Control of *Salmonella* in Low-moisture Foods II: Hygiene Practices to Minimize *Salmonella* Contamination and Growth

Part two of a three-part series

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ABSTRACT

Although low-moisture food products do not support *Salmonella* growth, the presence of low numbers of *Salmonella* can still cause illness. Therefore, the presence of the organism in low-moisture ready-to-eat foods must be prevented. To address the need for industry-wide guidance, the Grocery Manufacturers Association formed a *Salmonella* Control Task Force to develop guidance on the control of *Salmonella* when manufacturing low-moisture foods. Two of the control elements, preventing ingress or spread in a facility and controlling raw materials and incoming ingredients, were described in a previous paper. Here we focus on stringent hygiene practices in the Primary *Salmonella* Control Area, including control of movement of personnel and material; hygienic design principles, with particular attention given to ensuring that moisture can be excluded from the processing environment; and preventing growth in the facility by control of moisture, which is critically important in preventing *Salmonella* contamination of low-moisture products.

INTRODUCTION

Over the past several decades, a number of outbreaks of salmonellosis have been associated with the consumption of low-moisture products such as chocolate, powdered infant formula, raw almonds, breakfast cereals, dry seasonings, paprika-seasoned potato chips, dried coconut, infant cereals and peanut butter. These outbreaks underscore the difficulty of eradicating *Salmonella* from the environment of dry product manufacturing facilities and highlight the need to reinforce industry preventive control measures through guidance based on the best available information. To address the need for industry-wide guidance, the Grocery Manufacturers Association (GMA) formed a *Salmonella* Control Task Force to develop guidance on the control of *Salmonella* when manufacturing low-moisture foods. Two of the control elements, preventing ingress or spread in a facility and controlling raw materials, were described in a previous paper *(12)*. Here we focus on stringent hygiene practices, hygienic design principles and preventing growth in the facility.

SALMONELLA CONTROL ELEMENT 2: ENHANCE THE STRINGENCY OF HYGIENE PRACTICES AND CONTROLS IN THE PRIMARY *SALMONELLA* CONTROL AREA

The Primary *Salmonella* Control Area (PSCA) in a low-moisture product facility is the area where handling of ingredients and product requires the highest level of hygiene control. In a facility where products receive a pathogen inactivation treatment, the PSCA is the area subsequent to the terminal lethality step. In a facility where no inactivation step is employed, e.g., a facility that produces a dry-blend mix, the entire process area may become the PSCA. Although there is a clear need to establish stringent hygiene control in the PSCA, practices in other areas of the facility should not be neglected, as they impact the hygiene conditions in the PSCA. In fact, maintaining stringent hygiene control in the PSCA depends on effective hygiene control in the rest of the processing area of the facility, which for comparison are designated the basic GMP area and, if one is established, the transitional area. The PSCA is sometimes referred to as the high hygiene zone or the high risk area (e.g., in Europe). The PSCA is also referred to as the ready-to-eat area, the critical side, or the dry side of the operation. The basic GMP area is also referred to as the basic hygiene area, the non-critical side or the wet side of the facility.

The separation of one manufacturing area in a facility from another is generally done to minimize contaminant transfer from one area to another, e.g., wet to dry areas, “dirty” (relatively speaking) to clean areas, raw material areas to finished product areas, or a basic hygiene area to a high hygiene area. Compartmentalization or segregation of the facility into specific areas is a common practice in food processing *(7, 9)*. The separation of the low-moisture product manufacturing plant into areas of different hygiene levels

FIGURE 1. Example of a conceptual plant layout showing the entire process area as Primary *Salmonella* Control Area (PSCA) in red. The non-process area (e.g., warehouse and office) is in green. This layout may be applicable to products such as dry blends and snack bars.

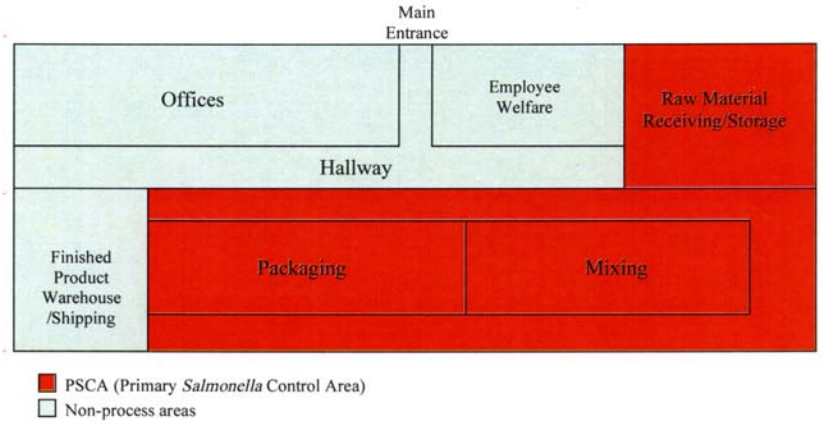


FIGURE 2. Example of a conceptual plant layout showing two process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red and a basic GMP area in blue. This layout may be applicable to products such as corn snack chips, cereals, and peanut butter.

