

CONTROLLING PATHOGENS IN DAIRY PROCESSING ENVIRONMENTS

GUIDANCE FOR THE U.S. DAIRY INDUSTRY



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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. **Following this guidance document has been proposed as a new Food Safety metric in the U.S. Dairy Stewardship Commitment and will be considered in the coming year's metric development and approval cycle. In the meantime, dairy processors can use this guidance to inform robust food safety programs and management systems to ensure alignment with the Stewardship Commitment's current Food Safety metrics.**

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 (Current and Proposed)	
Indicator	Metric
Food Safety (Current)	<ul style="list-style-type: none">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)
Food Safety (Proposed)	<ul style="list-style-type: none">Commit to follow the <i>Controlling Pathogens in Dairy Processing Environments</i> guidance to the extent applicable for your company and products

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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, the 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. 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 Principle #4 Effective Cleaning and Sanitation Procedures and Controls of the guidance.

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



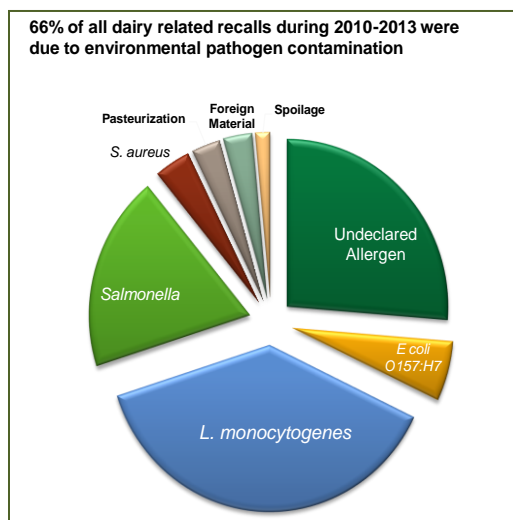
INTRODUCTION

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.

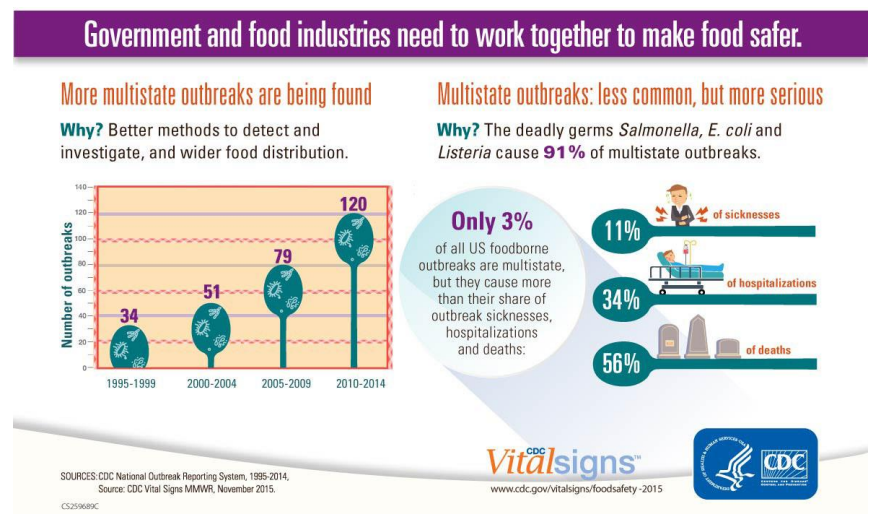
Dairy Pathogen Concerns

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 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.

Fig. 1 Pathogen Recall and Outbreak History



FDA Recall database



Detection of pathogen outbreaks are on the rise, but the number of individuals effected in each incident is decreasing

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-compromised 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
<i>Bacillus cereus</i>	Ingestion of toxin	Yes	Yes
<i>Cronobacter sakazakii</i>	Infection	Rare	Yes
<i>Listeria monocytogenes</i>	Infection	Yes	Rare*
Pathogenic <i>E. coli</i>	Infection followed by toxin	Yes	No
<i>Salmonella</i>	Infection	Yes	Yes
<i>Staphylococcus aureus</i>	Toxin	Yes	Yes

*Can be a risk if mishandled during intermediate steps when foods or ingredients 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

Target organism	Temperature Requirement °F (°C)			pH	Water activity	Aerobic or Anaerobic	Spore former	Max. % water phase salt
	Minimum growth	Maximum growth	Optimum growth					
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	50 (10)	118 (48)	95-104 (35-40)	4.6-9.0	0.94	Anaerobe	Yes	10
• Proteolytic ABF								
• 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.

