run, four 375 samples would be tested for a total of 1,500 grams.

For Food Category II of the above example, two 375 gram samples would be composited from the samples collected across the production run for a total of 750 grams.

For Food Category III of the above example, one 375 gram sample would be composited from the samples collected across the production run.

Appendix F – Dry Powder Processing Equipment Entry (EXAMPLE)

1.0 PURPOSE

1.1 Define the process for controlled entry into dry powder processing equipment in the event of a planned or unplanned breach.

1.2 It would be preferred to limit entry into these systems; however, when entry or access is required, it is essential that procedures are defined to mitigate the microbial risk to our dry powder systems to ensure consumer safety.

1.3 Each facility shall conduct a risk assessment of foreseeable breach activities and ensure the right level of control is defined for the activity.

2.0 SCOPE

2.1 This policy applies to planned and unplanned entry into processing equipment used in the manufacture, conveyance, and packaging of dry powders.

2.2 Examples of equipment in scope include, but is not limited to, dryer, baghouse, cyclone, bin, sifter, powder conveying line, rotary valve, in-line magnet, air filter, flexible boot, etc.

2.3 Examples of activities in scope includes, but is not limited to, dryer, baghouse, cyclone, and bin inspection or sweeping, sifter inspection, unplugging powder conveying lines, rotary valve inspection, in-line magnet checks, air filter change, flexible boot change, and any opening of the system for routine sample collection.

2.4 In all activities described, extreme care must be taken to keep the environment dry and to not introduce any moisture when performing the defined tasks. Always thoroughly dry tools, gloves, surfaces, etc. as appropriate.

3.0 PROCEDURE

3.1 Tools/Supplies Needed

- 3.1.1 Alcohol-based sanitizer
- 3.1.2 Sanitizing alcohol wipes
- 3.1.3 Gloves
- 3.1.4 Arm Sleeves or gloves that extend past the elbow
- 3.1.5 Lint free paper towel
- 3.1.6 Clean parts cart or sanitary mat
- 3.1.7 Tools, dedicated to the specific room or area, as needed based on equipment (i.e., brushes, vacuum, tools to open ports)

3.2 Steps for Minimally Invasive Routine Activities (Magnet Check, Sample Collection, Visual Inspection, etc.)

- 3.2.1 Prepare tools, clean parts tray, gloves, etc. necessary for the task near to the area you will be opening
- 3.2.2 Put on new gloves and arm sleeves, or long gloves that extend past the elbow
- 3.2.3 Conduct dry cleaning by brushing, dry wiping or vacuuming up loose powder or other debris in the area to be opened
- 3.2.4 Conduct sanitation by using alcohol wipes on the area to be opened, with focus on the entry point
- 3.2.5 Wait for the entry point to dry fully
- 3.2.6 Sanitize gloved hands – allow to air dry
- 3.2.7 Open or dismantle the entry point and place all parts on a clean parts cart or sanitary mat
- 3.2.8 Re-sanitize gloved hands - allow to air dry
- 3.2.9 Perform the routine activity (i.e., collect the sample, clean the magnet, inspect the chamber, etc.)
- 3.2.10 Dry clean the removed parts and sanitize as necessary with an alcohol wipe
- 3.2.11 Allow sanitized parts to fully dry
- 3.2.12 Remove any loose powder generated near point of entry with an alcohol wipe; do not allow loose powder back into the system
- 3.2.13 Reassemble and reinstall removed parts
- 3.2.14 Sanitize sealed entry point
- 3.2.15 Fully dry area with paper towels
- 3.2.16 Inspect the work area and very no loose or extraneous material will be left behind
- 3.2.17 Vacuum area to remove any loose debris or soil
- 3.2.18 Sanitize area as appropriate

3.3 Steps for Invasive Non-Routine Activities (repairs, system upset due to blockage, etc.)

- 3.3.1 Prepare tools, clean parts tray, gloves, etc. necessary for the task near to the area you will be opening
  - 3.3.1.1 NOTE: Prepare for and conduct extra cleaning and others precaution for any tools NOT dedicated to the specific area or room brought from different hygiene or allergen areas
- 3.3.2 Put on new gloves and arm sleeves, or long gloves that extend past the elbow

3.3.3 Conduct dry cleaning by brushing, dry wiping or vacuuming up loose powder or other debris in the area to be opened

3.3.4 Conduct sanitation by using alcohol wipes on the area to be opened, with focus on the entry point

3.3.5 Wait for the entry point to dry fully

3.3.6 Sanitize gloved hands - allow to air dry

3.3.7 Sanitize necessary tools, parts and implements including parts to be installed or perform the action with alcohol wipes

3.3.8 Allow sanitized parts to fully dry

3.3.9 Open or dismantle the entry point and place all parts on a clean parts cart or sanitary mat

3.3.10 Re-sanitize gloved hands - allow to air dry

3.3.11 Perform the action

3.3.12 Remove any loose powder generated near point of entry with an alcohol wipe; do not allow loose powder back into the system

3.3.13 Reseal the entry point

3.3.14 Sanitize sealed entry point

3.3.15 Fully dry area with paper towels

3.3.16 Inspect the work area and very no loose or extraneous material will be left behind

3.3.17 Vacuum area to remove any loose debris or soil

3.3.18 Sanitize area as appropriate

3.4 Additional Steps for Physical Entry into a Product Contact Vessel: Establishing a temporary red line area to separate the environment from the closed system

3.4.1 Individual entering the system, including contractors, must change into a clean captive uniform

3.4.2 Individual entering the system must further protect the exposed product by putting on a new Tyvek jumpsuit with full balaclava head and face covering

3.4.3 Individual entering the system must further protect the exposed product by putting on a new pair of rubber boots (from supply room) that have been sanitized using spray or wipes.

3.4.3.1 Allow sanitized boots to dry fully

3.4.3.2 NOTE: Boots must only be put on immediately prior to entry into the system and cannot touch the floor

3.4.4 Individual entering the system must wear bump cap sanitized with alcohol prior to entry into the system.

3.4.4.1 Allow sanitized bump cap to dry fully

3.4.5 Sanitize any necessary tools and equipment with alcohol wipes

3.4.5.1 Allow sanitized tools and equipment to dry fully

3.4.6 After work is completed, follow steps defined in Routine Entry to clean and inspect the work area.

3.4.7 If entry work was not performed in a sanitary manner, document time of breach.

3.4.7.1 Conduct a CIP or other means of establishing a hygienic separation before resuming production

Appendix G – Hygienic Separation In Continuous Dairy Powder Systems

Framework for Establishing Hygienic Separation in Continuous Dairy Powder Systems in the Event of a Pathogen Positive in Finished Product

Acknowledgements

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Content Topics

1. Purpose and Background

1.1. Purpose of this Guidance Document

Continuous commercial dairy drying systems can produce a large quantity of product within a short timeframe. Combined with long production runs between extensive cleaning periods and/or complete wet washes, this can lead to large amounts of product potentially being subject to a product recall. To avoid such a massive loss of a critical food supply and crippling financial impacts on a company or the industry, preventive measures must be diligently employed. Regardless of the preventative measures employed, experience tells us that failures can still occur. When failures occur, understanding and assessing the likely or unlikely product risks of such events is worth the investment in time and resources. This guidance document intends to provide a framework for:

1) Analyzing an event in which a dairy powder produced from a continuous operation test positive for a pathogen.

2) Determining reasonable and defendable hygienic separation points before and after the positive product finding; and

3)Utilizing information and data to best identify the amount of non-contaminated powders that would otherwise be deemed necessary to discard while ensuring food safety risks are minimized.

Each scenario involving a positive pathogen finding in a continuous dairy powder operation is unique and needs to undergo a full investigation on its own merits. However, a standardized approach can help facilitate a timely and proper response. In some circumstances, engagement with a food safety professional external to the organization may prove useful in working through the investigation, analyzing the data, and developing recommendations. Engaging legal counsel to ensure compliance with statutory and regulatory requirements is also recommended.

1.2. Background

Drying is a traditional, cost-effective, and reliable method used to preserve food. To this day, low-moisture foods, including dairy powders, constitute a substantial part of the human diet. Because of their low water activity, which does not allow for the growth of microorganisms, these foods have a long shelf life, from months to years. Even though growth cannot occur, many microorganisms and pathogens, such as *Salmonella*, demonstrate the uncanny ability to survive in low water activity food matrices. Desiccation and heat tolerant strains/serovars can remain dormant in dairy powders for extended periods of time. Dairy powders are typically produced as an ingredient for subsequent use in many applications: chocolates, confections, powdered beverages including infant formulas, and seasoning blends that are considered Ready to Eat (RTE). These RTE consumer products may not include a microbiological kill step during their subsequent manufacturing steps. As such, it is important to implement aggressive and effective preventative controls and food safety programs to minimize the risk of cross contamination from *Salmonella* or other environmental pathogens.

The CDC estimates every year that roughly 1 out of 6 Americans gets some type of food poisoning, which equates to 48 million people each year. This results in approximately 128,000 hospitalizations and 3000 deaths. There is an estimated cost of $152 billion a year in healthcare, workplace, and other economic losses to the United States. One of the leading organisms that is responsible for a portion of these illnesses is *Salmonella.* The presence of this organism in finished dry dairy products has led to recalls and outbreaks. Table 1 below lists a few examples of past recalls, including international instances associated with dairy powders and dried cheese. Fortunately, the industry has implemented numerous controls over the years; and now the incidence of *Salmonella* in dairy powders is considered relatively rare (Hayman et al. JFP Vol. 83, No. 10, 2020[3]).

Table 1. Recent Incidents of Pathogen Contamination Events in Dry Dairy Based Products

Year	Product	Hazard	Location
2009	Powdered Milk/Dried Whey	Salmonella	Minnesota
2016	Dried Grated Cheese	Salmonella	New York
2016	Powdered Milk/Powdered Buttermilk	Salmonella	Multi State
2018	Dried Whey	Salmonella	Multi state
2018	Infant Formula	Salmonella	France
2019	Infant Formula	Cronobacter	Canada
2022	Infant Formula	Cronobacter	Multi State

Although dairy powders undergo pasteurization, a kill step and preventative control, which inactivates vegetative pathogens in the milk prior to drying, post-pasteurization controls are critical to prevent cross contamination from *Salmonella* in the environment. One of the most significant downstream control measures is limiting the presence of water that can lead to the growth and spread of *Salmonella* if already present in the environment. In dairy powder processing environments and dryer systems (parts of which are designed for dry cleaning only), the use of wet cleaning should be restricted and only used when considered essential. Restricting water usage results in extended continuous runs between wet washing of weeks, or even months, apart.

In addition, prevention of cross contamination events is achieved through adequate facility and product contact air filtration, dryer operational controls, maintaining the hygienic integrity of the system, sanitary equipment design, robust and routine cleaning protocols, strict hygienic zoning controls, restricting to highest risk areas. The use of environmental monitoring for pathogens and indicator organisms along with product testing provides verification of effectiveness of these cross-contamination prevention programs.

1.3. Definitions

Breach - Any exposure/intrusion, planned or unplanned, of the dairy powder system or controlled hygiene area where precautionary measures are required to minimize the risk of cross contamination. An example would be pulling dryer magnets for inspection or opening the sifter.

Clean Break – The action of performing cleaning and sanitizing on food manufacturing equipment. This term may be associated with removing microbiological contamination (i.e., pathogens) associated with a positive finished product test and restoring the condition of the equipment to sanitary conditions that are suitable for continuing production with respect to finished product safety. These may be planned to mitigate the magnitude of product impact in the event of a pathogen detection or unplanned as a response to a pathogen detection.