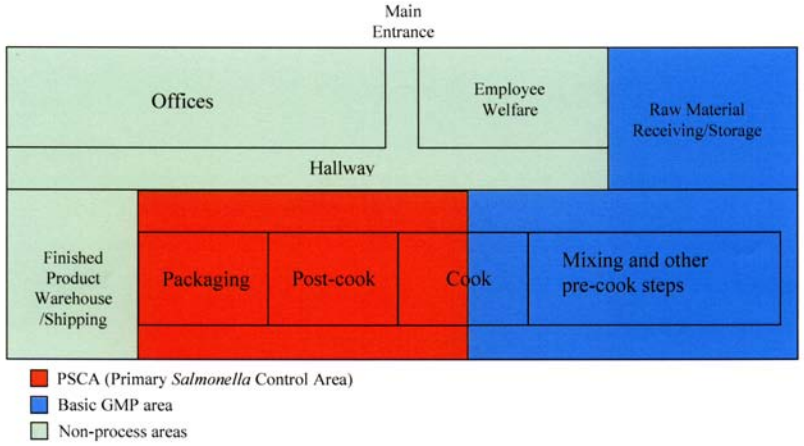
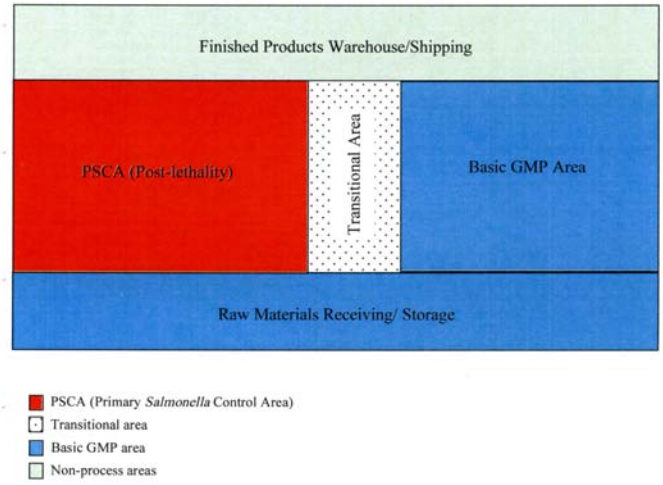


FIGURE 3. Example of a conceptual plant layout showing three process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red, a transitional area in a dotted pattern, and a basic GMP area in blue. The non-process area (e.g., warehouse, shipping) is in green (offices and employee welfare areas are not shown). This layout may be applicable to products such infant formula.



with the establishment of a PSCA that is separated from the rest of the processing area is one of the first steps leading to effective *Salmonella* control (Fig. 1–3). Depending on the product and process and the intended consumer (e.g., general public, infants), the number of hygiene areas established in a facility in addition to the PSCA may vary. The objective is to minimize to the greatest possible extent the spread of *Salmonella* into the PSCA where preventing product contamination is the most critical.

Clearly defining the control measures necessary in the different areas is important to effectively control *Salmonella* in the processing environment, especially in the PSCA, and thus prevent contamination of finished products. As indicated previously, in the PSCA, processed products (and components of the products) not subjected to a further inactivation step are exposed to the environment and are vulnerable to contamination with *Salmonella* if the organism is present. As product contamination could have serious consequences for consumers, maintaining enhanced hygiene stringency in the PSCA area is extremely important. To ensure this high level of hygiene control in the PSCA, maintaining hygienic control of the basic GMP and the transitional areas must also be exercised. In comparison to the PSCA, the basic GMP area in the processing environment and the transitional area (if one is established, see below) are areas where *Salmonella* may occasionally be present. The occasional *Salmonella* contamination in these areas has a low likelihood of leading to finished product contamination, provided that the problem is detected and corrected in a timely manner. GMPs must be applied and adequate sanitation must be carried out (with wet or dry cleaning procedures as appropriate) in the basic and transitional areas to minimize potential *Salmonella* harborage sites that could become a source of contamination in the PSCA.

The degree of hygiene control in the facility may depend on the type of the operation and the analysis of the potential for *Salmonella* introduction. Generally, the stringency of hygiene control should increase from the basic GMP area to the transitional area to the PSCA. Particular emphasis should be placed on control measures for (physical) separation, passage of traffic (personnel, equipment, materials, etc.), air flow, cleaning processes and whether or not wet cleaning is permitted and how water is used (discussed further in Element 4), and verification (discussed further in Element 7) *(3)*.

The degree of separation between the different hygiene areas within a facility may vary, depending on the product and

TABLE 1. Example of desirable features for a buffer area at the entrance to the Primary *Salmonella* Control Area (PSCA)

- Entry and exit doors of the buffer area to the PSCA are tightly fitted; internal cores are filled and if necessary equipped with self-closing devices.
- Insect light traps, if used, are installed outside the entry door to the buffer area (i.e., the door facing the non-critical side).
- Floor is properly sloped for drainage and sloped towards the non-critical side. Preferably no drains are installed in the area.
- A bench is provided for shoe change. Two sets of open shelves are provided: one for "dirty" shoes worn before entering the buffer zone, and the other for clean shoes worn in the PSCA. Air exhaust is used (if necessary such as when the buffer area is small) to remove shoe odors.
- Hands-free hand washing sink is provided and it is located on the non-critical side of the buffer area or just outside the buffer area on the non-critical side. Drying hands with paper towels is recommended. Hand washing is done on the non-critical side because wherever there is a handwashing station, the surrounding floor may become wet. Moisture on the floor should be minimized to the extent possible in this area, and care should be taken that this moisture not be transferred to the PSCA.
- After shoe-change and other changes, hands may be treated with a disinfectant spray.

process *(9)*. Barriers are placed between the different hygiene areas to restrict traffic and prevent vectors (potential sources of *Salmonella*) from passing between the basic GMP area and the PSCA. Examples of vectors include dirt on shoes or clothing, pallets and packaging materials, pests, dust, and sometimes water. Examples of physical barriers are walls, doors, split conveyors, filters, etc. Examples of other barriers are pallet exchange, shoe-change, removal of outer bag packaging, marked limits on floors, etc. Whenever possible and necessary, there should be no direct connection between the PSCA and the basic GMP area. Access to the PSCA should ideally be through a buffer area (i.e., a vestibule or anteroom, hygiene juncture) where personnel take steps to minimize carrying contaminants into the PSCA. In addition, hygienic facility design and plant layout to direct the flow of personnel and traffic is an effective control measure to minimize the transfer of contaminants from one area to another *(10)*. The air supply to the PSCA should be suitably filtered to prevent airborne contamination. Ideally, the PSCA should be maintained under positive air pressure to prevent the entry of contaminated air from the outside or from surrounding areas of the manufacturing facility *(2, 7, 9)*.

The determination of whether a location in the facility belongs to the PSCA, the transitional area or the basic GMP area should be based on an evaluation of risk. An area can be evaluated based on the probability of *Salmonella* being present and the proximity of the area to the finished product. For example, a location that is "medium" or "high" on the probability axis, and "near" on the proximity axis would belong to the PSCA (Fig. 4), while a location that is far away on the proximity axis, or medium distance on the proximity axis and low on the probability axis would fall into the basic GMP area. By using this approach, a facility may be divided into areas with different levels of hygiene control. An evaluation of risk and mitigation strategies can also be used to determine the appropriate control measures for the PSCA. For example, in a facility that uses raw materials known to be contaminated with *Salmonella* or in the event of the presence of persistent *Salmonella*, more stringent controls would be needed.

