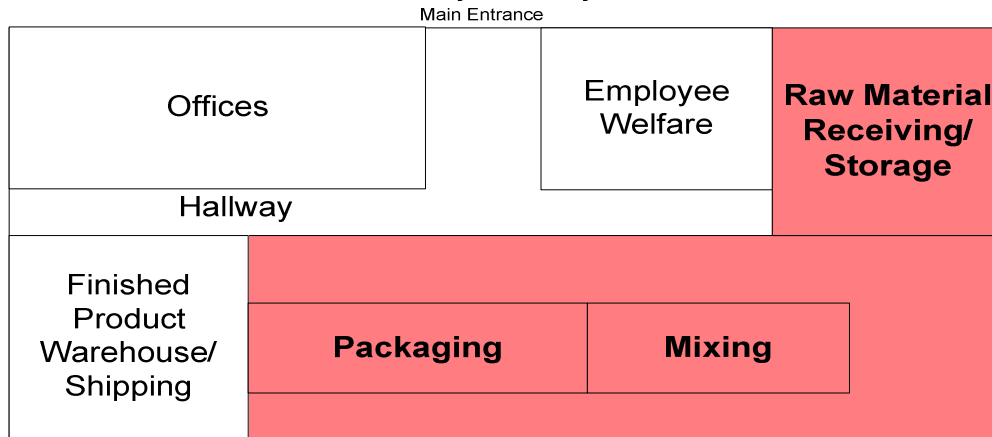


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This information is a combination of industry best practices and regulations in place to control Salmonella contamination (**regulations are **bolded** and best practices are *italicized***). The following diagrams illustrate different Primary Salmonella Control Areas (PSCA) for different food product operations. Depending on the operation, a facility may be divided into one, two, or three processing areas in addition to non-processing areas. The layouts may be used to demonstrate how *Salmonella* may enter and spread throughout a facility if hygiene practices and controls are not in place.

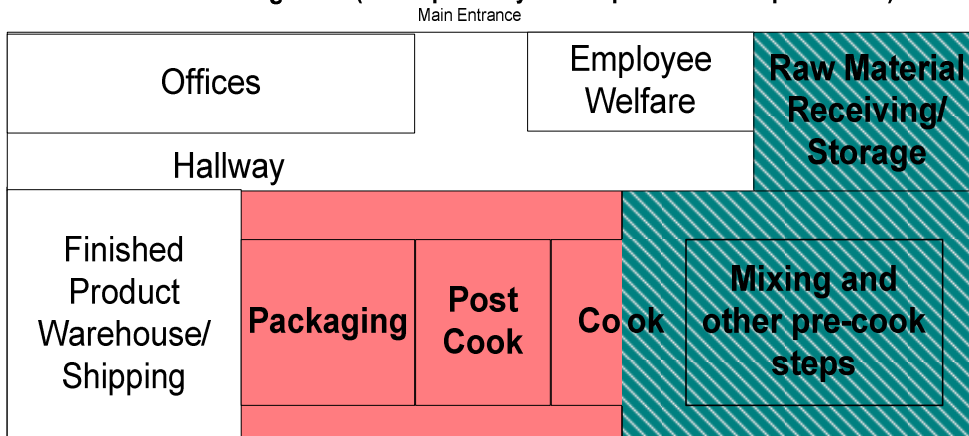
Food Processing Plant (layout for Dry Blends and Snack bars)



- Non-process areas
- Primary *Salmonella* Control Areas

GMA, Control of Salmonella in Low Moisture Foods, February 4, 2009

Food Processing Plant (conceptual layout for peanut butter processor)