Episodic Event – A pathogen event where the root cause investigation and/or resampling data indicates that an event occurred that allowed cross contamination but that it likely passed through the powder system without harborage.

Harborage site (niche) – A site in the environment or on equipment (e.g., junctions, cracks, holes, and dead-end areas) that enables the accumulation of residues (food debris, dust, and water) and permits the growth of microorganisms such as *L. monocytogenes* and *Salmonella*. These sites may be difficult to inspect or access and therefore can protect environmental pathogens during routine cleaning and sanitizing.

Hygienic Separation (also Hygienic Break) - In a continuous dairy powder system, the use of data, process records, root cause analysis findings, and/or investigative product testing to establish evidence-based food safety brackets for product disposition where appropriate. Hygienic separation may or may not be at a specific "clean break."

Indicator microorganisms - Groups of microorganisms that can be used to assess hygienic conditions and, where appropriate, indicate growth conditions that could be favorable to pathogens with similar growth characteristics.

Lot – An amount of material produced under similar conditions and conforming to a consistent set of specifications. The amount of material produced in a continuous dairy powder system designated as a lot has different meanings among companies and at times, different facilities within a company. It can be limited by either volume, time, and/or testing. An example of product lot separation may be a packaging day provided that all material is from the same source (i.e., loads of dairy), including packaging material. More information on lot definition best practices can be found in the Innovation Center for U.S. Dairy's Guidance for Dairy Product Enhanced Traceability[1].

Pathogen Environmental Monitoring Program (PEMP) - A testing protocol for sampling the manufacturing environment for pathogenic microorganisms. It is designed to verify the effectiveness of sanitation and environmental control programs such as hygienic zoning.

Presumptive positive- A preliminary test result indicating there is a potential for a positive result once additional confirmatory work is completed.

Rework - Any product collected from the system or finished product that is added back, in accordance with a company's rework policies, to the system for reprocessing.

Resampling – Analyzing any additional units collected as part of the original sampling procedure or a new sample collected from the same lot tested originally. Any sample tested as part of an investigation that is not the original sample retain is considered a resample. Resampling material and then testing it is not considered retesting. Resampling changes the characteristics of the initial sampling plan, for example, by increasing the probability of rejecting lots of poor quality.

Retesting – Testing the original retain sample additional time(s) to confirm or provide additional information on an original result.

Resident microorganism - Bacterial pathogens that become established in a harborage site, multiply, and persist for extended periods of time, even years. This is the opposite of a transient microorganism. Common cleaning and sanitation practices are adequate to control the presence of transient contaminants, but such practices do not control the presence of resident contaminants once they have become established. Sanitation controls, including proper personnel practices and equipment and facility design, are key to preventing transient bacterial pathogens from becoming resident strains. Once an environmental pathogen has become established as a "resident strain," there is a persistent contamination risk for foods processed in that facility. The facility will need to use intensified sanitation procedures to eliminate the contamination.

Sanitation Verification – Protocols designed to verify effectiveness of sanitation efforts using visual inspection, ATP and/or microbiological testing.

System Purge - A complete or partial system purge is the purposeful starting and stopping of the dryer system to remove moisture and product build up by cycling through temperatures, pressures, and air velocities. It can be used as part of a hygienic separation. A system purge may be required due to:

- Corrective action resulting from a positive pathogen test result.
- Cleaning- which may be a complete system cleaning or separate sections cleaned such as main chamber, fluid bed, cyclones, baghouse, or components of the conveying and storage systems.
- Product changeover for allergen separation as part of allergen cleaning procedures
- Repair or modification of the dryer system, indicated by an investigation or corrective actions or equipment modification plans.

Transient microorganism – Bacterial pathogens that have only recently been introduced into the facility. This is the opposite of a resident microorganism. These organisms are typically introduced into the processing facility through, for example, incoming raw materials, personnel, or pests. It is important to ensure that these microorganisms remain transient and do not become established in the environment where they can grow and multiply. Generally, though, the proper application of cleaning and sanitizing in accordance with CGMPs is adequate to control the transient bacteria in the processing facility.

2. Foundational Programs

2.1. The Pathogen Equation and Beyond

Foundational food safety programs focused on preventing environmental cross contamination must be in place, and shown to be effective, for a hygienic separation other than a traditional clean break to be considered in a continuous dairy powder system. A deeper dive into these foundational programs is included in the Innovation Center for U.S. Dairy's "Controlling Pathogens in Dairy Processing Environments: Guidance for the U.S. Dairy Industry[2]"(www.usdairy.com/foodsafety). This reference document includes the pathogen equation (illustrated below) highlighting the key foundational programs required to keep pathogens under control and avoid environmental cross contamination. These, along with other supportive programs (i.e., traceability, powder sequencing and flow through, preventative maintenance, etc.), and verification activities, must be considered when conducting a root cause analysis.

Separate Raw from Ready-to-Eat/Hygienic Zoning

History has shown that there is a greater likelihood of finding pathogens or other undesirable organisms in non-critical or raw manufacturing areas than in controlled production or Ready-to-Eat (RTE) areas. Managing the flow of personnel, supplies, air movement (dust and aerosols) and equipment significantly reduces the potential for cross-contamination.

Hygienic zoning is the process of assessing risks then defining and creating barriers to manage these risks and ultimately protect the product stream. The zoning concept can be employed to clearly separate raw wet from dry RTE areas (critical in dry product operations) and between areas of varying hygienic levels (see Table 2. below).

Table 2. Hygiene Level/Zone

Hygiene Level	Typical Processes
Critical; High Hygiene; Extra Care	Filler & packaging equipment, bin storage and conveying, direct product contact or open product, no subsequent kill step
High/Ready-to-Eat	Pasteurized product, concentrates for spray-drying with no subsequent kill step
Medium/ Basic GMP	Further heat treatment required, preliminary processing of product
General/Low	No Exposed product - Warehousing and receiving, raw ingredient storage, maintenance, corridors, pasteurizer rooms, and control rooms
Raw	Raw milk silos, raw milk receiving

(Zone names may differ by company, but processes that fall into each are typically similar. The FDA Food Safety Preventive Controls Alliance, Preventive Controls Qualified Individual training also provides an alternate hygienic zoning scheme.)

Good Manufacturing Practices and Controlled Conditions

Following current Good Manufacturing Practices (GMPs) (CFR 21 Part 117) is required by law and is one of the most fundamental expectations in the food industry to prevent contamination of products. GMPs are very broad in scope and apply to personnel, product, facilities, and production practices. Two critical GMPs for continuous dairy powder operations are controlling the presence of moisture that can fuel microbial growth and ensuring hygienic integrity of the system post-pasteurization. Identifying and eliminating water leaks, limiting water usage, minimizing breaches of the closed system, addressing powder leaks and cracks/openings/holes, and incorporating hygienic controls to ensure the hygienic integrity of the system must be employed along with monitoring and documentation of any deficiencies.

Sanitary Facility and Equipment Design

Sanitary design involves the design, construction, and installation of equipment and facilities in a manner to support effective and efficient cleaning/sanitizing and to facilitate a thorough product purging. Surfaces which are difficult to clean can be challenging and/or overlooked during a sanitation cycle, resulting in microbial harborage and growth. It is important to fully assess cleanability and identify continuous improvements to facility and equipment design. Design deficiencies that may lead to microbial risks should be documented and corrected where possible.

Effective Cleaning and Sanitation Procedures and Controls

Cleaning and sanitizing need to always be timely and effective to maintain pathogen control in the plant environment and the processing equipment. A standard protocol for cleaning with 7 steps has proven to be both efficient and effective in maintaining sanitary conditions. After sanitation it is important to visually verify CIP lines are properly drained and all internal spray devices are closed. In addition, it is imperative to verify and validate that the dryer system is clean and completely dry prior to startup.

Pathogen Environmental Monitoring Program

A robust and effective Pathogen Environmental Monitoring Program (PEMP) measures the success of a dairy plant's sanitation and environmental pathogen control programs by assessing the conditions during and after production using seek and destroy tactics along with aggressive sampling and testing. PEMP results along with root cause analysis are used to drive corrective actions and continuous improvement through additional preventive actions where identified. The ultimate goal is to minimize the risk of cross contamination and prevent pathogens from taking up residence in the production environment.

2.2. Food Safety Culture

It goes without saying that to have successful and reliable foundational programs, a culture of food safety pervasive throughout the organization is optimal. Leadership is looked to for providing resources, and reinforcing communications, accountability, and behavioral examples to support these programs. The concept of food safety is paramount and should be every employee's responsibility.

3. Verification Activities

3.1. Microbiological Testing Programs

The previously discussed proactive, foundational programs must include verification through microbiological testing of finished product, process and side-stream samples, and the processing environment. It is important for the plant to establish and track its baseline microbiological profile so personnel can determine when any unusual conditions or trends occur. "In specification" or "baseline" test results should demonstrate that the drying system has the capability of producing safe and hygienic product under normal operating conditions. The side-stream product (i.e., sifter tailings), should also meet the minimal limits for food safety even if it is classified as animal feed. Conducting a facility risk assessment as outlined in "Controlling Pathogens in Dairy Processing Environments: Guidance for the U.S Dairy Industry"[2] will help identify the points where pathogens may be found in the plant and provide guidance for developing a robust sampling plan.

Product Pathogen Testing (In Process and Finished Product)

Microbiological test results of finished dry powder and in process product stream samples should be evaluated through trending and timeline graphing to demonstrate process control. This data will provide critical evidence of process control and support root cause analysis in the event of a pathogen positive.

Use of Indicator Testing

Common indicator tests utilized with dairy powder products include Standard Plate Count (SPC), Enterobacteriaceae (EB), coliforms, yeast, and mold. Indicator data is typically more useful for trending because detection is more common than that of pathogens allowing a baseline to be established and allowing unexpected trends to be identified. This is especially true for SPC because it encompasses a broader spectrum of microorganisms.

An increasing trend in the level of organisms detected and/or the frequency of detection can be useful to investigate an assignable root cause. Indicator results can provide insight into specific sanitation conditions in the plant, employee compliance to GMP practices and the potential for post heat-treatment contamination. Most importantly, an increase in indicator organisms can indicate that the process has gone out of control (e.g., water introduction) and can allow for proactive actions to be taken to reduce the likelihood of pathogen presence. Acceptable action limits can be found in literature or determined through trending of historical data.

Additionally, testing beyond customer specifications can prove useful in providing more consistent information for trending. For example, jumping between customer requests for coliform testing versus EB counts/detection can make the data disjointed. However, constant testing for EB at the correct detection limit can provide continuity.

Statistical Sampling Plans

The use of a statistically valid and robust finished product sampling scheme gives reassurance that the results reflect the system's level of control. Each plant should use a statistical sampling plan that requires an appropriate number of samples across the production run to adequately demonstrate process control and properly represent the entire lot. There may be instances where an increased sampling protocol may be required, such as at start-up after a major cleaning event and/or after a pathogen detection.

When using an autosampler, the autosampler reliability tool (as found in the Pathogen Control Guidance Document for the US Dairy Industry, Appendix D) can help to validate the autosampler settings for number and size of samples. When utilizing manual sampling, the manual sampling plan should be routinely verified to ensure compliance to the statistically valid sampling plan and executed by trained individuals. Adjustment options for the auto-sampler should have limited access to prevent inadvertent adjustments that would invalidate the unit.