Common industry practices

- ❑ Establish designated areas in the facility with different levels of hygiene controls to minimize the spread of *Salmonella*.
  - – Establish a Primary *Salmonella* Control Area (PSCA) within the process area of the facility.
  - – Depending on the type of operation, a facility may generally be divided into one, two, or three processing areas (in addition to the non-processing areas). For example, an operation that does not employ an inactivation step may designate the entire processing area as the PSCA, e.g., a spice blending operation, a snack bar or nutrition bar operation, and other mix and pack operations (Fig. 1). An operation that employs an inactivation step may designate the processing area after the inactivation step as the PSCA and the rest of the processing area as the basic GMP area, e.g., a corn snack chip operation (Fig. 2). In addition to the basic GMP area and the PSCA, an operation with an inactivation step may employ a transitional area to further enhance hygiene control in the PSCA, e.g., a powdered infant formula operation (Fig. 3). In general, the more sensitive the product or the consumer, the more important the separation of the facility into different hygiene areas to facilitate the implementation of enhanced controls in the PSCA.
  - – Depending on the type of operation and the hazard analysis, it may be desirable to establish a buffer area upon entrance into the facility and/or upon entrance into the PSCA. The buffer area is where traffic restriction can be implemented and different types of hygiene procedures can be applied. The buffer area, if established, should be designed to reduce the potential for introducing contamination into the PSCA, either through workers or through other items such as packaging materials, cleaning tools, and equipment. Examples of desirable features for buffer areas at entrances to the PSCA in an infant formula facility are listed in Table 1.
- ❑ Establish barriers for the PSCA. Barriers can be established at entrances and exits of the PSCA, or exits of the basic GMP and transitional areas. The barriers serve to completely or partially separate the PSCA from the rest of the facility. Physical separation of the PSCA from the rest of the processing area is par-

FIGURE 4. An example of using a risk evaluation approach for determining hygiene areas in a facility. In this approach, the risk of *Salmonella* contamination in finished product is proportional to the probability that *Salmonella* is present in the process area and the proximity of the area to the product before packaging.

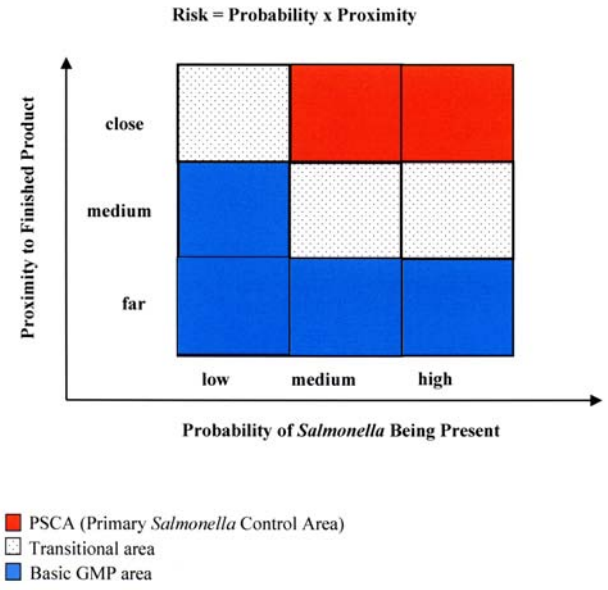


FIGURE 5. Ends of a horizontal screw conveyor – always a potential area of stagnant product build-up.

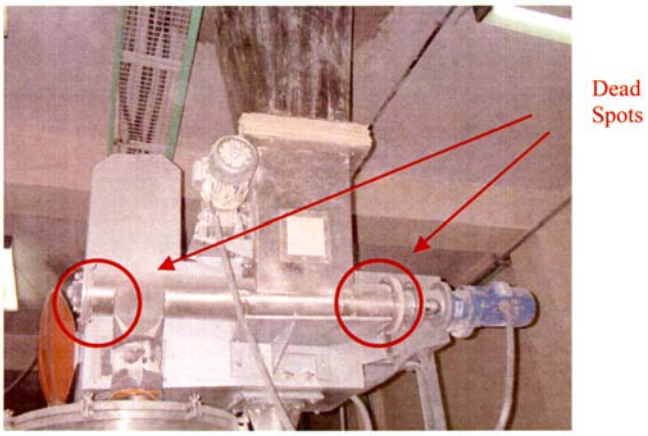
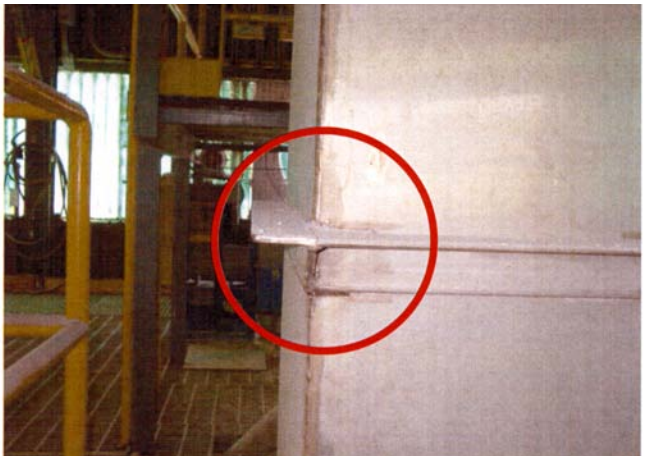


FIGURE 6. A flat surface that can collect product (this should be eliminated or sloped).



ticularly important for operations that use raw ingredients in which *Salmonella* is unavoidable (e.g., raw cocoa beans, raw nuts and grains).