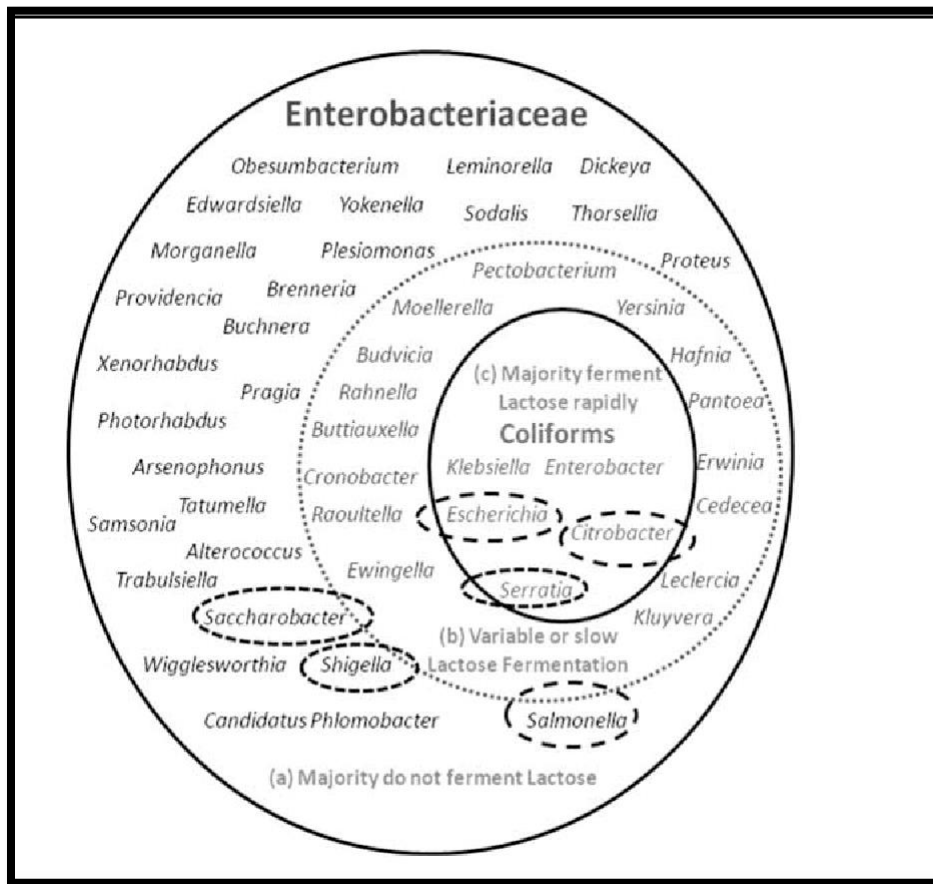
Indicator Testing and Its Role in Controlling Pathogens

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 indicate 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, but are a non-hazardous species, or 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.

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



Baylis, C. et al. "The Enterobacteriaceae and their significance to the food industry." (2011).

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” on page 58 for more details.

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 Consideration 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 Preventive 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, consult resources that are included on page 77, “Additional Resources.”

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.

Hygiene Zoning

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. 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

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

people 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 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 the food safety at the highest risk room of the process. Three zones are a 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

Controlling the Traffic: People and Materials

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 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 and 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 to 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.