PEMP Tracking and Trending

A robust PEMP must include tracking and trending of results using maps and data reviews to drive additional corrective actions and guide program improvements. For example, sporadic positives in a given area may require special investigational sampling and root cause analysis to regain control. In addition, sampling patterns or frequencies may be adjusted to target problematic areas.

Pathogen Isolate Characterization

Often it is enough to know that you have a pathogen in the environment to drive corrective actions. In these cases, traditional testing to genus/species level is common and may be acceptable. However, multiple positives in the environment may require more in-depth identification to characterize and differentiate isolates. This is also true for product positive isolates, which is explained in 4.4.

Whole Genome Sequencing (WGS) is the latest technology in microbial identification and provides a DNA fingerprint of the organism and further clarity on whether an isolate is a resident or transient strain. WGS is widely used by CDC, FDA, and USDA when positives are identified as pathogens. Regulators may review a plant's results to determine if positives over time are the same strain or closely related to each other.

Finding the same strain over time may indicate the plant's sanitation and GMP practices are inadequate. Although helpful, it is not always necessary to go to the level of WGS to identify similar traits in repeat positives. Many companies use full O and H antigen serology or other genetic approaches, such as a RiboPrint™ analysis, which provide a level of information in between traditional speciation methods and WGS.

3.2. Additional Verification Activities

In addition to the above, additional industry verification activities that might prove useful include internal GMP audits and inspections; procedural reviews (i.e., bag-house filter changes); SSOP reviews and observations; Pre-Op checklists; War on Water audits; Sanitary Design audits; etc.

3.3. Records

The adage "*If it isn't written down it didn't happen*" certainly is applicable when it comes to assessing and justifying hygienic separation. Written programs/procedures without complete and accurate records will make root cause analysis more difficult. Section 5 provides a list of common records that should be reviewed when considering hygienic separation. Personnel creating the records should have basic record keeping skills and record storage and retention must be well defined to have a robust record history.

4. Managing a Product Positive Event

Appendix 1 provides a flow diagram depicting the typical sequence of events when a product positive notification is received.

4.1. Response Team

As with many plant initiatives and challenges, it is wise to have a cross functional team assigned to help assess, investigate, and address a pathogen event. This Food Safety/Quality Assurance led team may be comprised of representatives from plant leadership, operations, sanitation, maintenance, engineering, line operators, and legal. Upon receipt of a finished product presumptive positive result, this team should be notified and at the ready to assist.

4.2. Product Hold and Scope

Once a presumptive positive notification is received, it is important to ensure that potentially impacted product is on hold, isolated to prevent shipment, and to include a regular physical warehouse verification. If a presumptive positive test result is reported, it should be assumed to positive pending confirmation and immediate corrective actions should be taken, including planning for investigative resampling and initiating a root cause investigation. The investigation should always start upon receiving a presumptive result and should not wait until the final confirmation result is received. This immediate action reduces implicating more product or the amount of hold times until testing is completed. During the confirmation process, ensure that the following product is on hold:

- All product associated with the impacted lot, preceding lots based on company policy (typically 2 previous lots) or back to the last clean break on all shared equipment, and all lots following until the investigation is complete
- All the side-stream products such as tailings, nuisance dust, scrape-down or plug-up lumps and any lots associated with any of these side-streams as well as any product associated with animal feed; and any products associated with dry blend rework (including original source of rework).

When determining scope of product potentially impacted, special consideration must be made for product sequencing and flow through. In many operations the first liquid into a drying process does not necessarily equate to the first powder packaged at the end of the process. This can be due to different process configurations, including different combinations of dryers, silos, packaging lines, etc. For example, there may be times where dried product is stored within the system (e.g., in a silo prior to packaging) while other product dried later is packaged first. It is important to understand and document this flow within the process because any justification for a hygienic break will be based on tracking of product within the system, as well as microbiological results in relation to the timing of the positive pathogen finding.

The Hold and Release program should consider all product that may be implicated. All lots and associated side-streams should be placed on physical and electronic hold.
Industry best practice is to keep product lots and associated side-streams on hold for the length of time it takes to get results for all pathogens tested on impacted lots. Considerations that may increase amount of held product:

- When samples are collected by a regulatory body for pathogen or compliance testing.
- Customer sampling and testing for compliance upon receipt at their factory or regulatory sampling at the customer's factory.

Note: Any product out of the manufacturer's control that may present a risk of serious adverse health consequences or death to humans and animals should be reported to the FDA Reportable Food Registry within 24 hours of this determination.

4.3. Immediate Corrective Action

Establish New Clean Break

Following the detection of a pathogen in finished product, the drying system should be thoroughly cleaned and sanitized. This will give the system a fresh "clean break" pending the root cause investigation. Cleaning and sanitizing to establish a clean break should include conducting all CIP washes on equipment, that are possible, and conducting tear down & manual cleaning of equipment of non-CIP equipment. Prior to any CIP or manual wet cleaning, the drying environment must be thoroughly dry cleaned to help protect against cross contamination as the closed system is opened up. Also, great care must be taken to minimize or eliminate the introduction of water into the dry clean only environment during CIPs or manual cleaning. If possible, manual wet cleaning should be conducted "off-line" and outside of the dry clean only area. Any moisture that is introduced into the drying environment must be completely removed/cleaned/sanitized and dried out. All equipment that is CIPed or manually wet cleaned and sanitized must be verified as dry prior to resuming production.

After cleaning and sanitizing, a system purge, along with intensified testing, is often used to help further create and verify "clean break" separation – especially in equipment that is not readily CIPed or disassembled for manual cleaning. A purge cycle consists of the start-up of the system, drying of a minimal amount of product, and system shutdown. Multiple start up and shut down cycles may be conducted to complete the purge process depending on the situation, as well as the size, complexity, and hours of operation of the dryer and packaging system. Start up and shut down cycles should take into consideration the inlet and burner fans, dryer conveying systems, and powder conveying systems to storage and to packaging spaces.

Intensified Product Sampling/Testing

After product positive test results, an intensified sampling plan for microbiological testing of the finished product, side streams, and/or the production environment is prudent. This may include collecting more samples than normally collected and/or in the case of product samples, testing a larger amount per lot than the normal program (e.g., testing 1500 g per lot or sublot versus 375 g).

The intensified sampling plan should be used until confidence in the ongoing hygienic conditions of the process and/or environment is reestablished, at which time the intensified level of sampling can return to normal.

Example of purge process and increased testing:

- 3-5 purges of the dryer, full start-up and shut-down
- Run each purge long enough to collect enough sample based on increased testing requirements
- Collect 5 pounds of sample from each purge and test for pathogen
    - *Salmonella* 5x375 grams
    - For each of the 3-5 purges, means there will be 15-25 375 gram aliquots

4.4. Confirm Results and Conduct Isolate Characterization

Confirmation

When the laboratory reports a presumptive positive, it should also communicate how and when confirmation work will be conducted. If the confirmation process is not completed for a presumptive result, then the result must be considered positive, and all subsequent corrective actions taken accordingly.

If presumptive results are confirmed negative, it may not be necessary to carry forward the complete investigation. However, persistence of presumptive results that confirm negative should be investigated to determine if closely related organisms may be present within the process/product or if the food matrix is interfering with the test method performance. Additionally, a presumptive which results in a negative confirmation could indicate sanitation deficiencies exist requiring investigation especially when the event repeats itself.

Isolate Characterization

Similar to environmental isolates as noted in section 3.1, it may be useful to characterize product isolates using differential technologies. This information can then be compared to previous product and environmental isolates to aid in the root cause determination. Resident and transient strains are equally problematic as they both could present a food safety risk to consumers if cross contamination were to occur. However, as noted in their definition, resident strains have a greater tendency to result in cross contamination simply because they have become more entrenched in the environment and are more difficult to control.

4.5 Accuracy of Results

Laboratory Errors

Although rare, laboratory errors can and have occurred. Any product investigation should at least consider and work to minimize this possibility in parallel with the plant investigation. Possible laboratory errors are contamination of a product sample with either a laboratory positive control or material from another product sample that was positive.

The laboratory should have their own internal QA investigation and should also report the results of that investigation to the appropriate responsible parties.

Note: Retesting and/or resampling product associated with initial confirmed positive and obtaining all negatives does not, by itself, mean the initial result was due to a lab error. It is not possible to test out of a positive result. A laboratory error can only be determined/confirmed by the laboratory that conducted the initial assay. Unless the initial testing laboratory provides a written declaration that the initial positive result was in error, the initial result must be considered correct.

Sampling Errors

Sampling and/or resampling at the plant could also be a cause of a false positive result due to cross contamination if aseptic procedures are not properly executed and should be investigated. Carefully review, inspect, and observe sampling systems (i.e., autosamplers) and procedures. Environmental sampling may be used to verify any possible routes of cross contamination.

4.6. Initiate Investigational Resampling

For scope and root cause analysis, it is important to understand the frequency, time frame, and location of any additional positives with the finished product. This can be achieved by conducting intensified resampling and testing of finished product from the implicated production run.

Note: Retesting and/or resampling product associated with initial confirmed positive and obtaining all negatives does not and cannot negate the original positive result. This resampling/testing is for investigational purposes only. Again, it is not possible to test out of a positive result.

Resampling of Affected and Adjacent Lots

Resampling is different than retesting. Resampling is conducted in the context of this document to find the beginning and/or end of a problem and support root cause analysis.

- When did the contamination event begin (or at least when is the earliest time that it can be detected through sampling and testing?)
- How long did the contamination event last?
- How much product may be implicated?
- Does this appear to be an episodic event?

This investigative resampling would usually include the preceding and following lots relative to the implicated lot. Additional lots may need to be included if there are clear connections to these lots by production records, process flow and/or test results. The scope of re-sampling should consider any lot-to-lot connections via side-streams or activities that include sifter tailings, bag house returns, scrape-down, nuisance dust from packaging line, rework, silo co-mingling, and/or animal feed streams.

Resampling Approaches and/or Additional Sampling

Statistical resampling protocols should have a similar or more sensitive and intensive sampling plan than the original sampling plan to detect pathogens. For example, an n=60, or greater, of each lot versus routine testing may be followed to achieve this.

"Grab Samples" from pallets

Retained samples from your routine product sampling program may not be adequate to fully characterize an event, especially for timeline sequencing. If manual sampling (grab samples from finished inventory) is required after product is packaged, an n=60 or greater statistically valid plan is recommended. Follow a documented plan to ensure uniform sampling across the lot. An example of manual sampling for product packaged in 25kg bags; 100g sub-samples are pulled from throughout the lot in question. The goal is to collect at least 4 composite samples of 375g (each 375g sample contains 15 samples of 25g) each to meet the n=60 (1500g total) of the statistical plan. The FDA BAM method recommends utilizing this sampling approach when testing Category 1 products for *Salmonella* and is commonly followed in the dairy industry when higher testing sensitivity is necessary. If executed properly, the resampling plan may help determine an assignable root cause.

5. Root Cause Analysis

5.1. Approach

When a finished product sample is reported as presumptive and/or confirmed positive for a pathogen, an investigation must be conducted in an attempt to determine the root cause for the product contamination. A good approach is to use multiple tools including records/document reviews, microbiological data, line inspections, observations of practices and operations in real-time and through available camera footage, plus interviewing key employees to build an entire picture of the circumstances surrounding the event. Each production facility, process design, and contamination event are unique and should be carefully considered when conducting a thorough root cause investigation. There is not a "one size fits all" approach for root cause identification. The following provides some examples of common investigational approaches to use when investigating a contamination event. This section provides guidance on information gathering to support the root cause investigation.