- Upon entrance to the facility, traffic may move between the basic GMP area and the transitional area without additional barriers. Movement of personnel and materials into the PSCA is controlled to various degrees depending on the type of operation. The riskier the product, the greater the need to have physical separation. For example, in powdered infant formula production, it is desirable to have a physical separation of the PSCA (walled off from the rest of the operation).
- Another example is peanut processing, where the raw side of the process is separated from the rest of the facility. The area in which raw peanuts are dumped into the roaster is physically separated from the roaster exit. A hygiene juncture is maintained at the entrance of the raw side of the process where gowning and boot changing, which may be color coded, occurs. The gowns and boots are removed when a worker exits the raw side, and a new set of attire is worn on the finished side. This is also the case for cocoa bean handling and processing.

❑ Control all traffic between the PSCA and the rest of the facility, including the movement of personnel and materials. Avoid activities that may lead to contamination of the PSCA. The following list of activities should be considered:

❑ Direct traffic between the raw side and the finished product side. Movement of personnel and materials (e.g., ingredients used in dry-mixing, packaging materials, pieces of equipment, carts, and cleaning tools) into the PSCA should be minimized and strictly controlled. Prior to entering the PSCA, personnel should follow established hygiene procedures in a buffer area or vestibule. These may include removing clothing/boots worn in the raw side of the process area and replacing them with clothing/shoes and other protective gar-

TABLE 2. Example of steps for implementation of barriers and other controls to maintain enhanced stringency of hygiene in the Primary *Salmonella* Control Area (PSCA)

Step 1	•	Form a multidisciplinary team.
Step 2	•	Define different areas within the facility in relation to hygienic requirements (e.g., PSCA, basic GMP area, transitional area). Establish required level of product protection using a hazard analysis or a risk assessment approach. The first priority is to prevent product contact surface contamination with *Salmonella*.
	•	Map all circulation of people, incoming materials, waste, rework, etc. on a flow chart. Access to the PSCA should be limited to essential persons or activities only.
	•	Establish barriers where appropriate and clearly define their purpose. Barriers should be acceptable and practical for all persons who enter the area regularly or for specific purposes (e.g., sampling, maintenance, etc.)
	•	Take into consideration elements such as drainage and floor slopes; drainage and equipment positions; personnel and material routes; rework handling; storage of spare parts, maintenance tools and cleaning equipment; fire protection devices; conveyors; Clean-In-Place circuits; waste collection; air conditioning; air handling system; etc.
Step 3	•	Define construction and equipment design standards to meet hygiene requirements.
	•	Protect the PSCA during equipment installation to ensure that uncontrolled items/personnel and potential contaminants of concern cannot pass.
Step 4	•	Establish routine procedures that describe what can and cannot pass the barriers and procedures for passing them.
	•	Establish procedures to monitor and document barrier efficiency.
	•	Establish procedures for maintenance, including routine and unscheduled maintenance.
Step 5	•	Establish a master sanitation schedule to assure timely and effective sanitation of equipment and the processing environment.
Step 6	•	Train all personnel who enter the PSCA and others concerned about the barriers and procedures, their purpose, use and maintenance. Retrain operators as often as necessary to maintain sanitary practices.

ments designated for use in the PSCA. Washing and drying hands prior to entering the PSCA is also important.
  - Dedicated workers may be assigned to hygienic areas at the facility.
  - Dedicated equipment, pallets, utensils and other tools should be used in the PSCA.
  - Bringing products and ingredients into the PSCA without appropriate decontamination/ treatment should be avoided. Additional controls are outlined in Element 5 for ingredients that are mixed into the finished product without a lethality step. Procedures for handling dry ingredients to be added to the finished product without a further inactivation step are elaborated in Element 5 *(12)*.

- ❑ Prevent or minimize dust moving into the PSCA from the other areas by physical separations such as walls and by other means such as air filters and positive air pressure in the PSCA relative to the other areas of the facility.
  - Air filters should be installed and maintained in the ventilation system. The type of filters may vary from simple dust filters to High Efficiency Particulate Air (HEPA) filters, depending on the product, process and the intended consumer.
  - Where necessary and depending on the product and hazard analysis, further steps may be taken to filter air used in direct contact with product (e.g., for product cooling or powder transport) by using a HEPA filter applied at a point close to the line. When using HEPA filtered air in direct contact with product, it is more efficient to apply the filtration close to the point of use rather than filtering all air entering the PSCA with a HEPA filter.
- ❑ Establish a master sanitation schedule to assure timely and effective sanitation for the basic GMP and transitional areas (if one is established).
  - Use wet or dry cleaning procedures as appropriate.
  - Dry cleaning involves the use of tools such as vacuum cleaners, brooms, and brushes. Dry cleaning in the basic GMP and transitional areas may be followed by a wet cleaning as appropriate.
  - To be effective, a wet cleaning should include complete cleaning and sanitizing cycles (for equipment, etc.). Partial wet cleaning without sanitizing should be avoided because a sanitizing step is critical to inactivate microorganisms after cleaning. Whenever water is introduced into the facility, thorough cleaning must be followed by sanitizing and drying as appropriate.
- ❑ Establish appropriate cleaning and hygiene procedures for the PSCA and the buffer/vestibule area at the entrance to the PSCA.
  - Use dry cleaning as the routine cleaning practices in the PSCA (discussed further in Element 4).
  - Use dry cleaning and controlled wet cleaning for the buffer/vestibule area leading to the PSCA (discussed further in Element 4). Keep the area as dry as possible.
  - Keep the PSCA dry, including floors, ceilings, equipment, products, and all other objects in the area. It is preferred that no drains are installed in this area; if there are drains, the floor surrounding them should

TABLE 3. Sanitary design principles for equipment[a]