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

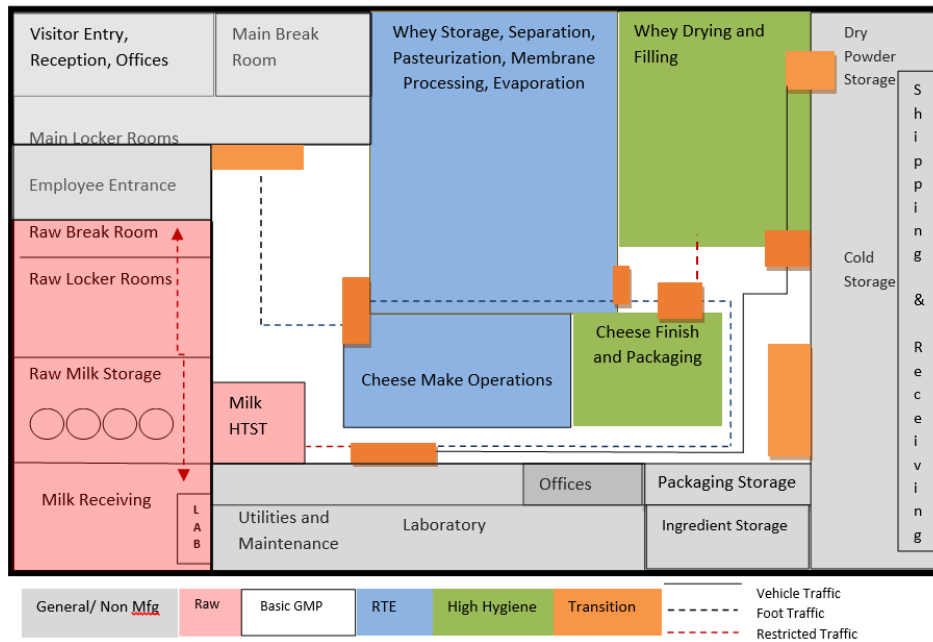


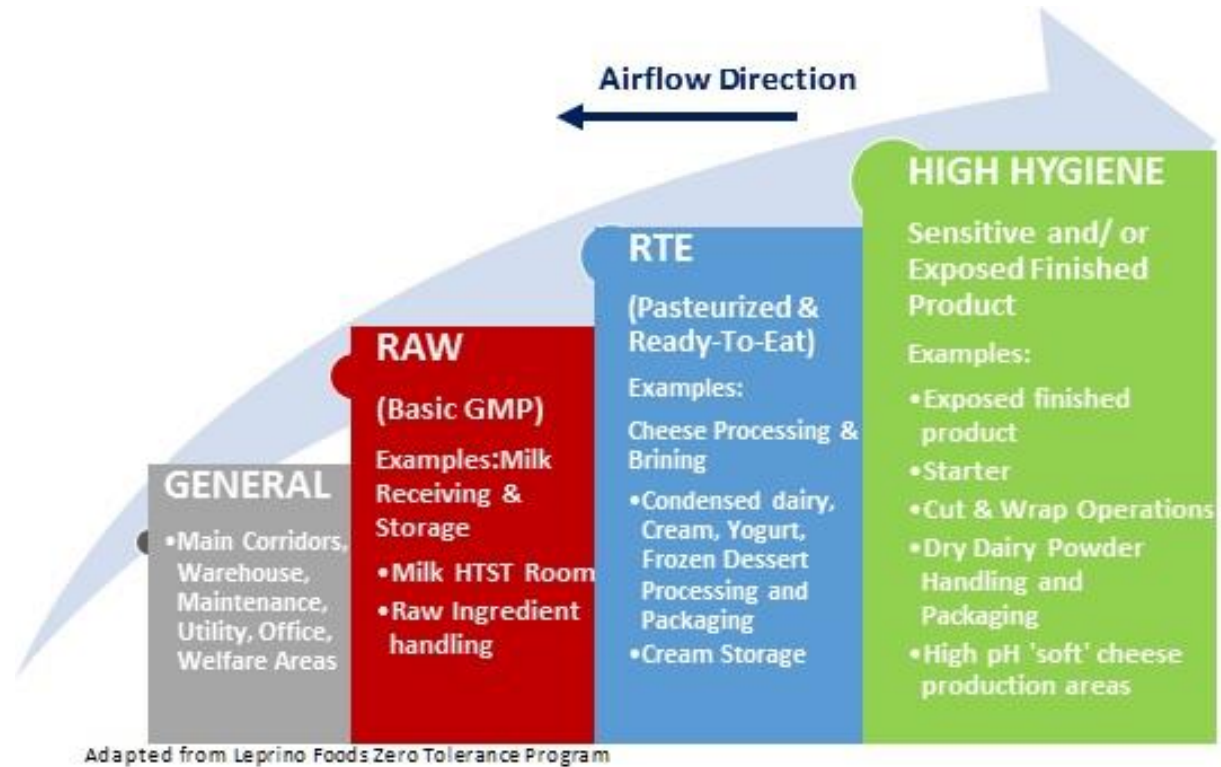
Fig. 4. An example of a Powder and Butter operation with hygiene zoning and hygiene junction rooms/airlocks



Controlling the Air

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 is covered on pages 32-35.

Fig. 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.

Floor Mitigation Tools

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 be very effective, but they can also 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.

One concern within production 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 the efficacy, where the 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.

Thermal Inactivation

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.

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*

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 Food¹⁴. 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.
- ✓ 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

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

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 the 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 cleaning at a predetermined frequency to limit nutrients for pathogen growth.

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.

Controlling Temperature and Humidity

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 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](#) and [Appendix B](#) for Equipment Design and Facility Design checklists.

Fig. 6. 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 weld 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 Standards⁹ and the Pasteurized Milk Ordinance³ (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 (Fig. 6). 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



Fig. 7. Drains

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 avoid floor cleanouts where 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.


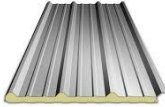

Maintenance of drains and drainage systems is extremely important as biofilms can form in the drains if they are not cleaned and sanitized properly. Written drain cleaning program and procedures are essential documentation. In addition, as drain backups are an unexpected potential source of large-area 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 (pg. 19). 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.

✓ 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.

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.

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 Fig. 7.

Fig 8. 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 PMO³ 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 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 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.

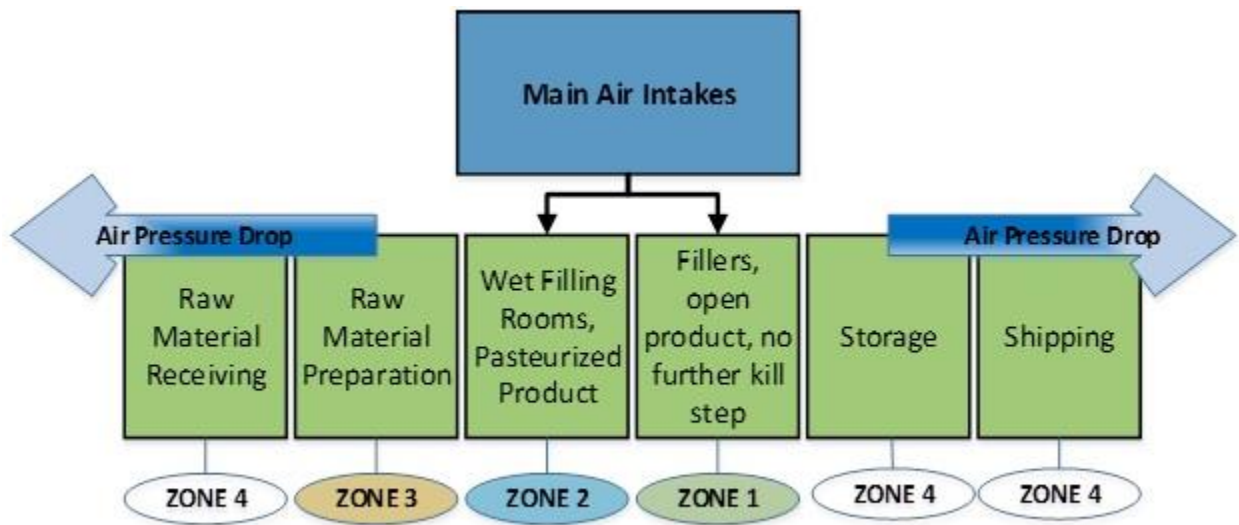
✓ HVAC

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 on “How to Control the Air” can be found on page 32. As a general guideline, room pressure is used to cause air to flow from high hygiene > RTE areas > raw areas (see Fig. 8). 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 page 32).

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.

Fig. 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.



✓ 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° F.

To mitigate 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.

How to Control the Air

Critical or high hygiene rooms should have forced ventilation with laminar flow to maintain positive air/over-pressure in that room compared to adjacent lower hygiene areas. Ideally, air should be filtered through a 3-stage filtration system: coarse (G1 to G4/Merv 1-8), then fine (P5 to P9/Merv 10-15), and subsequently HEPA (H10-H14/Merv 20) for as much as 99.999% filtering ability. Information regarding filtration standards can be located through: ASHRAE 52.2-2002 and C EN 779-2002. Less critical areas of the facility may only have fine filtration and in dry storage areas only coarse filtration. In the most critical areas of the facility, the use of UV lights after HEPA filtration is beneficial.