- The key root cause questions to be answered include:
    - What can I learn or need to learn about the scope of contamination?
    - How may the contamination have occurred?
    - What may have happened during production or sampling, that could have resulted in the positive result?
    - Does this appear to be an "episodic" or an "internal harborage" event?
    - Can a hygienic break be identified to properly bracket product for disposition?

Typical process and QA records to review and possible evidence to gather when investigating if there were deviations from normal operations or processing conditions include, but are not limited to:

- Process control records
    - Pasteurization records
    - Evaporator records
    - Dryer records
- Maintenance records for preventive maintenance performed
    - Work orders or red tags
    - Filter changes
    - HVAC maintenance

- Routine or special case intrusions into the system
    - Clearing powder plugs/build up
    - Magnet checks
    - Leak detection/repair
- Monitoring of sifter overs, humidity, and air pressurization records
    - Weather
    - Structural failure
    - Contractor activity
    - Unexpected down times
    - Other unusual events
    - Internal audit reports
    - Finished product microbiological test results
    - Sanitation verification results
    - PEMP results and trending

5.2. Microbiological Data

Pathogen Environmental Monitoring Program (PEMP) Testing

Like product testing results, the results from the PEMP can be valuable during an investigation into a pathogen positive event in finished product. It is important that these programs are robust and well maintained to be of value during the investigation, including thorough documentation of program activity to establish a detailed timeline of events. It will be important to understand any recent pathogen findings in the environment. When reviewing and trending data as part of an investigation, a timeframe of at least the previous 12 months (accounting for seasonal impact and rotating sampling sites/areas over time) may be appropriate.

If there has been recent activity, consideration must be given as to which zone the positive was found. If zone 2 (near product contact), there may be a higher likelihood that a product cross contamination event could have occurred compared with zone 3 or zone 4. It will also be important to understand if the true source of the pathogen was determined and then eliminated, or if the true source was not determined with confidence. Another consideration is recent environmental events (e.g., plant construction, roof leak) where the environment could have been compromised. If an event took place, samples should have been collected and the results may offer evidence of environmental concerns.

As part of an investigation, it may be valuable to initiate additional intense sampling of the environment (i.e., a swab-a-thon). A survey of the environment, along with specific attention to potential cross contamination areas, may aid in the investigation. Questions to consider:

- Over the past 12 months have any pathogen positives been experienced in the process environment where this product was produced, conveyed, or packaged?
- Were any positives in close proximity to zone 1?
- Did the vector sampling and investigation at the time provide an assignable root cause?
- Did subsequent testing verify effectiveness of corrective actions?
- Are there any plausible scenarios where cross contamination from this/these environmental sites could enter the product stream?
- Were isolates characterized to allow comparison to product isolates?
- Have any PEMP resident strains been identified and are there any matches with the positive product?

Characterizing environmental isolates to understand if you are or may be dealing with a resident strain is a proactive approach.

More aggressive control measures may be needed, including PEMP vectoring for root cause/niche sources and deep clean sanitation tactics to handle resident strains. The PEMP vectoring will often reveal a resident situation where initial corrective actions in a particular area do not result in timely remediation. On the other hand, finding a specific strain more than one time does not automatically mean you have a resident strain. A transient strain could be introduced at different times from external sources. If PEMP vectoring and corrective actions appear to remediate, but then the same strain is found in another location at a later time with similar successful remediation, part of the root cause should focus on introduction from external sources, such as foot/wheeled traffic from non-manufacturing areas, water ingress into the building, building air systems, and pest control.

Indicator data review as part of the investigation

A review of indicator organism results can also be useful during an investigation. It will be important to understand the trending of the data versus baseline and/or acceptance limits. Questions to consider:

- Are there any unusual trends in the indicator data that may point to a developing internal system harborage or possible sanitation/GMP failures?
- Are there any spikes in indicator data that match the product positive timeline and may indicate presence of uncontrolled water fueling microbial growth in the process or the process environment?

5.3. Maintenance Activity

Certain types of maintenance activities may contribute to cross contamination risks and must be included as part of the root cause investigation. Questions to consider:

- Was there scheduled or unscheduled maintenance activity on the line or in the production area during or before the contamination event. Are there adequate records for these events?
- If maintenance activity occurred, do you have a procedure outlining how to protect the product zone during these events? Are there records that show these procedures were followed?
- Have interviews of maintenance, engineering, contractors, and operations occurred to verify the information found in the records?
- Does a documented maintenance program for dedicated/captive tools and their sanitation exist? Are there records confirming procedures were followed?
- Are maintenance tools dedicated and swabbed as a part of the control program?

5.4. Downtime

Non-operating times often present a risk due to temperature variation, potential condensation formation, and system breaches that may occur. Questions to consider:

- Was there scheduled or unscheduled downtime during or before the contamination event?
- Was there an unusual amount of downtime and what was the reason for the downtime?
- Are there robust records of activities associated with the downtime?
- Did excessive downtime anywhere in the system interfere with normal rework, traceability, or other powder handling practices?
- Did the downtime create conditions within the system that increased risk?
- Was the system breached?

5.5 Sanitation Activities

Sanitation is conducted to remove soils and undesirable microorganisms from equipment and environmental surfaces. However, sanitation can become a source of contamination if not properly executed. Questions to consider:

- Were there any abnormal findings in the sanitation documentation?
- Was anyone new or unfamiliar with sanitation practices involved, such as a trainee or someone filling in during a normal operator's vacation or absence?
- Were the employees trained against the Sanitation SOPs and is training documented?
- Have we cleaned a known positive area with commonly shared cleaning utensils like vacuums, brushes, or wipes?
- Was this a wet or dry sanitation?
- Any unusual circumstances occur during cleaning?
- Was the system verified as completely dry, if wet sanitation took place, before starting back up?
- Was compressed air used in the environment or introduced into the dryer system?

5.6. Construction Events

Walls, floors, ceilings, and support structures are known harborage sites for pathogens which could be released by construction work. In addition, maintenance and contractor equipment or activities could introduce and spread external pathogens if containment measures are inadequate. Questions to consider:

- Was there construction activity on the line or in/near the production area during or before the contamination event?
- What were the controls set-up to protect the product zone if construction was in the area?
- What data is available to verify the construction zone was being controlled?
- Were any deviations recorded?
- What controls for dust from construction zones and air handling were put in place?
- What legacy construction has happened in the impacted area of the plant?
- Were extra environmental swabs taken within the construction areas? Any positives?

5.7. Other Production Records and Abnormalities

Production records provide an insight into any deviations or loss of control during production campaigns. Good records will show if any potential issues or problems occurred and when. Below are examples of production areas and records, along with potential findings that may indicate varying levels of loss of control, that should be reviewed. Some of these activities represent routine and non-routine opening of the system that could be a source of cross contamination.

- Sifters/screens – Increased or less than normal amounts of tailings, clumps or clumping that may indicate the unintended introduction of moisture or water somewhere in the system.
- Powder mills
- Magnets
    - Excessive metal on magnet
    - Cracks in magnet
    - Leaks around magnet door gasket
- Rotary air lock issues and/or seal vent line plugged/compromised
- Tube selector or other valve issues related to powder conveyance

- Bag houses – Inspection or replacement of dropped or ripped bag filter
- Fluid bed/static bed – Blinded or high level, possibly requiring scraping
- System pressure variations beyond normal
- Utility interruptions or surges
- Identification of worn or cracked direct product contact equipment (boots, rotary valves, stainless steel components, sifters, etc.)

5.8.Plant Trials and Projects

Review records for any trials or projects that may have changed normal operation. Activity examples include:

- Were any additional sampling locations included in the sampling plans?
- Were any manual processes used during the operations?
- Was any new equipment being used?
- Were there any new personnel in the production area?
- Were there new ingredients introduced to the system?

5.9.Introduction of water to the dry environment

Review records for any potential introduction of water and/or moisture to the dry environment that could fuel excessive microbial growth increasing the risk of spread. Examples may include:

- Were any overhead water leaks identified, especially if caused by roof or utility issues?
- Was any water in compressed air lines identified with no submicron filters at point of use?
- Was pneumatic air conveying dehumidifier inspected to ensure it was not full of water, leaking or having very dirty or cracked coils?
- Were there any leaking water flush check-valves on hard piped water flush lines?
- Were CIP pop outs inspected?
- Were there any failed high pressure pump packings or centrifugal pump water seal?
- Was there any water trapped between ferrule and plastic boot material on drop leg boots on cyclones or transition ducts?
- Were sonic horns or fluidizers in product lines supplied with compressed air inspected?
- Were there any issues with utilities outside the hygiene zone in which moisture may leak into room through entryways?
- Was the fire suppression system in the room and dryer inspected for leaks?
- Was there any other evidence of water use, standing water, condensations, or drain back-ups?

5.10.Operator Interviews

Were areas verified dry prior to starting back up after a controlled wet clean or unplanned personnel activity that introduces water? Engage operators in the effort to characterize any-unusual activities that may have taken place on or near the line. Interviewing them can uncover additional information or add clarity to records. The person being interviewed should understand the purpose and importance of the questioning to encourage an open dialogue and should be encouraged to be forthcoming, even if mistakes are identified.

Key questions:

- What might an operator have seen, heard, or performed that was not previously documented or part of normal plant operations?
- What might an operator be able to add to the operational records with their observations?
- Are there notes in operation/equipment logs that need clarification?
- Ask the operators to walk you through the process of setting up for production and/or CIP? Compare against the SSOP/SOP and note anything unusual or that has been normalized but may be a contributing factor.

5.11. System Breaches

Any disruption to the normal operations of the manufacturing process could be a breach and should be considered for breach control protocols. Routine breaches are necessary planned activities that are performed at a set frequency to maintain process control in sensitive areas and should have documented procedures and verification to reduce the risk of contaminating the system. Examples of routine breaches:

- Magnet checks, sifter-checks, mill checks
- Rotary airlock maintenance
- Blower dehumidifier cabinet cleaning
- Supply or conveying air filter changes
- Building HVAC filter changes for high care areas
- Checking integrity of dryer system filters
- Guillotine/blank entry/exit
- U-tube, Baghouse, or Fluid bed inspections

Whether a breach was planned or unplanned, it can increase the risk to the product zone.

Documented procedures should be in place to make sure trained personnel handle the system breach appropriately and avoid contaminating the system. Enhanced environmental swabbing after start-up can be performed to verify sanitation effectiveness.
Questions to consider:

- Was there a planned or unplanned breach during this time period? Capture details.
- Were any issues encountered that may have put product at additional risk?
- Was the High Hygiene area (i.e., filling room) breached or have greater personnel activity than normal?
- Were protocols followed and documented?

Appendix 2 captures the above considerations and questions in a format titled “Root Cause Investigation Coversheet” that can help organize your root cause investigation.

6. Assessing Your Situation Based on Investigation Findings

6.1. Response Team Review

The response team should meet to review all root cause investigational findings to draw a reasonable conclusion as to the cause of the cross contamination and determine, based on the pattern of resampling results, if this was an episodic event and if a hygienic separation could be established before and after the positive event.

To assist in the discussion, assemble the data in an easy-to-follow format. The team lead should start by presenting the compiled evidence to the response team. Each member of the team should keep a healthy skepticism about the facts of the event. This is the time to ask challenging questions. Are all the important elements of the event supported with data or facts? If not, are there any additional data or facts that can be gathered to solidify parts of the story?