1. **Cleanable.** Equipment should be constructed to facilitate effective cleaning that is verified by environmental monitoring.
2. **Made of Compatible Materials.** Construction materials used for equipment must be compatible with the product, environment, and dry cleaning and, when needed, wet cleaning and sanitizing.
3. **Accessible for Inspection, Maintenance, Cleaning and Sanitation.** When needed, equipment should be easily disassembled for sanitation without requiring special tools not normally used in food facilities.
4. **No Liquid Collection.** No stagnant product build-up or liquid collection areas. Equipment should be self-draining to assure that residues do not accumulate or pool on the equipment.
5. **Hollow Areas Eliminated or Sealed.** Hollow areas of equipment must be eliminated whenever possible or permanently sealed. Items such as bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps and sleeves should be continuously welded to the surface and not attached via drilled and tapped holes.
6. **No Niches** (e.g., no pits, cracks, corrosion, crevices, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets, or dead ends). Welds should be ground and polished smooth.
7. **Sanitary Operational Performance.** During normal operations, the equipment must perform so that it does not contribute to unsanitary conditions or the harborage and growth of bacteria.
   - 7.1. **Hygienic Design of Maintenance Enclosures.** Human/machine interfaces such as push buttons, valve handles, switches and touch screens, must be designed to ensure product and other residues (including liquid) do not penetrate or accumulate in or on the enclosure or interface.
   - 7.2. **Hygiene Compatibility with Other Plant Systems.** Equipment design should ensure hygienic compatibility with other equipment and systems, such as electrical, hydraulic, steam, air and water systems.
8. **Validate Cleaning and Sanitizing Protocols.** Procedures for cleaning and sanitation must be clearly written, designed and proven effective and efficient. Chemicals recommended for cleaning and sanitation must be compatible with the equipment and the manufacturing environment.
9. **Separate Processes Wherever Possible.** Operations of different processes in food manufacturing plants should be properly separated to prevent cross contamination and/or adulteration.
10. **Meet Personnel Hygiene and Sanitation Requirements.** All plant personnel, contractors and visitors must be trained and required to follow plant hygienic and sanitation requirements – NO EXCEPTIONS

[a]Adapted from an American Meat Institute document *(1, 13)* targeted to *Listeria* control in high-moisture products. In many cases, the general principles for sanitary design for high-moisture are appropriate to low-moisture products.

be properly sloped for drainage and kept dry under normal conditions.
  - Maintain the PSCA to avoid cracked or damaged floors, hollow unsealed objects and poorly installed equipment.
  - Keep the air used in the PSCA dry, including air entering the area and used to dry the product. If compressed air is used, steps should be taken to continuously dry the air, as moisture may be trapped in the compressed air.

- ❑ Product accumulation (i.e., on walls, ceilings, conveyor belts, lids and walls of batch tanks or mixing tanks, and the bottom of a bucket elevator) should be removed in a timely fashion through routine housekeeping. This is particularly important for products that are hygroscopic or in environments of high humidity leading to moisture absorption and localized condensation.
  - Poor equipment design may lead to residue accumulation and should be corrected to eliminate the problem where feasible (see more discussion in Element 3).
- ❑ An example of steps for implementing barriers and other controls in the PSCA is shown in Table 2. All or some of these steps may be used as appropriate, depending on the product and process.

SALMONELLA CONTROL ELEMENT 3: APPLY HYGIENIC DESIGN PRINCIPLES TO BUILDING AND EQUIPMENT DESIGN

It is probable that a food manufacturing facility will be challenged with the introduction of *Salmonella* through numerous vectors, including contaminated ingredients, employee or equipment traffic, or infrastructure issues (breached roofs or drainage). The application of appropriate hygienic design standards to building design and layout, equipment, process and infrastructure is essential to ensure that if *Salmonella* is introduced it does not find a niche and become a resident/endemic strain but rather remains transient.

Optimal hygienic design of equipment and infrastructure is recognized as critical to the business by manufacturers of microbiologically perishable foods. Optimal design and equipment maintenance for these processes is directly related to achieving desired product shelf-life, minimizing consumer complaints and enhancing company profitability. Conversely, manufacturers of low-moisture products too often have not had hygienic design and maintenance of equipment and infrastructure as a primary focus, given that product shelf-life is not dictated by microbial growth. The industry hygienic design mindset has been shaped by the belief that microbial issues are not a concern because of the stability of low water activity foods. Indeed, microbial growth will not occur in foods maintained at water activity below 0.60.

Highly visible recalls associated with these low water activity foods have convinced manufacturers of low-moisture products that their foods are susceptible to post-process contamination by infectious, pathogenic microorganisms. These pathogens will not grow in the food, yet they may survive for the duration of the product shelf-life and cause foodborne illness if consumed.

TABLE 4. Types of cleaning in a low-moisture product manufacturing facility

Dry cleaning	No water is used. Dry cleaning is the physical removal of residues (food particles, dust, etc.) by actions such as sweeping, brushing, scraping, or vacuuming the residues from equipment surfaces and the plant environment.
Wet cleaning	Water can be applied. However, certain practices should be avoided, e.g., excessive use of water (floor is flooded with water), high pressure hoses. Instead, water should be used on an as-needed basis and should be minimized and isolated to specific areas where possible. Complete drying after the wet cleaning is essential.
Controlled wet cleaning	A limited amount of water is used. Complete drying must follow immediately after the controlled wet cleaning. Specific pieces of equipment may be moved out of the Primary *Salmonella* Control Area, wet cleaned, sanitized, dried and then returned.

The manufacture of foods is accomplished by processes within areas of the manufacturing facility with differing requirements for water. The requirement for water during processing or sanitation typically defines the equipment and process hygienic design standards. These differing design standards do not reflect a lower hygienic expectation, but rather the appropriate approach to maintaining the equipment and process in a hygienic state, given the risk that water presents in terms of microbial growth. The equipment, surroundings and infrastructure that remain in a dry state (e.g., grain silos, dry blending, chocolate processing) generally will not be exposed to water and therefore have design standards that differ from the standards of equipment requiring water for food processing or sanitation.

Because limiting water is the primary means of controlling *Salmonella* in low-moisture food manufacturing, it is imperative that the relationship of each process point and installation to water sources be evaluated. Simply put, the type of cleaning necessary at each process point will determine water usage. Food allergens often complicate this evaluation, as installations may need to be designed to remove food allergens by using water that otherwise would not be required. The selection of the appropriate hygienic design standards begins with identification of the method of cleaning that will be employed at each process point. It is important that the key stakeholders define the hygienic needs (i.e., type of cleaning) of an installation and forecast the future usage of the manufacturing line and process. New manufacturing line installation is very expensive, and the desire for manufacturing flexibility is very high. The cost of retrofitting a manufacturing line and surrounding infrastructure designed to operate in a dry state to one that accommodates water is much higher than if the process had been designed originally to accommodate water.