Table 6. 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	
HEPA Class	Clean Rooms	Merv 20	H14	U15	> 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		
Pre-Filter Class	Gross Filtration	Merv 9	F5		
		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 78F (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 through-out 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.

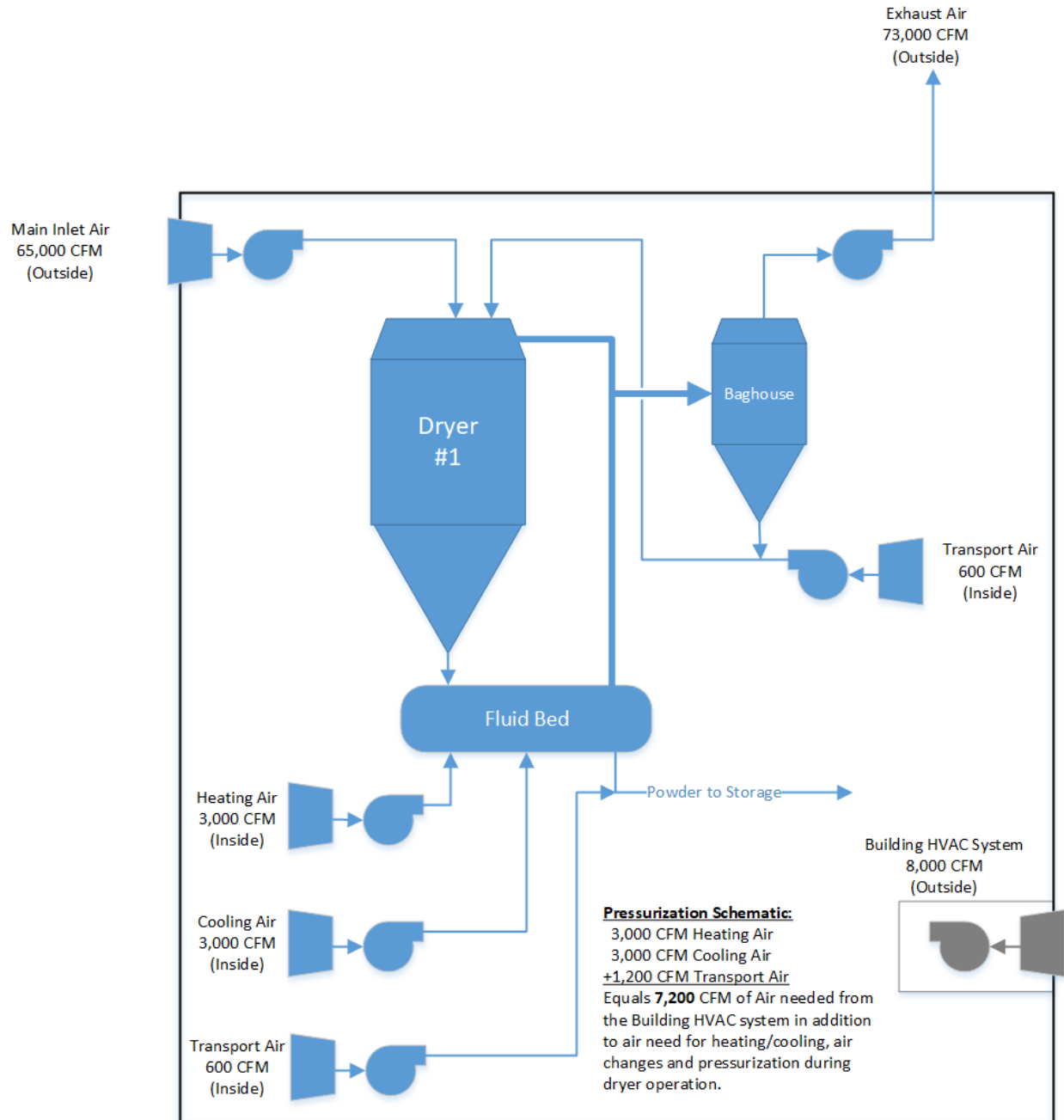
Considerations for Dry Dairy Processing

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, 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.

Fig. 10. Dryer Air Flow Diagram

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 below. A simple air balance needs to be completed that takes into account both operating and non-operating dryer conditions. The example below shows that there is a difference in 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.



HVAC Special Considerations - Dry Dairy Operations

Special considerations for dryer buildings and powder handling areas are needed for a 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 Fig. 9) 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:

- 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. Recognizing and preparing for either planned or unplanned events (Table 7) is key to controlling food safety risks. A major risk introduced by special circumstances is the potential for contamination because of non-routine traffic (people), traffic patterns (room segregation, alternate routes, etc.), infrastructure and/or system breaches, or changed sanitation procedures. Several illness outbreaks have been attributed to construction which introduced pathogens into the plant environment.

Table 7. 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, 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

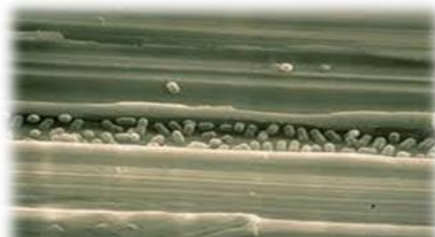
Following sanitary design principles is critical to ensure cleanability and to eliminate harborage sites where microorganisms are protected from cleaning and sanitation. The equipment sanitary design checklist (**Appendix A**) can help identify areas of improvement on either new or existing equipment. 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. (Fig. 10 and Fig. 11)

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



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



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✓ **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 (Fig. 12 and Fig. 13). 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.