6.2. Assignable Root Cause

Based on the investigational work conducted, can an assignable root cause be reasonably linked to the timing of the event as supported by the resampling results and data/facts collected?
In reality, there are times where a root cause cannot be reasonably assigned. Do not try to force fit a scenario if the documented data and records do not support it. This will need to be taken into consideration when determining hygienic separation as discussed in the following section. Obviously, an assignable root cause is advantageous in support of decision making and corrective action and preventive action (CAPA) next steps. However, if the investigative resampling strongly supports a limited episodic event, the lack of an assignable root cause becomes less of a hurdle.

6.3.Resampling

As noted in section 4.6, additional intensified resampling (this sampling is in additions to the investigative sampling) is useful during an investigation to establish the level and scope of contamination present. Results of the resampling can be difficult to interpret at times but can also bring clarity to the situation. No additional positives are good news in that whatever cross contamination occurred, it was at a very low level; however, it can also leave you with additional questions. Additional positives are an obvious concern but can possibly help define the type of contamination experienced. Upon receipt of the resampling test results, it is sound practice to lay the results out on a timeline to discern any potential patterns. Patterns are typically one of two types – single or multiple clusters.

Single Cluster Positive(s):

A single positive sample or a single cluster of positive samples may indicate that once the product or product stream was contaminated, the contaminated material moved through the production system and was purged from the system. The investigation should be focused on identifying the likely contamination event and resampling product made before, during, and after the positive samples to confirm that this is an isolated or "episodic" event.

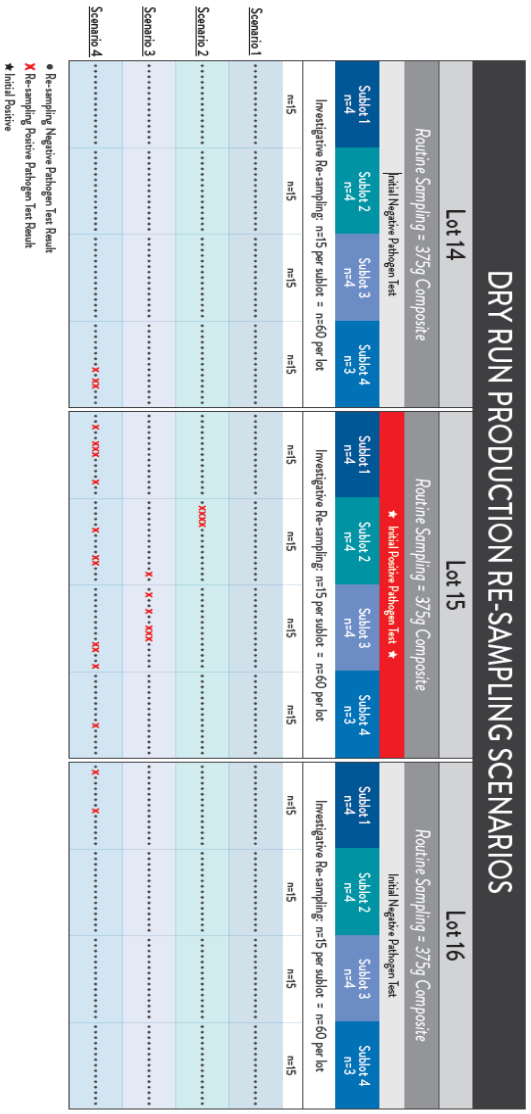
Multiple Cluster Positives

Multiple positive samples or clusters of positive samples may indicate more than one "episodic" contamination event introducing the pathogen to the product stream or that once the product was contaminated, the contaminated material has become hung up at spots within the system. Alternatively, the initial contamination level may be low and therefore only detected intermittently by the sampling plan. The investigation should be focused on identifying the likely contamination event(s), resampling product made before, during, and after the positive samples, and identifying any potential hang up points within the process such as ledges, elbows, or nooks within the equipment.

Figure 1 below illustrates 4 different hypothetical scenarios on how to interpret and react to each unique data set when trying to establish hygienic separation after a positive result. In these scenarios, one of the initial composite samples of lot #15 of a production campaign tested positive for *Salmonella*. The standard testing plan includes 1-375g composite per lot made up of 15-25g samples. In response, intensive re-sampling and testing for *Salmonella* was conducted on each of lots 14, 15 and 16. In this example, each lot was tested at n=60 with all 60 individual 25g samples tested separately for *Salmonella* to help create a timeline of results. The results of the re-samples are different for each scenario, with positive results noted by a red "x."

Note: Each company develops run, lot, sublot, and testing protocols based on process design, business needs and customer requirements. The following depicts a generic example for discussion purposes only.

Figure 1. Resampling Scenarios



6.4.Discussion on Scenarios Depicted in Figure 1.

Scenario 1 - No Additional Positives

In Scenario 1, no additional positives were found after intensive resampling of the implicated lot #15 or the buffer lots 14 and 16. This would strongly indicate that this was a very focused episodic event. While no additional positives were found, it is still recommended to complete and document all appropriate remediation steps and root cause analysis.

Note: The fact that no additional positives were found upon resampling does not negate or override the initial positive. Companies in this situation should consider the totality of the evidence. If an assignable root cause (ARC) is identified and the timing aligns with production of the implicated Lot #15 and all additional microbiological data is typical, they may consider release of lots prior to buffer lot #14 and after buffer lot #16 but choose to reject both buffer lots #14 and 16 in addition to the positive lot #15 to be conservative.

Scenario 2 - Single Cluster Positives

In Scenario 2, the intensive resampling of lots #14, 15 and 16, indicated the contamination was an isolated event closely clustered around the original positive result. There were no additional positives in adjacent lots which reasonably indicates the contamination moved through the system and there is not a systemic contamination. Data indicates this was likely an episodic event.

Similar to Scenario 1, companies in this situation should consider the totality of the evidence. If an assignable root cause (ARC) is identified and the timing aligns with production of the implicated Lot #15 and all additional microbiological data is typical, they may consider release of lots prior to buffer lot #14 and after buffer lot #16 but choose to reject both buffer lots #14 and 16 in addition to the positive Lot #15 to be conservative. Since the resampling did detect more than one positive, release of buffer lot #14 would be more difficult and likely not considered. If no ARC is identified, intensified resampling and lot rejections may expand because of the lack of clarity of impacted product.

Scenario 3 - Multiple Cluster Positives

For Scenario 3, the resampling activities indicated the contamination had less consistent and non-discreet grouping of positives; but may still be limited in scope. To further clarify these results, a company may prudently expand testing to additional production lots, such as lots #13 & #17 per this example. Obviously, a larger portion of the production must be placed on hold pending these results.

Again, considerations for identifying hygienic separation and product disposition will depend on whether an ARC was determined, and timing was in conjunction with the test results. If an ARC is identified and evidence and subsequent resampling (no additional positive detected) indicates a larger but still episodic event, companies would reject all lots with any positive test. Results, and likely several buffer lots as well. However, consideration must give to this being a harborage versus an episodic issue. If no ARC or a weakly linked ARC was determined, further intensified resampling and investigation may be needed to better define where the appropriate hygienic separation can be established.

Scenario 4-Multiple Cluster Positives

In Scenario 4, the resampling activities have not established a bracket of lots that test negative for pathogens on either side of the original positive incident. A company presented with this scenario will have to carefully consider its next remediation and mitigation activities including consideration of all product produced between the current clean break wet wash brackets. The company should start sampling additional lots on either side of the incident to investigate the scope of the contamination and attempt to establish a proper hygienic separation break or utilize the last documented sanitation clean break. This testing could have food safety and/or regulatory considerations if product is outside of company control and should be considered carefully by company leadership and appropriate legal counsel. This data indicates that there may have been an intermittent contamination event or possibly an internal harborage point. The root cause investigation and possible internal system and/or disassembled equipment sampling/testing is critical to help form appropriate corrective actions beyond clean & purge.

All product lots and any side-stream material determined to be implicated will need to be safely and appropriately dispositioned. Product from the entire campaign, and any side-steams, back to the last validated clean break may need to be recalled from the market.

6.5.Applying Hygienic Separation Concept using the Above Example Scenarios

Table 3 summarizes and expands upon the scenarios presented above and provides considerations and thought processes for hygienic separation. Questions to help drive disposition decisions include:

- What was the pattern of positives if any from the investigative resampling?
- Do you have a full grasp of product flow and know all associated product?
- Have there been any upward trends or unusual spikes in product indicator counts?
- Have there been any unusual PEMP findings indicating a potential product stream risk?
- Does the evidence suggest that the event is episodic versus an internal harborage?
- Were you able to identify a reasonable assignable root cause?

Table 3. Scenario Examples

Scenario #	Resample Pattern of Results	Assignable Root Cause Identified	Episodic Event	Hygienic Separation* Possible (* Other than clean break)
1	No Clusters	None Identified	Very Likely	Yes
2	Single Focused Cluster	Yes; unplanned breach for maintenance work	Likely	Yes with caution; consider exapnding resampling to verify
3	Multiple Clusters Limited Time Period	Yes; planned breach but SOP failures noted	Likely	Possible; expand resampling to verify; closely review records for expand lots
4	Multiple Clusters Broad Time Period	Yes; niche condensation identified	No	Unsupportable
	Examples above assume investigation found that all PEMP and microbiological data were typical.			

7. "Putting It All Together"

7.1. Data Driven Product Disposition

In summary, each event will have its own unique circumstances, and the information discussed in this document must be collected and reviewed together, as a complete scenario, in order to make the best decision for product disposition that minimizes food safety risks.

Utilize the information and tools in this guidance as appropriate to assist in managing, investigating, and documenting any events you may experience. It will always be easier to defend any decision including hygienic separation when supported by well documented data and facts. Document the decision made regarding the disposition of the product and why that conclusion was made based on the facts.

7.2.CAPA

There are always learnings to be gained from every event with an opportunity for continuous improvement. The response team should determine and document all immediate, short, and long-term corrective and preventative actions.

7.3.Documentation

It is critical to capture all results, records, corrective actions, and response team notes in support of any product disposition decisions. Maintain records per company policy or legal team recommendations. These investigation and disposition documents may be reviewed years later with new people on the team having to answer the questions accurately and concisely. Consider the audience as you finalize the disposition and investigation report.