A multidisciplinary food safety team should determine the current and, to the extent possible, future plans for the manufacturing line and surrounding infrastructure. From these plans, the team should identify the new line's and infrastructure's relationship to water. The hygienic design standards will focus primarily on accessibility for dry cleaning and dust control if the equipment and process will remain in a dry state and receive only dry sanitation. Conversely, if the installation requires water, the focus on the installation and infrastructure will require a design that accommodates water, prevents microbial growth niches and receives microbiologically focused sanitation.

Common industry practices

- ❑ Building design and layout should be based on hygienic principles, using common practices such as those outlined in the literature *(2, 4, 5, 6, 8)*.
- ❑ A common approach should be applied to sanitary design that keeps the equipment design as simple as possible and strives for a minimum number of parts, with all parts and assemblies accessible for inspection and cleaning. A program should be established for design review of equipment based on sanitary design principles, including some or all of the principles outlined in Table 3 as appropriate.
  - – Review new equipment prior to purchase for sanitary design and layout. The proposed layout and placement in the facility should be evaluated to confirm that access necessary for proper cleaning is not compromised. The presence of the new equipment should not compromise the cleanability of existing machinery.
  - – A similar review should be conducted for equipment that is relocated from one facility to another.
  - – Plans to modify existing equipment should be reviewed by the plant food safety team prior to beginning the alteration.
  - – Existing equipment should be periodically reviewed to verify that it still meets sanitary design principles and has not been altered in a manner that would compromise the sanitary design or cleanability of the equipment. Existing equipment should be modified when necessary to eliminate difficult-to-clean areas (such as unsealed hollow components, scratched surfaces, crevices, poor sanitary welds, etc.) and design features that may lead to residue build-up or stagnant products. Examples of poor design features are shown in Figures 5 and 6.
- ❑ If water will be used, the infrastructure and equipment must be designed to accommodate water. Development of microbial growth niches must be prevented. Water drainage from the process in the facility must ensure rapid drying. Additionally, the infrastructure must be designed to prevent entry of unwanted water from surrounding processes or from outside the facility.
- ❑ Particular attention should be given to sanitary design, layout and maintenance of equipment located in the Primary *Salmonella* Control Area (PSCA) to ensure that moisture can be excluded from the processing environment, including the utilization of dry cleaning procedures (see more details in Element 4). Conditions leading to the formation of condensate should be eliminated or minimized to the greatest extent possible.

TABLE 5. Examples of common industry procedures for controlled wet cleaning

- Remove as much residue as possible by dry cleaning.
- Avoid overuse or careless use of water. Procedures for collecting water should be in place to prevent water spreading on the floor or following product conveyance lines or other connections to non-wet cleaned areas of the facility.
- Commercial pre-moistened sanitizing wipes may be used to spot-clean specialized areas with minimal introduction of water.
- Never use high pressure water application, even for situations such as to get rid of dry build-ups, as the over-spray will spread to other areas and contaminants can be aerosolized.
- When drains are not used for wet cleaning they must be sealed.
- During cleaning, there should be no changes in procedures for entering the Primary *Salmonella* Control Area — all barriers still apply, e.g., entering through the buffer area and following required procedures.
- Always apply a sanitizing step following the controlled wet cleaning.
- Ensure prompt and complete drying of all areas and components involved (equipment, parts, floors, the environment, etc.) after controlled wet cleaning. All equipment parts and environmental sites must be visually inspected for any remaining wet spots before the sites are released for production. Consideration should be given to evaluating the microbiological quality of the first product through the equipment to verify the efficacy of the controlled wet cleaning process.

- ❑ Hygienic design standards and strict adherence to sanitation performance specifications must be applied to construction and major maintenance activities. These activities can dislodge microbial growth niches and lead to widespread contamination of the facility. The plant food safety team should evaluate this work and conduct an evaluation of the risk of introducing physical, biological or chemical hazards into the facility. Based on this evaluation they should define and implement the appropriate preventive measures, such as temporary isolation of the construction or maintenance sites, rerouting of employee and equipment traffic, proper handling of waste material egress, maintaining negative pressure in the work site, etc.
- ❑ Equipment maintenance should follow hygienic procedures such as those described in Element 1 *(12)* and Element 2 as appropriate. Unscheduled maintenance is particularly risky, and hygienic procedures should be strictly followed.
- ❑ A wide range of accessory tools such as supports and ladders may be located inside large equipment or inside the PSCA. Hygienic design is critical and these tools/structures should not have features such as hollow bodies, loose parts or uncleanable surfaces.
- ❑ Elevated infrastructure should be designed to minimize dust and dry material accumulation, especially when pipes, overhead structures and platforms are **directly** above exposed products or production lines.

SALMONELLA CONTROL ELEMENT 4: PREVENT OR MINIMIZE GROWTH OF *SALMONELLA* WITHIN THE FACILITY

Moisture control is critically important in preventing *Salmonella* contamination in low-moisture products *(11)*. Water in the dry processing environment is one of the most significant risk factors (perhaps the single most important factor) for *Salmonella* contamination, as water allows for pathogen growth, significantly increasing the risk for product contamination. Industry experience indicates that the presence of water, even in very small amounts present for short, sporadic time periods, may allow *Salmonella* to grow in the environment. At times, moisture is obvious in the form of water droplets or puddles; at other times, it may be from sporadic sources such as roof leaks. However, many sources of moisture, such as high relative humidity or moisture accumulating inside of equipment, are not visually apparent.

Salmonella can, to varying degrees, be introduced into low-moisture product manufacturing facilities and become established in those environments. Harborage sites may develop and become a source of product contamination unless these sites are identified and eliminated *(2)*. A harborage site, or niche, is a site in the environment or on equipment (junctions, cracks, holes, dead-end areas, etc.) that enables the accumulation of residues (food debris, dust, and water) and permits the growth of microorganisms such as *Salmonella.* These sites may be difficult to inspect or access and therefore can protect *Salmonella* during routine cleaning and sanitizing.