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



Fig. 14. Example of compatible material covered with stainless steel



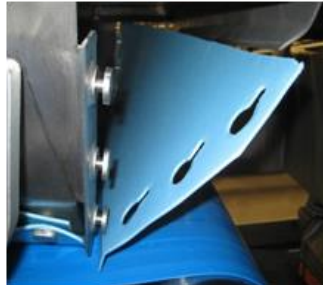
✓ **Accessible for Inspection, Maintenance, Cleaning, and Sanitation**

- 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. (Fig. 14 and Fig. 15) All product contact surfaces should maintain a minimum 18" floor clearance to minimize potential for contamination 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.

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



Fig 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 typically 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. (Fig. 16 and Fig. 17)

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



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



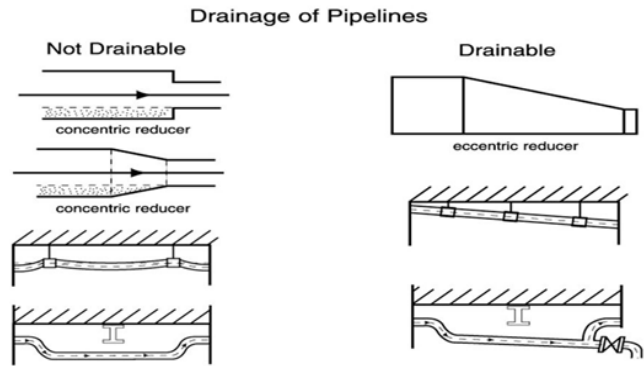
✓ Self-Draining Surfaces

- 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.

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



Fig. 20. Non-drainable and drainable designs of piping



- ✓ 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.

Fig. 21. Hollow square tubing not hermetically sealed (missed weld on one side of the leg)

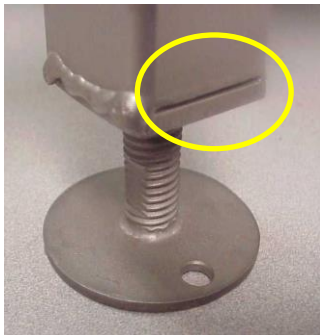


Fig. 22. Example of adjustable ball foot design – welded or gasket to seal and avoid debris infiltration

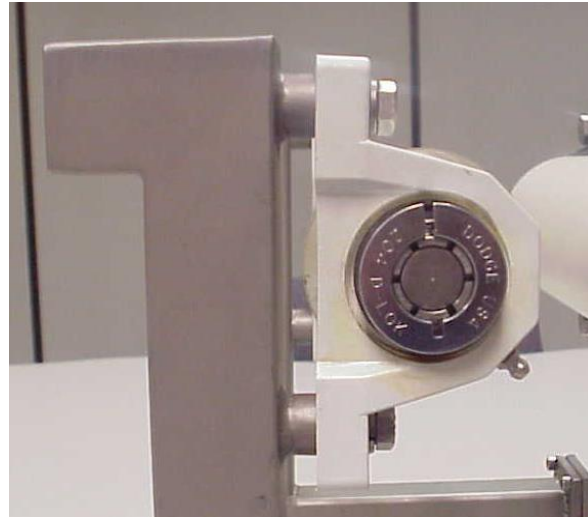


- ✓ No Niches
 - Prevent accumulations of water, moisture, or soil by minimizing overlapping surfaces, seams, recesses, sandwich joints, and dead spots. Equipment should be built from single pieces of material whenever possible to minimize assembly with bolts, press-fits, or other fasteners. Avoid threaded parts including threaded legs.

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



Fig. 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) for corrosion resistance and to enable cleaning.
- ✓ 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 Fig. 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.

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.

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 chemical (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 8. 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.

Wet Cleaning

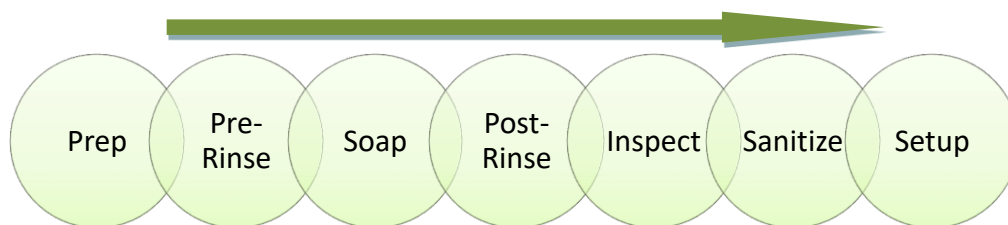
7- Step Manual Cleaning and Sanitation – Wet Environment

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.

1. Pre-Sanitation Preparation

Remove all production supplies and waste, dry clean to remove as much product debris as possible. Do

Fig 25. Seven Steps of Sanitation



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° 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 a bucket and brush scrubbing or the 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 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.