References:

1. Innovation Center for U.S. Dairy Guidance for Dairy Product Enhanced Traceability Voluntary Practices and Protocols for Strengthening the U.S. Dairy Supply Chain. 2016.
2. Controlling Pathogens in Dairy Processing Environments: Guidance for the US Dairy Industry. October 1, 2020, Version 1.1.
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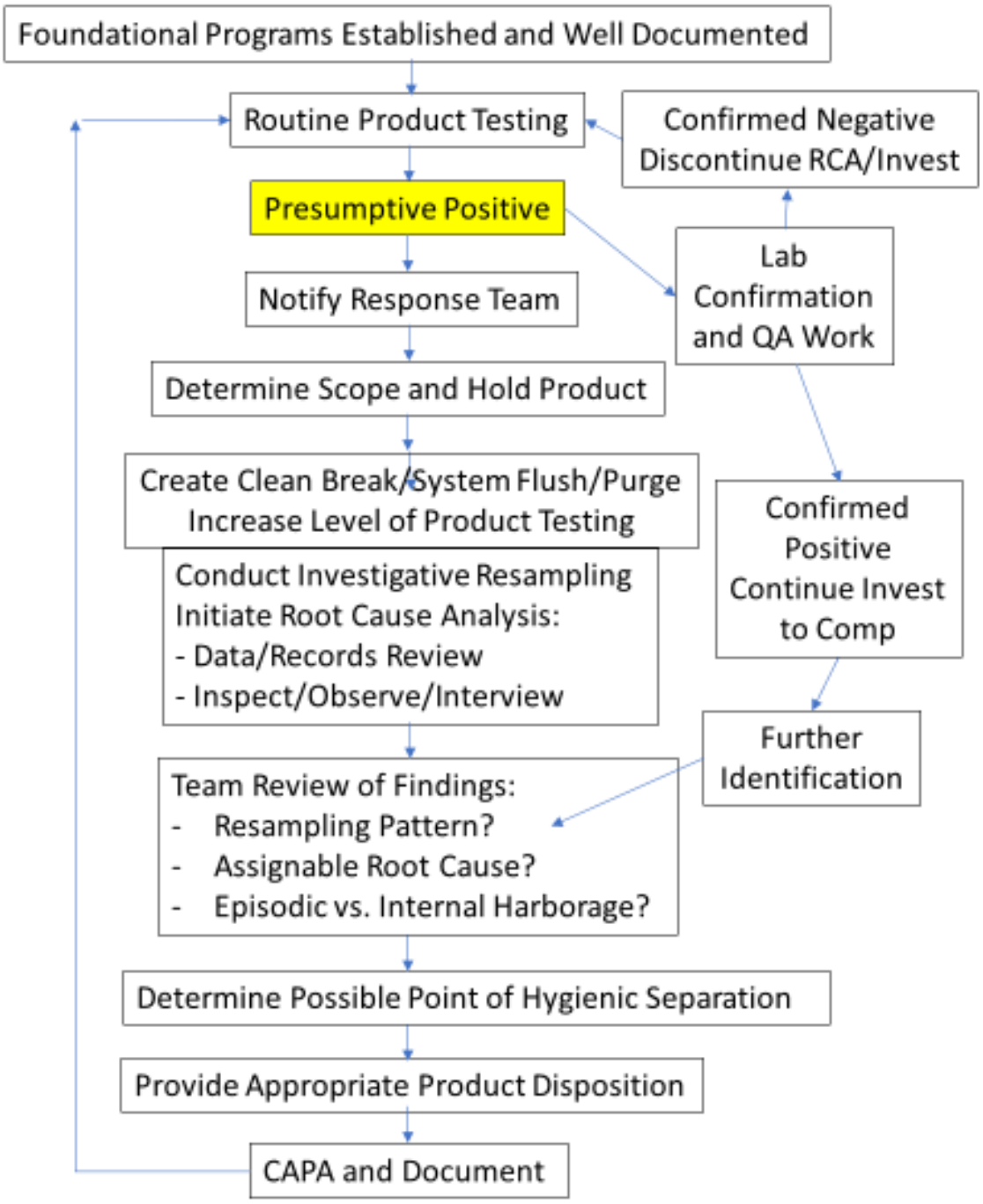
4. Cook, D. (2021, April 15). Cronobacter: Pathogen Considerations beyond Salmonella in Dairy Powders. Food Safety. April/May 2021. Online version
5. Control of Salmonella in Low-Moisture Foods. GMA. 2009 February 4.
6. Hasmukh, P. Best Practices for Excellence in Milk Powder Manufacturing: A guide for manufacturers. U.S. Dairy Export Council. 2013

Positive Event Action Steps



Root Cause Investigation Coversheet

Records Review:

Records to Review	Reviewed	Date Range	Any Deficiencies or Abnormalities
• Process control records			
• Pasteurization records			
• Evaporator records			
• Dryer records			
• Maintenance records for preventive maintenance performed			
• Work orders or red tags			
• Filter changes			
• HVAC maintenance			
• Routine or special case intrusions into the system			
• Clearing powder plugs/build up			
• Magnet checks			
• Leak detection/repair			
• Monitoring of sifter overs, humidity, and air pressurization records			
• Weather			
• Structural failure			
• Contractor activity			
• Unexpected down times			
• Other unusual events			
• Finished product microbiological test results			
• Sanitation records, pre-op and verification results			
• PEM/EMP results and trending			
• Other			

Investigational Questions:

Maintenance Activity

Was there scheduled or unscheduled maintenance activity on the line or in the production area during or before the contamination event. Are there adequate records for these events?

If maintenance activity occurred, do you have a procedure outlining how to protect the product zone during these events? Are there records that show these procedures were followed?

Have interviews of maintenance, engineering, contractors, and operations occurred to verify the information found in the records?

Does a documented maintenance program for dedicated/captive tools and their sanitation exist? Are there records confirming procedures were followed?

Are maintenance tools dedicated and swabbed as a part of an PEMP?

Downtime

Was there scheduled or unscheduled downtime during or before the contamination event?

Was there an unusual amount of downtime?

What was the reason for the downtime?

Are there robust records of activities associated with the downtime?

Did excessive downtime anywhere in the system interfere with normal rework, traceability, or other powder handling practices?

Did the downtime create conditions within the system that increased risk?

Was the system breached?

Was the High Hygiene area (filling room) breached or have greater personnel activity than normal?

Sanitation Activity

Were there any abnormal findings in the sanitation documentation?

Was anyone new or unfamiliar with sanitation practices involved, such as a trainee or someone filling in during a normal operator's vacation or absence?

Were the employees trained against the Sanitation SOPs and is training documented?

Have we cleaned a known positive area with commonly shared cleaning utensils like vacuums, brushes, or wipes?

Was this a wet or dry sanitation?

Any unusual circumstances occur during cleaning?

Did we conduct maintenance during the sanitation cycle?

Was the system verified it was completely dry, if wet sanitation, before starting back up?

Construction Activity

Was there construction activity on the line or in/near the production area during or before the contamination event?

What were the controls set-up to protect the product zone if construction was in the area?

Were any deviations recorded?

What data is available to verify the construction zone was being controlled?

What data and/or documentation is available for contractor and people controls?

What controls for dust from construction zones and air handling were put in place?

What legacy construction has happened in the impacted area of the plant?

Were extra environmental swabs taken within the construction areas?

Other Production Records and Abnormalities

Sifters/screens – Increased or less than normal amounts of tailings, clumps or clumping that may indicate the unintended introduction of moisture or water somewhere in the system, scorch or extraneous

Powder mills

Magnets

Excessive metal on magnet

Cracks in magnet

Leaks around magnet door gasket

Bag houses – Inspection or replacement of dropped or ripped bag filter

Fluid bed/static bed – Blinded or high level, possibly requiring scraping

System pressure variations beyond normal.

Utility interruptions or surges.

Identification of worn or cracked direct product contact equipment

Plant Trials and Projects

Were any additional sampling locations included in the sampling plans?

Were any manual processes used during the operations?

Was any new equipment being used?

Were there any new personnel in the production area?

Were there new ingredients introduced to the system?

Introduction of water to the dry environment

Overhead water leaks caused by roof or utility issues

Water in compressed air lines with no submicron filters at point of use

Pneumatic air conveying dehumidifier full of water, leaking or very dirty coils.

Leaking water flush check-valves on hard piped water flush lines

Failed high pressure pump packings or centrifugal pump water seal.

Water trapped between ferrule and plastic boot material on drop leg boots on cyclones or transition ducts

Sonic horns or fluidizers in product lines supplied with compressed air

Issues with utilities outside the hygiene zone in which moisture may leak into room through entryways.

After a controlled wet clean or unplanned personnel activity that introduces water, the area needs to be verified dry prior to starting back up

Is this appropriate here, if these are in the dry area, this may not be abnormal introduction of water?

Interviews

What might an operator have seen, heard, or performed that was not previously documented or part of normal plant operations?

What might an operator be able to add to the operational records with their observations?

Are there notes in operation/equipment logs that need clarification?

System Breaches

Magnet checks, sifter-checks, mill checks, rotary airlock maintenance

Blower dehumidifier cabinet cleaning

Supply or conveying air filter changes

Building HVAC filter changes for high care areas

Checking integrity of dryer system filters

System Inspection

CIP "pop-outs"

Bag house manifolds

Atomizer portals

Pneumatic conveyance flanges

Dehumidifiers

Air system filtration

Rotary feed valves

HPP

Internal dryer shells

Product Disposition Questions:

What was the pattern of positives if any from the investigative resampling?

Do you have a full grasp of product flow and know all associated product is on hold and accounted for?

Have there been any upward trends or unusual spikes in product indicator counts?

Have there been any unusual PEMP findings indicating a potential product stream risk?

Does the evidence suggest that the event is episodic versus an internal harborage?

Were you able to identify a reasonable assignable cause?

Appendix H – Brine System Food Safety Best Practices

Dairy Brine Food Safety Best Practices

SECTION 1: OVERVIEW

1.1 Scope and Purpose

Brines increase salt content, reduce moisture, help control cheese starter and non-starter microbiological growth, impart flavor, aid in cheese temperature control, and restrict the growth of salt-sensitive microorganisms in cheese. This document focuses on the FOOD SAFETY elements of brine system programs, with an emphasis on microbiological controls. Other important attributes are briefly covered as they relate to practices that support the food safety programs. Brine should be considered to be an ingredient, not just a processing aid, and must be sourced and handled accordingly.

1.2 Other Applicable References

The Best Practices for Cheese Brine Systems from Dairy Practices Council (DPC.org) is an additional resource for the construction, preparation, maintenance, and many other brine system considerations.

SECTION 2: BRINE MAKING AND STORAGE

2.1 Brine Definition

Brine is simply a salt solution in water that typically ranges from 21% - 23% salinity. Once the brine is mixed it is typically pH adjusted to a similar pH as the cheese being brined and cooled to 4°C to 20°C. Other important considerations are water and salt quality.

There are three general types of brine systems:

1. Static brine systems, where cheese is placed in pits or tanks with little or no brine circulation,
2. Classic brine systems, where brine is circulated around stationary cheese, and
3. Dynamic channeled systems, where both cheese and brine flow together through a channel system, are used to salt a variety of cheeses including mozzarella, provolone, Gouda, Munster, Feta, and parmesan (Johnson Industries).

2.2 Brine Water and Salt -- Quality and Food Safety Considerations

- Water Quality – Brine must be made only with potable water that meets all preventive controls requirements. Water quality expectations can be found in the Pasteurized Milk Ordinance (PMO) for water sourced from municipalities or wells.

- Salt (NaCl) Quality – Brine must be made with only food grade salt free of any chemical contaminants.
    - Sea Salt is not recommended for making brine due to a risk of chemical and pathogen contaminants.
        - If flow agents are utilized in the salt, this could become problematic in managing suspended solids in the brine without effective filtration.
        - Salt without flow agents will likely require some type of grinding or breaking step to become flowable for the process.

2.3 Brine Storage Considerations

- Operational Balance
    - Several factors can impact the volume of brine such as the amount of cheese in the system, losses, and evaporation. A balance needs to be maintained to account for this fluctuation in brine volume. It is important to monitor and manage balance tanks and ensure they are cleaned when the entire brine system is emptied and cleaned.
- Treatment of brine and cleaning of brine system
    - It is critical for brine quality and food safety to identify enough storage to allow for all the brine to be removed from the "flume" into tanks, silos, or other suitable storage locations. This complete removal of brine typically serves two purposes.
    - It allows the emptied flume and all adjacent equipment to be cleaned, inspected, and repaired.
    - It allows the brine to be pasteurized/treated and returned to the flume without recontamination of the brine and handling equipment. The frequency that the brine system is completely emptied and cleaned is driven either by time (annually, quarterly, etc.) or by quality indicators and action limits based on the facility's trending of the data.

Note: When pasteurized/treated brine is put back into the system the temperature, salinity, and calcium levels should be monitored and adjusted to operational levels according to the facility's SOPs.