Growth of *Salmonella* is possible only in the presence of water. Since food particles and dust are normally expected to be present in processing areas, adequate nutrients are always available to microorganisms. Growth cannot occur, however, if the plant environment is sufficiently dry. The potential *Salmonella* harborage sites become more significant when water is present for a sufficient period of time.

The presence of water in the dry processing environment can result from improper use of water during cleaning, which has been linked to the occurrence and spread of *Salmonella (2)*. Other events resulting in the presence of water in a dry area include condensate formation, leaking water or steam valves, infiltration of water following heavy rains (e.g., leaky roofs), the use of water showers in the case of fire emergencies, etc. *(2)*. Efforts must be made to remove water immediately from the PSCA in such events in order to keep the plant environment as dry as possible. Dry conditions must be maintained at all time in the PSCA, except for the occasions when controlled wet cleaning is deemed essential. Potential problems arise when there is visible water present in the dry areas or when there are areas in which standing water has dried. *Salmonella* may be found not only in wet spots but also in spots where standing water has dried *(14)*. The latter situation may present an additional risk of spread via the generation of airborne contaminated dust.

Dry cleaning is typically employed when conducting sanitation in the PSCA. The objective is to eliminate water from the area so that, despite the presence of food and other substrates, microorganisms (including *Salmonella*) will not grow. Without growth, *Salmonella*, if present, remains at very low levels, thus reducing the risk of product contamination. Dry cleaning has been successfully applied for many years in production of low-moisture

TABLE 6. Examples of tools for dry cleaning and their uses

Tools	Design features and usage
Brushes, scrapers	- Choose tools with sanitary design that do not create hygienic problems. These tools should be cleanable, durable and without loose parts. The handles and supports should have no spaces where residues can accumulate. If the handle is hollow (e.g., to control weight for practical reasons), it should be sealed.
	- A tool that is used for cleaning product contact surfaces should not be used for cleaning floors, drains, and ceilings.
	- Provide a designated area to store cleaning tools not in use, e.g., hooks, hangers, storage cabinets, etc.
	- Check all brushes and scrapers regularly and replace them as needed. Do not use tools that are worn and could become potential sources of foreign materials and contamination.
	- Dry clean the tools. Wet cleaning is done only in designated areas and only if the tools can be dried promptly and completely; it must be done using controlled wet cleaning.
Vacuum cleaners	- Portable vacuum cleaners with appropriate design features are recommended for dry cleaning to avoid or limit the spread of dust. A vacuum cleaner has the advantage of collecting and retaining residues in a dust container. They can also reach difficult-to-reach places. For example, a vacuum cleaner is preferred to remove residues on overhead structures such as wiring supports and pipes (using a brush in this case would create and spread dust).
	- Desirable design features for vacuum cleaners are described in Table 7.
	- A vacuum cleaner used in the Primary *Salmonella* Control Area (PSCA) should not be used outside the area. A vacuum cleaner that is used for cleaning inside equipment should not be used for cleaning the floor. Dedicated accessories should be used accordingly. The dust bag should be removed in an area isolated and as far away as possible from the process line (but still in the PSCA). The vacuum cleaner dedicated to the PSCA should not be taken outside the PSCA for emptying because it could transport contaminants on its return.
	- A vacuum cleaner will be an efficient tool only if it is well maintained in such a way that it does not become a carrier of contamination, e.g., protected against water and moisture, making sure attachments are well fitted. If a vacuum cleaner used in the PSCA needs cleaning or maintenance, it can be done in a dedicated/isolated area in the PSCA or it can be protected by a plastic cover and transported on a pallet to a dedicated area outside the PSCA. After maintenance, the vacuum cleaner should be dry-cleaned. On rare occasions when necessary (e.g., when contamination is detected), the exterior of the vacuum cleaner can be subjected to controlled wet cleaning, sanitizing, and drying prior to use again.
	- Filter(s) should be properly maintained on a regular basis and replaced when necessary.
	- Central vacuum cleaners, if they are used, should be used with caution because these tend to have lengthy pipes that are difficult to clean and maintain. They can also harbor insects.

foods such as dried milk and infant cereals to prevent product recontamination with *Salmonella*.

Dry cleaning is especially important in older facilities or in older areas of facilities that were not originally designed on the basis of current sanitary design principles. In such facilities, in spite of regular maintenance, there may be cracks or other harborage sites that may be difficult to eliminate. Even if dust or food residues may enter such a site, potential problems can be minimized if the residues and the sites are dry. Once water enters the harborage site, microbial growth can occur and the potential risk of contamination to the environment and eventually to the product is increased. Many years of industry experience shows that, even though the environment may appear a little dusty after dry cleaning, this is a far more hygienic condition (on a microbial level) than a wet-cleaned environment without visual dust. Serious *Salmonella* problems may develop when wet cleaning introduces moisture under equipment supports, into floor cracks and other difficult-to-clean or "hidden" spots where complete drying is not achieved.

Product accumulation should be removed as soon as possible *(11)*. Occasionally there are special circumstances, such as finding environmental sites positive for *Salmonella*, which requires that equipment not designed for wet cleaning be wet cleaned. Extreme care must be taken to understand the risks and to formulate a plan that will successfully eliminate the contamination without spreading and enhancing the problem. Dry and controlled wet cleaning may be required, including clean-out-of-place with disassembly, cleaning and sanitizing, drying and reassembly. It is recommended that a multidisciplinary team be formed that has the appropriate expertise to plan and oversee this type of high-risk operation.

Common industry practices

- ❏ Minimize the use of water in the entire plant environment.
- ❏ Specify the type of cleaning practices to be used in different hygiene areas, i.e., the basic area, transitional area, and PSCA. There are three types of cleaning (Table 4): dry, controlled wet and wet cleaning. Dry, wet and controlled wet cleaning in the different hygiene areas should be used at appropriate frequencies, which may be modified based on the specific product and process.
- ❏ Choose dry cleaning as the routine cleaning practice in the PSCA. Use controlled wet cleaning infrequently in a prudent manner and on an as-needed basis. Do not use wet cleaning or use it only in very rare cases in

TABLE 7. Desirable design features for vacuum cleaners based on the location of use

For use outside the Primary *Salmonella* Control Area (PSCA):

- Practical easy-to-empty vacuum cleaners equipped with a normal dust trap filter (for both large and small particles, but not necessarily a microbiological filter) and a removable and replaceable bag. To prevent dust from re-circulating to the air with the exhaust, a filter is installed on the outlet of the vacuum cleaner and maintained properly.