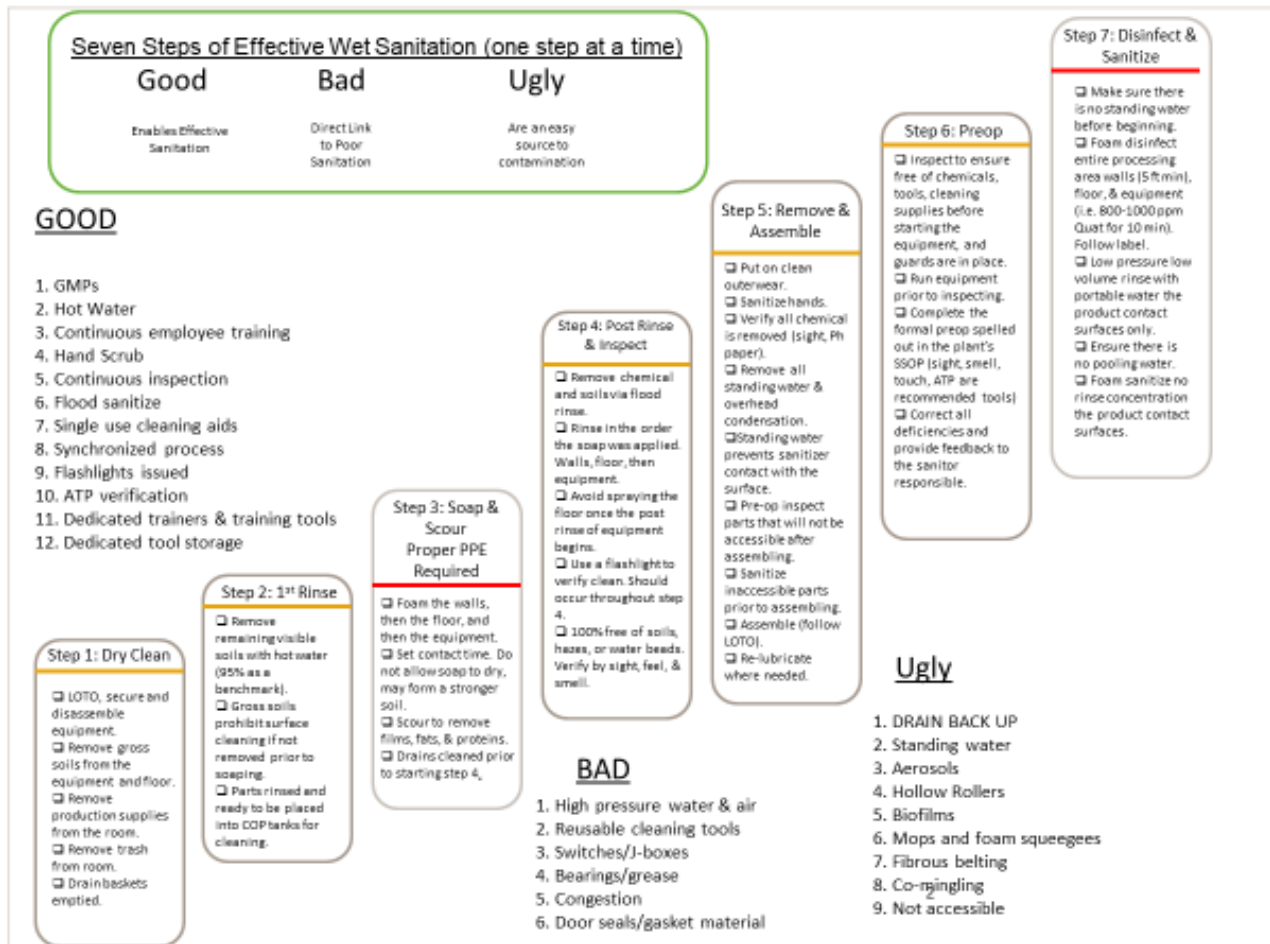
6. Sanitize

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.

Fig. 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 require that the equipment is 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 assure 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 (Fig. 26 and 27). It is recommended that temperatures and chemical titrations are performed during the COP wash to assure concentrations are within range and the results are documented.



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



Fig.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, a 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 is 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 page 8). 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 to 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 °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.

DRY Cleaning

Cleaning in 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 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

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 when using chlorine dioxide.*

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 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.