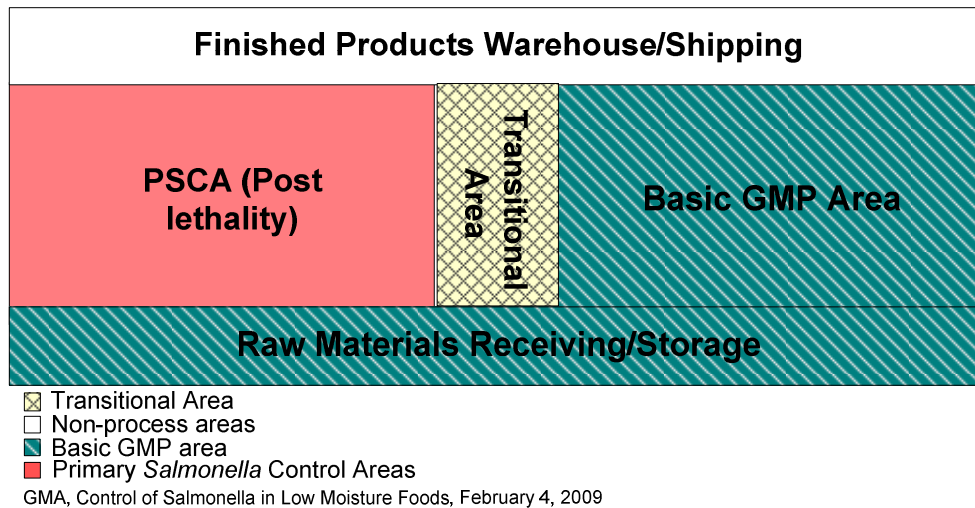
- Non-process areas
- Primary *Salmonella* Control Areas
- Basic GMP area

GMA, Control of Salmonella in Low Moisture Foods, February 4, 2009

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

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Food Processing Plant (layout for infant formula)



Some industry best practices for controlling *Salmonella* in manufacturing plants similar in design to the previous illustrations are listed below, the GMA Microbiological Safety Committee and Scientific and Regulatory Affairs Council recommends that food industry institute best practices and incorporate the following seven elements to control *Salmonella* in low moisture products:

1. Prevent ingress or spread of Salmonella in the processing facility. Determine potential sources and minimize ingress or spread in the processing area:
 - a. Facility
 - **check integrity of roof, floor, walls, and drain pipes above processing lines**
 - **inspect for openings, leaks, and pests on routine basis and take immediate action**
 - b. Air flow
 - **examine intake and exhaust vents for sanitary design, cleanability, proper filters, positive pressure**
 - **correct condensation dripping from exhaust vents above processing line**
 - c. Water quality and usage
 - **ensure fire suppression systems internal to food equipment have potable water supply**
 - *minimize use of water in the dry processing area to necessary amounts*
 - d. Personnel and traffic movement
 - **educate and monitor full-time and temporary employees on contamination sources/ adherence to traffic pattern/proper hygienic practices**
 - e. Equipment
 - **evaluate for proper design/use**
 - *develop cleaning, sanitizing and drying equipment SSOPs*
 - **ensure only clean, sanitized, dry equipment is brought into processing area**
 - f. Incoming raw material
 - *segregate ingredients known to be contaminated with Salmonella*
 - g. Minimize cross contamination
 - *separate processed foods from ready-to-eat, or ready-to-use foods*
 - *use dedicated forklifts, utensils, tools*
 - *monitor traffic patterns*

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- *inspect and maintain pallet and trailers*
 - *do not expose pallets to pest or bird activity, or store pallets outside*
 - *maintain highest room air pressure in PSCA*
 - h. Control construction or other activities
2. Enhance the stringency of hygiene practices and controls in the primary Salmonella Control Area to minimize spread of Salmonella in the processing area:
- a. *Designate separate areas in facility for different levels of hygiene control*
 - *set up different processing operation areas, designate PSCA, and establish buffer areas at main entrance or PSCA doorways*
 - **implement hygiene procedures appropriate for each area**
 - b. *Set up barriers for PSCA*
 - *the riskier the product the greater the need for physical separation such as a wall (i.e. powdered infant formula production should be walled off from rest of operation)*
 - *if roasting or baking equipment openings (raw entrance opening versus cooked exit opening) are used as hygiene junctures, then use color coded employee gowning and boot changing*
 - c. *Control traffic between PSCA and rest of facility*
 - *assign dedicated workers, equipment, pallets, utensils and other tools to PSCA*
 - *prior to entering PSCA, personnel should conduct hygienic procedures in buffer area*
 - *prohibit products and ingredients not properly decontaminated from PSCA*
 - d. *Use physical separations or other means to minimize dust movement into PSCA*
 - *install and maintain air filters in ventilation system*
 - *when using HEPA filters, install close to point of use rather than entire PSCA*
 - e. *Set up a master sanitation schedule*
 - *dry cleaning: use dedicated tools*
 - **wet cleaning: include cleaning, sanitizing, and drying steps**
 - f. **Use appropriate cleaning and hygiene procedures for the PSCA**
 - *PSCA: use dry cleaning*
 - *buffer area: dry and controlled wet cleaning; prefer no drains in this area*
 - *avoid cracked floors and unsealed equipment in PSCA*
 - *keep air dry in PSCA*
 - g. **Routinely remove product residue from food and non-food contact surfaces of food equipment**
 - **correct poor equipment design problems**
3. Apply hygienic design principles to the building and equipment design:
- a. **Base building design and layout on hygienic principles**
 - b. *Keep equipment design simple*
 - c. **If using water: equipment and infrastructure must be properly designed to prevent development of microbial growth niches, drain rapidly and dry quickly**
 - d. **Exclude moisture and condensate from PSCA**
 - *use dry cleaning procedures*
 - e. **Construction and maintenance activities must follow hygienic design standards and sanitation specifications**
 - *preventive measures such as temporary isolation of construction sites, re-routing traffic patterns, and etc... may be needed*
 - f. **Maintain equipment using hygienic procedures and schedules**