2.4 Brine Quantity

Brine volume should be 5 times the volume of cheese to ensure the uptake of salt. (Bintis, 2006, pg. 271). Note: Although Bintis references a 5 to 1 brine to cheese ratio, the ratio would require a huge volume of brine and space be allocated to salting when a large static or pick and pull brine system is considered. By having brine of a known and controlled concentration circulate around each cheese, less brine is required and the cheese to salt ratio may be less than 5 to 1.

2.5 Brine Circulation

Brine circulation is important in both the classic and dynamic brining systems because it minimizes salt striation and salt dilution at the cheese-brine interface as whey is expelled from the cheese. It also helps maintain a constant temperature throughout the brine in high-capacity brining operations. However, it is less important in classic pit brine systems where there may be little to no circulation.

2.6 Importance of Creating a "Clean Break"

For all types of brine systems, it is important to periodically create a "clean break" in which it can be convincingly demonstrated that the brine's impact on product quality or food safety is limited to a particular period of time or "lot". Steps used to create the clean break must be documented each time a clean break is created. A clean break may be created by:

1. Complete and permanent disposal of 100% of the brine followed by a complete cleaning of the brine making, storage, and handling systems (pipes, pumps, etc.)
2. Microbiological treatment (pasteurization or other) of the brine to achieve desired micro levels without possibility of recontamination of the brine or ancillary equipment.
3. A validated sanitation process and verification of the system cleanliness must be conducted prior to the reintroduction of treated or new brine solution.
4. Documentation of the brine plan with robust environmental monitoring plan which provides verification of the effectiveness of hygienic and sanitation programs.

SECTION 3: MONITORING BRINE QUALITY AND FOOD SAFETY

3.1 Visual Examination of Brine

Visual appearance is an important indicator of the quality of the brine. Brine should be clear with a light greenish color sheen. Brine that is discolored or contains a high amount of solids may be an indication of issues with brine quality.

3.2 Chemical and Physical Examination of Brine

A. **Salinity (NaCl)**

A typical brine will contain approximately 21-23% (w/w) food-grade salt and resulting in approximately 90% saturation (Kosikowski, 1997). The salt concentration should be monitored and maintained throughout the brining process by adding salt, as needed.

Testing salt content. A Baume hydrometer (salometer), pH meter with a sodium-sensitive electrode, or salt analyzer (platinum electrodes or flow-through style) may be used to monitor the salt concentration of brine. Hydrometers are easy to use but as dissolved solids from the cheese increase, their ability to accurately measure salt is reduced because the hydrometer cannot distinguish between dissolved salt and dissolved cheese solids. Therefore, a sodium-sensitive electrode or salt analyzer should be used to calibrate the hydrometer and confirm the sodium chloride content. Both the pH meter and a salt analyzer require additional training, but each will provide sodium ion readings that may be converted to % salt and neither are affected by dissolved cheese solids. (Wendorff, AOAC).

B. Calcium

The calcium content of the brine should be like that of the cheese to avoid leaching calcium from the cheese into the brine and producing cheese with soft rind. Unless calcium is added, calcium from the cheese will leach into the brine until an equilibrium is reached. Add between 0.1 % to 0.3% $CaCl_2$ to new brines (Kristensen, 1999, Kindstedt, 2005). (Kindstedt, 1991 recommends adding 0.06% $CaCl_2$ to Mozzarella brines). As whey is expelled from the cheese into the brine, the calcium content of the brine will be diluted so monitoring and adding calcium to maintain brine-calcium concentrations will be necessary. Because calcium helps firm up the cheese surface, the addition of too much calcium can make the cheese surface uncharacteristically firm (Wendorff, CDR).

C. pH

It is recommended to keep brine pH below 5.4 as a food safety best practice. Ideally, brine pH should be the same as the cheese being brined, but when the cheese pH is higher than 5.4 it is still recommended to maintain the brine at 5.4. When brines are more alkaline than the cheese, they may cause the surface caseins to swell, retain moisture, and may cause the surface to become slimy. Adding acidulants such as lactic or acetic acid to new brines to lower the pH of the brine to that of the cheese helps eliminate this defect. In established brines, expelled whey should maintain the pH. However, the pH should be routinely monitored and adjusted with lactic acid, acetic acid, sodium hydroxide, or potassium hydroxide to maintain the target pH. If brines have pH values above 5.4, additional considerations will likely be necessary to control the outgrowth of undesirable microorganisms.

D. Temperature

Temperature is important as a pathogen and quality control tool. Brine temperatures may vary depending on the type of cheese being made and the function of the brine. When used for salt uptake and cooling the cheese, brine temperatures are likely held warmer, 7°C to 10°C (45°F to 50°F), than brines used primarily for cooling of the cheese, at 2°C to 7°C (35°F to 45°F). Low brine temperatures retard the growth of *Lactobacillus casei*, which can cause a soft surface in cheese (Wendorff). Optimally, brine should be maintained at 50° F or less.

During brining, sodium and calcium ions move from the brine into the cheese. At the same time, water, calcium ions, and phosphate ions move from the cheese into the brine (Geurts et. al., 1974) In general, water moves out of the cheese twice as fast as salt moves in. Warmer brine temperatures increase both the diffusion rate and the quantity of salt absorbed by the cheese (Turhan & Kaletune, 1992). Cheese can expand or contract if moved from a cold brine to warm brine or from a warm brine to a cold brine (McMahon et. al., 2009). Therefore, keeping the brine temperatures within narrow limits minimizes temperature-related structural changes.

3.3 Microbiological Examination of Brine

Microbiological control programs are critically important to manage quality and food safety of the brines. Often these programs focus on quality controls for yeast and mold with less emphasis of specific measures for control of pathogens. If brine systems are poorly managed, they can harbor spoilage and/or pathogenic organisms. The quality of the cheese rinds may become contaminated microbiological organisms originating from the immersed cheese, water, salt, equipment, and plant environment. Undesirable organisms can include yeasts, molds, lactobacilli, micrococci, staphylococci, Enterobacteriaceae, and pathogenic bacteria such as *Listeria monocytogenes*, *Escherichia coli*, Salmonella, and *Staphylococcus aureus*. Therefore, it is imperative to have robust and documented monitoring programs to keep brines free of pathogens.

3.3.1 Minimum Monitoring Program Requirements

1. Selection of indicator organisms to be monitored to predict the presence of spoilage and the potential of pathogenic organisms.
2. Documented monitoring frequency and sampling locations.
3. Standards and action limits (upper/lower control limits) for monitored organisms.
4. Corrective and Preventive actions (CAPA) taken to ensure product safety when limits are exceeded.

A. Indicator Organism Selection

Indicator organism monitoring may include yeast, mold, coliforms, and/or Enterobacteriaceae (EB) to monitor the microbiological quality of brines. The monitoring of psychrotrophic bacteria may also be beneficial, especially if off-flavors are encountered in the cheese.

- When testing brine for *pathogen* indicators, it would be considered the equivalent to a Zone 1 sample and specific considerations must be made. Refer to the FDA's Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry, Draft Guidance 7 for additional information.
- Each company will need to design a plan appropriate for its own situation, based on the risks presented by its plant characteristics and processing conditions, to develop its Zone 1 testing program. More information on Zone 1 monitoring can be found in the FDA's Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry, Draft Guidance 7.
- It is strongly advised that you involve an internal or external Food Safety Expert to develop your Zone 1 monitoring program to determine which specific sites to sample and how product will be controlled pending sampling results from routine and non-routine sampling of Zone 1.
- As FDA Listeria control guidance describes, only test for Listeria *species* in Zone 1 (not Lm). Testing for and finding Listeria spp. on a product contact surface does not automatically mean that product is contaminated, but appropriate and aggressive corrective actions must be taken and documented.

B. Monitoring Frequency and Sampling Locations

Monitoring must be done on a set, documented schedule at a frequency that demonstrates control (i.e., weekly) and include enough brine samples to be representative of the system. Ensure samples are taken from all tanks in a multi-tank system or at various points throughout a channeled system.

As brine actively or passively circulates around the cheese, cheese solids from the surface and interior of the cheese become incorporated into the brine. Some cheese solids dissolve, but others do not and either settle to the bottom of the tank as a sludge or remain suspended provided that the brine circulation is sufficient to do so. Milkfat that has been released from the cheese surface or expelled from the interior of the cheese floats to the top of the brine and can create a foam consisting of milkfat, cheese protein, and salt. Therefore, it is possible to have three very different zones or micro-environments within the tank or channels i.e., brine, cheese, and brine surface.

Routine sampling from each micro-environment may not be practical on a weekly basis but as brine tanks are emptied for cleaning, maintenance, or as other opportunities arise, they should be tested for a facility's documented indicator organisms. In addition, indicator testing before and after filtration systems, heat-treating units, and high-count areas of the brine system will provide valuable information about the quality of the brine.

C. Microbiological Standards and Action Limits

Determining Standards and Limits: Specific specifications, action limits, and corrective actions must be devised and documented for each organism in your plan. Since the goal is to have as few problematic organisms in the brine as possible, an "Ideal" or target level for coliform, yeast, and mold should be established (Table 1). Microbial limits will differ depending on the cheese, brining system, and cheese production process. If SPC were included in a monitoring program, a target of ≤ 2500 cfu/ml could be used for cultured cheeses. However, this value may be significantly less for non-cultured cheeses or significantly higher for cheeses that are salted in brines to which cultures have been added to enhance cheese flavor. Therefore, limits should be customized to meet the needs of the brine system with consideration to the cheese culturing systems. Consult your internal or external food safety experts to determine targets, alert limits, and action limits, as well as appropriate actions for your particular situation. Below is a recommended *starting point* for microbiological limits. Microbiological standards should be established for each brine system and cheese type being brined (Table 1).

Table 1. Microbiological limits for cheese brine

	Target	Alert Limit	Action Limit
Microorganism	cfu/ml	cfu/ml	cfu/ml
Coliform	≤ 10	> 10	> 100
Yeast	≤ 100	> 100	> 1000
Mold	≤ 100	> 100	> 1000
Enterobacteriaceae (EB)	≤ 10	> 10	> 100

In addition to a low ideal target value, an *Alert Limit* and an *Action Limit* should be established. Exceeding an alert limit should cause concern unless, for example, there was a known event which would cause a drift in the process or product. An action is not necessarily required, but it is a flag to pay attention to and monitor this specific process or parameter. Whenever a process or product exceeds the Action Limit, immediate action is required. Corrections and/or corrective actions must be implemented. For events or trends in which action limits are exceeded, an investigation should be done with root cause analysis and corrective and preventive actions identified and documented.

D. Responses and Corrective Actions:

When microbiological counts exceed the Alert Limits (Table 1), intervention may be warranted. However, action is necessary when counts exceed the Action Limit thresholds as these values represent the highest allowed limits for your brine system. Actions would include verifying that brine pH, calcium, and salinity levels are within your established ranges. It may be necessary to drain and clean tanks and clean suspect areas of a channel system. Consult with your sanitation specialist for proper cleaning chemicals and methods.

Heat treating the brine from a drained tank before it is reintroduced into the cleaned tank or increasing the heat-treatment frequency of the brine may be warranted. Additional monitoring will be needed after corrective actions to ensure the system is under control.

Environmental Monitoring Recommendations

In addition to pathogen indicator testing, it is recommended that air quality and contact surfaces be swabbed and tested for other microbiological organisms.