For use inside the PSCA:

- Should be made of stainless steel except certain accessories, contain a multiple-stage filtration system with replaceable bag for dust collection, and have practical and easy-to-clean or easy-to-replace accessories.
- Should have a detachable stainless steel trolley, straight stainless steel wands, flexible plastic hose, round brush, crevice cone or floor nozzle to be used as appropriate for the purpose.
- Exhaust fan and motor of the vacuum cleaner should be located above the dust collector;
- Accessories and spare parts can be easily obtained when replacement is needed;
- Accessories fit tightly when attached;
- Exterior is cleanable;
- Absence of fittings (wheels, etc.) that can accumulate dust.
- The vacuum cleaner should have a multiple-stage filtration system, which may include features such as a large main filter to ensure even airflow; a microfilter to protect the motor and acts as a barrier to small size particles; a HEPA (High Efficiency Particulate Air) filter with 99.97% efficiency in removing particles and bacteria down to 0.3 microns; and/or a ULPA (Ultra Low Penetration Air) filter that retains 99.999% at 0.12 microns. A HEPA filter should be used for at least some part of many operations (e.g., for a unit used to clean product contact surfaces). Whether a ULPA filter is needed would depend on the nature of the product and the point/area of use (e.g., equipment vs. floor in PSCA, inner surface vs. outer surface of equipment).

the PSCA, e.g., in response to a product contamination incident.

- ❏ When controlled wet cleaning is necessary, care must be exercised such that only the minimum amount of water is used. Table 5 lists common procedures for controlled wet cleaning. It is recommended that the environment of the wet-cleaned area be tested for *Salmonella* to verify sanitation effectiveness – see Element 7 *(3)*. Areas/situations where controlled wet cleaning may be necessary include the following:
  - – In the case of an unusual event, such as a roof leak or a faulty sprinkler that may lead to potential product contact surface contamination in the PSCA, production should be stopped. The leak should be fixed, and the area cleaned, sanitized, and dried before production resumes.
  - – Wherever possible, remove parts of equipment and conduct controlled wet cleaning on them in a room dedicated to cleaning.
  - – When controlled wet cleaning is done in a certain area of the PSCA, the area should be segregated and care must be taken so that the cleaning activities do not adversely impact the adjacent areas.
  - – Other examples of situations in which controlled wet cleaning is needed include when the buffer area upon entry to the PSCA becomes dirty and requires cleaning, when there is a need to remove sticky build-ups and to remove allergens, etc.
- ❏ Eliminate water in the PSCA. Water distribution systems (piping, etc.) should also be limited to the greatest extent possible.
  - – In order to maintain the PSCA as dry as possible, the use of "dry drains" (i.e., drains that are physically capped with an impermeable barrier when not being used to collect water) is recommended.
  - – In production where hygroscopic products are made, procedures should be in place to remove as soon as possible accumulated product to avoid moisture build-up and localized condensation.
- ❏ Establish appropriate dry cleaning procedures for the PSCA.
  - – The goal of dry cleaning is to collect, remove and dispose of residues without redistributing them or cross contaminating the environment. Examples of dry cleaning tools and their uses are described in Table 6. Personnel responsible for maintenance, cleaning and checking the tools should be designated and properly trained.
  - – In addition to tools such as brushes and scrapers, vacuum cleaners are useful for dry cleaning. When vacuum cleaners are used, it is desirable to dedicate individual vacuum cleaners to specific areas, so that vacuumed material can be tested as part of the environmental monitoring program – see Element 7 *(3)*. If the material tests positive for *Salmonella*, there is a limited area to search for the source of the contamination. In addition, the contaminated vacuum has not been used in other areas around the plant and the contamination is confined. Desirable design features for vacuum cleaners are described in Table 7.
  - – The objective of dry cleaning is to remove residues without the use of water by using tools or cleaning aids that do not entail the application of water or other aqueous solutions. Where appropriate, "blasting" with dry CO_2 pellets or other dry abrasives can be an effective method for removing stubborn residues on equipment or facility surfaces without introducing water. Hot oil may also be used to flush the interior of equipment used to handle low-moisture products such as peanut butter or chocolate.

- Sanitizers that will rapidly evaporate after contact, such as alcohol-based sanitizers, provide a means to spot-sanitize equipment with a very minimal introduction of water. For example, critical or sensitive spots (such as electrical equipment control panels) can be dry-cleaned and then sanitized with an alcohol-based sanitizer. However, it is not possible to sanitize a dirty surface, such as an area with dry soils that cannot be removed effectively. These sanitizers are flammable; caution should be taken to prevent explosion or fire during application.
- Compressed air should generally not be used for dry cleaning except in special situations (e.g., to dislodge dust from inaccessible points). Moreover, if and when compressed air is used, it should be dried and filtered to exclude microorganisms and moisture prior to use. Water traps in compressed air systems can be included as part of the environmental monitoring program and be tested for indicator organisms (e.g., Enterobacteriaceae), as well as *Salmonella*.
- Dry cleaning should be monitored and verified by visual observations and environmental monitoring.

❑ Separation of cleaning tools used in different hygiene areas is important and can be accomplished using color coding or other suitable means.

CONCLUSIONS

The Primary *Salmonella* Control Area (PSCA) in a low-moisture product facility is the area where handling of ingredients and product requires the highest level of hygiene control. All traffic between the PSCA and the rest of the facility, including the movement of personnel and materials, must be controlled. Building design and layout should be based on hygienic principles. Particular attention should be given to sanitary design, layout and maintenance of equipment located in the PSCA to ensure that moisture can be excluded from the processing environment, including the utilization of dry cleaning procedures. Moisture control is critically important in preventing *Salmonella* contamination in low-moisture products. Dry conditions must be maintained at all times in the PSCA, except for the occasions when controlled wet cleaning is deemed essential, e.g., in response to a product contamination incident.

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