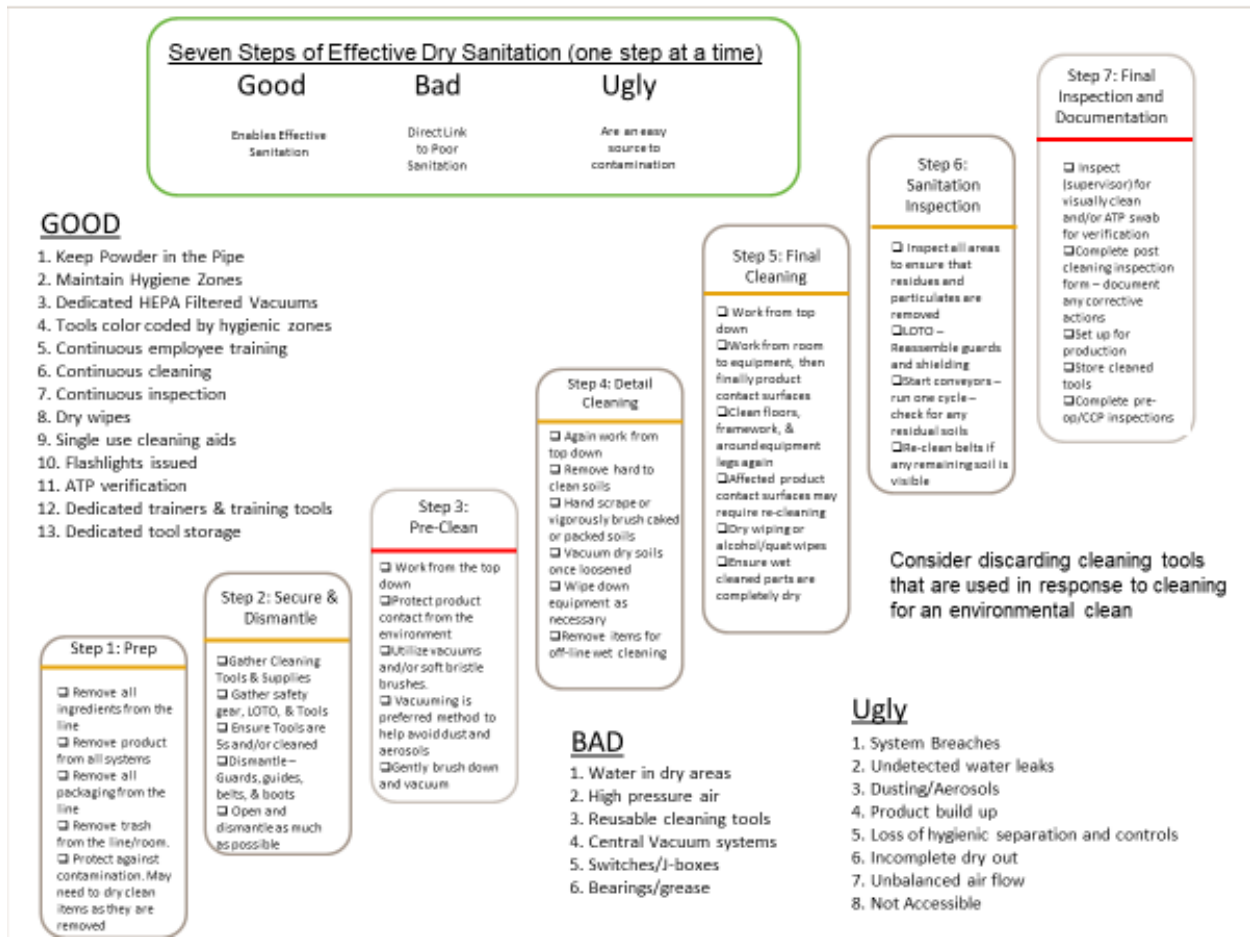
6. Sanitation Inspections

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 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.

Fig. 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 is 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 F is common.

Fig. 30. Dedicated HEPA filtered vacuum cleaners.



Fig. 31. Overhead pipe exterior cleaning tools.



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



Fig. 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 page 8). 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 as been performed to remove as much product as possible. 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

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.

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 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

Facility-Specific Risk Assessment

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 testing⁷⁷ It is generally accepted that the use of indicator organisms for target pathogens of concern is part of a robust PEMP plan.

Developing a Pathogen Monitoring Plan

What to Test For - Wet Processing areas: *Listeria* species. or *L. monocytogenes (Lm)*

Listeria species are a broad group of indicator microorganisms which, when detected, signal that conditions are also favorable for the pathogen *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.

What to Test For - 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.

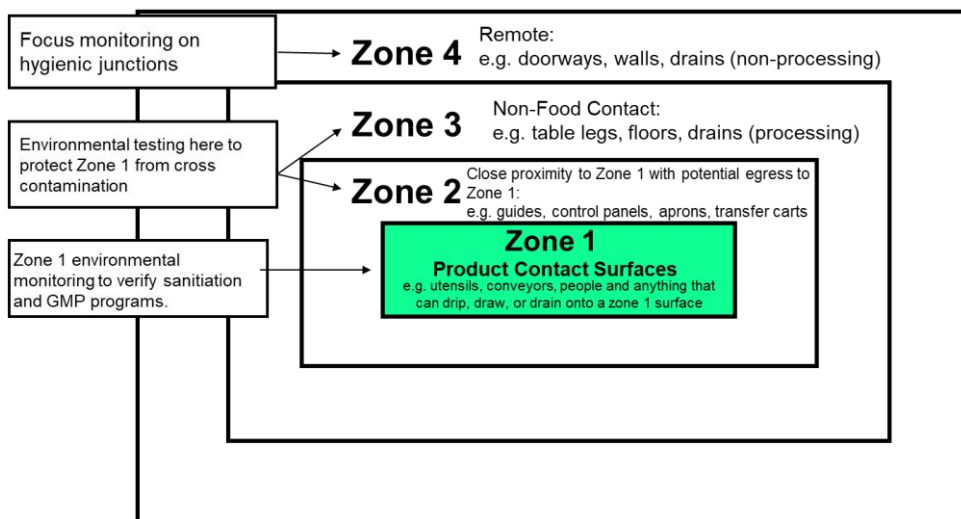
- Any detected requires immediate corrective actions
<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048694.htm>

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 contamination¹³ (Fig. 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 9).

Fig. 34. Environmental monitoring zones



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

Table 9. 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:

- If Zone 1 testing is included as part of your monitoring program, it is part of the verification program to monitor the effectiveness of your control programs, such as GMPs (Principle #2 page 19) and sanitation (Principle #4 pages 43 & 49), against target pathogens.
- In breach remediation situations zone 1 testing may be needed and it is imperative to consider how, when, and why to sample and how the results could impact other product produced on the line or in the same are.
- 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. 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*). Testing for and finding *Listeria* species. on a product contact surface does not automatically mean that product is contaminated, but appropriate and aggressive corrective actions need to be taken and documented.
- 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.

- 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.
- 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.
- 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

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, plant areas and zones*
- *Make investigative swabs part of routine sampling*
- *Aggressively look for potential microbial harborage points or niches*

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 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.

NOTE

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

- 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.
- 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 as 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 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.

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 (Fig. 37). During operation, other sites adjacent to the bearing housing were also positive.

Fig. 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 need 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

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.

degrees) for potential sources. 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 stationary 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 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.
- 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/sign-offs) 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 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 target pathogen(s) or 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

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

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 dryer system. The problem occurred when the hose became contaminated from the major washes and did not dry appropriately before putting back into use.

Corrective Actions and Preventive Actions

- ✓ 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 best food safety 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.