- Cleaned equipment ATP and TPC – Non-pathogenic specific ATP, Total Plate Count, and coliform swabs taken on equipment after cleaning and prior to use are helpful in determining the effectiveness of sanitation protocols in Zone 1 (food contact surfaces).
- Air plates (yeast and mold) are useful in evaluating the cleanliness of the air that circulates in the brining room. Air plates should be placed at representative locations throughout the processing area and the inside of air ducts going to and from the brine room. Room air quality, like any other test, must have action limits. It might also be important to note that you may want to be looking at the air data with respect to a baseline value of performance as opposed to just the action limits. The baseline value may indicate a shift in air quality over time that wouldn't reach the action limit until it become too late and at that point you are likely to not be able to react in time to avoid defects and or/product loss due to spoilage.
    - Room fogging with approved, non-residual sanitizers may be considered if yeast and mold (Y&M) counts exceed action limits. This should be part of a routine MSS program as well as a reaction to AAL air counts at high enough levels so long as you can cover the brine system to protect it from the sanitizer.
    - Note: If you cannot cover the brine tank/system, it is not suggested to fog due to risk of contamination of the brine with the fogging chemical.
- Refer to FDA's Listeria Guidance Document, Section VIII, for additional monitoring guidance.

HVAC System and Filters

HVAC systems containing high efficiency (HEPA) filters are critically important in providing and maintaining adequate room air quality. The HVAC filters must be monitored for effectiveness as part of the facility PM program and replaced on a routine basis. Change frequency is determined by their effectiveness as measured by an increase in back pressure, or other operational methods.

SECTION 4: PATHOGEN ENVIRONMENTAL MONITORING OF THE CHEESE MANUFACTURING FACILITY

4.1 Industry and Regulatory Guidance

Information on *environmental* monitoring programs is provided in The Innovation Center for US Dairy "**Controlling Pathogen in Dairy Processing Environments – Guidance for the Us Dairy: Principle #5: Pathogen Environmental Monitoring"**

Typically, routine environmental monitoring for pathogen species is focused in Zone 2 and Zone 3 of a facility, and not in Zone 1 areas due to potential product implications in the event of unfavorable results. Aggressive monitoring and corrective actions in Zone 2 and Zone 3 will help to reduce the risk of pathogens in Zone 1.

4.2 Pathogenic Organisms of Concern

Of primary concern are pathogens such as *Listeria monocytogenes, and Salmonella spp.*

- *Listeria monocytogenes* grows or survives in cool moist environments and can tolerate high salt levels (Dongyou et. al, 2005). Areas where condensation occurs such as drip pans or troughs, pipes near the ceiling, areas where moisture collects such as floor drains, and damp corners are all locations of concern. Testing for *Listeria* species, rather than specifically for *L. monocytogenes*, increases the sensitivity of an environmental monitoring program because *Listeria* species will be found more frequently. In addition, test results for *Listeria* species will generally be available faster than for *L. monocytogenes* allowing more rapid intervention. Detection of any Listeria species in the environment should be cause for concern and requires aggressive, and immediate corrective action.

- *Salmonella* can grow in moist areas, but are less tolerant to salt than *Listeria* spp., and can grow in many dryer conditions (Aw < 0.85). As with *Listeria*, the presence of *Salmonella* is determined by testing for general *Salmonella* species rather than for a specific *Salmonella* species. Detection in the environment requires corrective action.

4.3 Corrective Actions

Immediate and effective corrective actions must be taken when positive environmental monitoring results are received and documented. This may range from increased cleaning to capital projects to correct identified issues.

SECTION 5: CLEANING AND MAINTAINING THE BRINE SYSTEM

5.1 Cleaning Brine Handling Systems

A. Open Systems -- Aboveground Flume/Pit Cleaning

Storage capacity is critical to move the brine from the "flume" into tanks/silos to enable both heat pasteurization of the brine and the full cleaning of the empty "flume" on some regular frequency. This is recommended to avoid poor quality of the brine, a product quality event, or a pathogen being found in the brine. The frequency requirements to do this pasteurization and cleaning of the flume will be driven by microbiological data, visual observation, flume design, filtration capability, and cheese capacity.

- Manual "flume" cleaning and sanitizing involves the 7-step cleaning process which would involve foaming and significant hand brush scrubbing which is well documented in the FDA's Listeria Guidance document, Section VII-A-1.

- When the flume is completely empty of brine it is an excellent time to do a thorough environmental room foaming/cleaning and sanitizing of the walls, floors and ceilings where mold/yeast and even pathogens can persist for the many months of running without the ability to do this cleaning. An effective means to cover open flume systems (i.e., flume covers) may be considered when conducting environmental cleaning near the open portions of the system and when sufficient storage capacity is not available.

- Master Sanitation Schedule (MSS) and Preventative (PM) work should also be scheduled and completed at this time when the brine is not in the "flume".

B. Closed Systems – Storage Vessels/Silo Tanks/Cooling Presses/Systems

Brine storage tanks and cooling systems shall be cleaned via CIP (clean-in-place) system and reference this sanitation section in the FDA's Listeria Guidance Document for more information on CIP cleaning and sanitizing requirements, Section VII-A-3. CIP cleaning of these "in the pipe" equipment is the most efficient and effective way to achieve good cleaning of these components.

C. Brine Racks / Ripening Racks / Cheese Molds

Racking and molds can be cleaned and sanitized via one of two methods: Manual 7-step cleaning in a dedicated sanitation room with foam and manual scrubbing refer to related sections in The Innovation Center for US Dairy **"Controlling Pathogen in Dairy Processing Environments – Guidance for the Us Dairy: Principle #4: Effective Cleaning and Sanitation Procedures and Controls,"** or

Using the preferred method an automated Automatic Cleaning System "ACS" very much like a dishwasher in your home. For cheese molds it's typically a long tunnel washer that automatically cleans and sanitizes the molds or for the racking it typically looks like a small chamber or the carwash you drive through where the racks are pushed in and cleaned and sanitized. Both of these ACS processes meet the four parameters in cleaning, requires attention to automation detail, must be maintained, validated and you can reference in the FDA's Listeria Guidance Document, Section VII-A-3 for more details on this technology.

5.2. Solids Removal / Brine Cleaning

A constant challenge with brine solutions is keeping them free of unwanted solids and microbial contaminants. Interventions are often used, depending on the size and scale of the brine system, to remove these unwanted solids. At minimum, brine solutions should be skimmed regularly or continuously to not allow the solids to build up. Advanced filtering systems such as Microfiltration (MF) and Ultrafiltration (UF) are very effective at removing the unwanted solids and microbial contaminates.

A. Brine Filtering Methods – Microfiltration (MF) and Ultrafiltration (UF)

- Microfiltration (MF) has proven to be superior technology for sanitation purification of the cheese brine as it's a clean process which removes the microorganisms, dead cells and physical contaminates from the brine and without any significant change to the chemical composition of the brine. This technology allows the cheese proteins to pass through the filters and eliminates > 99.5% of the microorganisms.

- Ultrafiltration (UF) filters down to an even greater level than does MF, but also removes the cheese proteins and other chemicals components that may be beneficial to cheese making.

Either filter system must be correctly sized to allow the total volume of the brine in the system to be completely filtered in a reasonable timeframe. This is necessary to shorten the growth log cycle of the quality microorganism of concern, which is typically yeast.

MF/UF filter systems consist of a series or bank of filter canister containing spiral filter material which are fibrous making them a challenge to clean. They must be cleaned at a frequency necessary to maintain good brine flow through them during production. If not cleaned correctly or regularly they become plugged creating low flow brine efficiency through them not maintaining good quality brine. The frequency of cleaning for a given facility should be based on microbiological and operational data.

Spiral filters due to their sensitive fibrous like paper materials have to be CIP cleaned (refer to Listeria Guidance Document page 43-51 for CIP information) and cleaned at a much lower temperature (< 120°F) with specialized caustic/surfactant enzymatic cleaners. Work closely with your chemical vendor in selecting the right series of cleaning products with their recommended cleaning CIP sequence for cleaning membranes optimize daily run times and overall operational life.

B. Brine Treatment Methods

Facilities may utilize various treatments for food safety and quality purposes, including:

1. Pasteurization
2. Anti-microbial agents / Bio-preservatives
3. Oxidizing agents – Chlorine/Hydrogen Peroxide
4. Other Treatment Methods

Note: If an oxidizing agent is utilized, such as chlorine or hydrogen peroxide, shelf life studies should be conducted on cheese styles and brine times to ensure product quality and functionality are not impacted.

Pasteurization:

Brine may be pasteurized through a unit that is timed and sealed by the appropriate regulatory authority. To determine if your brine should be pasteurized and at what frequency, the facility should conduct a risk assessment and consider all environmental monitoring, in-process, finished product testing relevant to brine quality and safety as well as the ability to create a clean break.

Pasteurization Steps:

The first step in pasteurizing brine is to remove the brine from your various tanks or pits into a clean storage silo or vessel. The storage vessel (s) should have the capacity to accommodate your brine volume. The brine system and/or any racking associated with your system should also be cleaned, reference the **7 Steps of Cleaning listed in the Pathogen Guidance Document.**

1. For the most efficient and effective pasteurization, solids should be clarified from the brine solution with mechanical clarification (if available), fat removed from the solution with mechanical separation (if available), and clarified, separated liquid pasteurized. The cooled, pasteurized brine should be pumped via clean piping or sanitary hoses into a clean intermediate storage tank or directly back into a clean and sanitized brine storage system. Once pasteurized brine is put back into the system, temperature, salinity, and calcium levels should be monitored and adjusted per the facility's SOPs.
2. Maintenance considerations:
    i. Brine HTST systems require a PM program to monitor plate and gasket integrity. It is recommended that plates, plate gaskets, and o-rings be inspected for pitting and integrity on a quarterly basis. Dye checks on plates for pin hole leaks should be conducted at least annually.
    ii. Because of the abrasive nature of brine, it is recommended that other brine storage and handling equipment be included in a PM program with an inspection and service frequency based on wear history.

Anti-Microbial Agents Preservatives:

In the US, preservatives such as benzoic acid, sodium benzoate, sorbic acid, potassium sorbate, and calcium and sodium propionate may be added to brine to inhibit the growth of undesirable yeast, mold, or bacteria (Bintsis, 2006). Although each has GRAS status and are safe from a consumer point of view, the FDA has established upper limits for their use presence in the food (21 CFR, Part 133). For example, sorbic acid and potassium sorbate may be used at levels not to exceed 0.2% and 0.3%, respectfully, while benzoic acid and sodium benzoate may be used at levels not to exceed 0.1%. International regulations may differ from those in the US and specific customers may have additional restrictions on the use of "approved" preservatives. Therefore, understanding their requirements is important.

Natamycin may be utilized to control yeasts, molds, and other indicator organisms that are not desirable, thus improving the quality of brine systems. If anti-mycotics are employed, consider a testing regimen of your product to insure regulatory compliance per the appropriate CFR: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.155.

Oxidizing agents – Chlorine, Hydrogen Peroxide:
Hydrogen Peroxide is an emerging treatment for controlling pathogens in cheese and/or other brines. Current studies in-process show promise in the efficacy of Listeria monocytogenes in brine. Consult the appropriate code of federal regulations (CFR) for current approvals of this chemical.

Other Treatment Methods:

Ozone injected directly into the brine circulation stream (2ppm max).

Regulatory Compliance Note: The treatment options offered in this document have been used successfully to maintain the quality and food safety. When considering ANY type of brine treatment method always consult the appropriate code of federal regulations (CFR) for the latest, current approvals of the material (s) to be utilized.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=178.1005

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