Fig. 378. Examples of Breaches

Routine/Planned	Unplanned	Controlled Hygiene Areas
<ul style="list-style-type: none">• Sampling• Magnet Inspections• Sifter Screen Inspections• Air Filter Changes• Maintenance Activities• Sanitation Activities<ul style="list-style-type: none">• Dryer system washes• Bin sweep outs• Critical care hygiene room cleaning	<ul style="list-style-type: none">• Sifter Cleaning• Flexible boot ruptures• Damaged rotary airlock• Wet chamber cleanout• Unplugging the system<ul style="list-style-type: none">• Main Chamber• Cyclone• Baghouses• Dehumidification boxes• Powder transfer• Powder silos	<ul style="list-style-type: none">• Roof Leaks• Drain back-ups• Loss of dryer pressure differential• Employees entering with non-compliant PPE• Unplanned construction• Identification of food pests• Dryer Fire

It is always of utmost 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 using; 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 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 to 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 type 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 (pg. 42). 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 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 manufacture started to track their system breaches to better understand how often the system was breached and if it was possible to reduce the number of routine breaches to the system. Below is an outline of the company’s approach, questions they asked and outcomes.

Data Collection:

- 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.

Fig. 39. Example of dryer breach log with a definition of a breach to remind operators what they are looking for

Dryer Breach Log
Username
Password
Login

Date	Time	Lot	Location	Reason	Comments	Initials
2020-05-06	19:45	20127	Baghouse 1 & 2 (Baghouse Level)	Baghouse Check		NA
2020-05-06	21:45	20127	Baghouse 1 & 2 (Baghouse Level)	Baghouse Check		NA
2020-05-07	00:10	20127	Baghouse 1 & 2 (Baghouse Level)	Baghouse Check		NA
2020-05-07	02:25	20127	Baghouse 1 & 2 (Baghouse Level)	Baghouse Check		NA
2020-05-07	05:00	20127	Baghouse 1 & 2 (Baghouse Level)	Baghouse Check		NA
2020-05-07	08:44	20127	Baghouse 1 & 2 (Baghouse Level)	Baghouse Check		KW

05/07/2020 09:52 AM
Lot
Fluid Bed
Samples
Comments
Initials
Add

Breach - Any exposure, planned or unplanned, of the dairy powder system or controlled hygiene area that poses a risk of contamination. Common breaches would be anytime we open the dryer system, i.e. opening fluid bed or opening the bottom of the baghouse to check for plugging. Any inspection of the main chamber or ducts would also fit into this definition.

- Sifter
- AF Chute
- Wellmix Heater
- Dehumidifier
- Baghouse 1 (Baghouse Level)
- Baghouse 2 (Baghouse Level)
- Baghouse 1 & 2 (Baghouse Level)
- Start Stop Bin
- Powder Bin 1
- Powder Bin 2
- Exhaust/Heat Recoup
- Baghouse 1 (Top Level)
- Baghouse 1 Transition Lines
- Baghouse 2 (Top Level)
- Baghouse 2 Transition Lines
- Burner
- Dryer Chamber
- Top of Dryer
- Other
- Inlet Cabinet
- Fluid Bed

- Samples
- Samples
- Inspection
- Cleaning
- Change Filters
- Baghouse Plug
- Baghouse Check
- Service Baghouse
- Spray Pattern Check
- Drop/Pull Lances
- Maintenance
- Other

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.

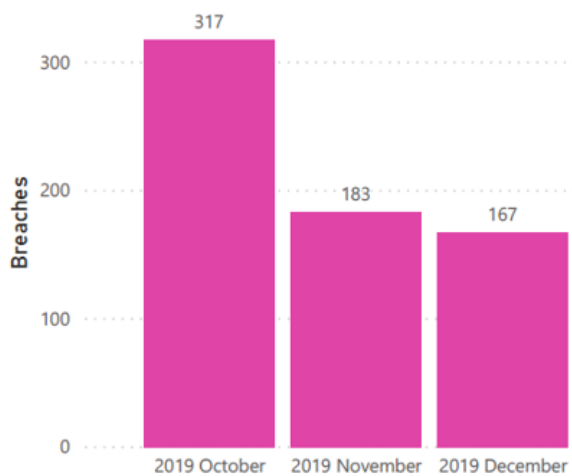
Communication:

- 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

Fig. 39. System breach tracking

Breaches per Month**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.

Pathogen Guidance Reference here

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 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, that 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, a 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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14. U.S Department of Health and Human Services/ U.S. Food and Drug Administration 21 CFR Parts 1, 11, 16, 106, 110 *et al.* 2015. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

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 - MICROBIOLOGICALLY 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 60° 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							
7.1	Buttons on control panels are easily cleaned & sanitized during operations.		S	M	U	NA	Deficiency
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							
8.1	Drives, chain guards, electrical control boxes, and bearings are not located over open product zones.		S	M	U	NA	Deficiency
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							
9.1	Exhaust systems have welded seams with adequate access for cleaning and inspection.		S	M	U	NA	Deficiency
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							
10.1	Water temperature, flow and pressure meets specified requirements at point of use		S	M	U	NA	Deficiency
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		

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

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		

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

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
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
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 160°F 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 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 on 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 assessed 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 may be 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 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 FORM 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 a 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 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* spp., *Salmonella* spp.) 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 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 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* spp., *Salmonella* spp. 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
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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 a 95% reliability that the presence of Salmonella will be detected. Note: all 750 grams of the sample is 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 includes, 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 verify 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 verify 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

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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 65 experts from 30 organizations involved across seven platforms. Learn more at: www.usdairy.com/foodsafety. If you have specific questions, please email innovationcenter@usdairy.com