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- g. Accessory tool such as ladders and supports inside equipment must not be hollow, loose, or non-cleanable
4. Prevent or minimize growth of Salmonella within the facility
- a. Minimize use of water in the entire plant environment
 - b. Specify different types of cleaning practices in the different hygiene areas
 - dry cleaning: no water used
 - controlled wet cleaning: very limited amount of water used
 - wet cleaning: apply water as needed, but no flooding or high pressure sprays
 - c. Use dry cleaning in PSCA
 - use controlled wet on an as needed basis
 - do not use wet cleaning
 - d. If controlled wet cleaning is used, recommend testing to verify sanitation effectiveness
 - e. **Stop production if an event such as a roof leak or faulty sprinkler may lead to product contact surface contamination**
 - **fix leak, and clean, sanitize, and dry area before resuming production**
 - if possible, remove parts of equipment and move them into a room dedicated to a controlled wet cleaning
 - f. Eliminate water distribution systems in PSCA
 - use dry drains that are only uncapped when needed
 - remove water ASAP if product is hygroscopic
 - g. Establish appropriate dry cleaning procedures in PSCA that collect, remove, and dispose of residues without recontamination
 - dedicated brushes/scrapers/vacuum cleaners, dry abrasives, quick evaporating sanitizers, compressed air
 - h. Use separate, color coded cleaning tools in different hygiene areas

| EXAMPLES OF TOOLS FOR DRY CLEANING AND THEIR USES | |
|--|--|
| Dedicated Food contact brushes, scrapers | <ul style="list-style-type: none"> • Sanitary design cleanable, durable and no loose parts, handles and supports with no spaces and if hollow, seal • Designate a storage area • Replace as needed • Dry clean the tools |
| Dedicated Vacuum Cleaners | <ul style="list-style-type: none"> • Use portable VCs to limit spread of dust • Dedicate to PSCA food contact equipment area only; do not use to clean floors • Remove dust bag in isolated area away from equipment or in plastic bag for transport • Change filters regularly • Central vacuums not recommended • Design standards for VCs used inside PSCA <ol style="list-style-type: none"> 1. Stainless steel unit, detachable trolley, wands, and flexible accessories 2. Fan and motor above unit 3. Easily replaceable accessories 4. Cleanable exterior 5. No fittings (such as wheels) 6. Multiple storage filtration system: large main filter to ensure even airflow; microfiber to protect motor and barrier to small size particles; HEPA filter with 99.97% efficiency to remove particles and bacteria down to 0.3 microns; and maybe UPLA filter that retains 99.99% at 12 microns. HEPA filter used at food contact surfaces and use of UPLA filter depends on food product. |

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Some industry best practices for controlling *Salmonella* in manufacturing plants similar in design to the previous illustrations are listed below:

| |
|--|
| COMMON INDUSTRY PROCEDURES FOR CONTROLLED WET CLEANING: |
| Salmonella needs water and other nutrients to grow. If plant environment is dry, potential harborage sites become more significant when water is present for a sufficient period of time. |
| <i>Remove as much residue as possible during dry cleaning</i> |
| <i>Avoid overuse or careless use of water. Have procedures for collecting water to prevent spreading water on floor, following product conveyance lines, or connections to non-wet cleaned areas of facility</i> |
| <i>To spot clean specialized areas with minimal introduction of water, commercial pre-moistened sanitizing wipes may be used</i> |
| <i>Never use high pressure water applications.</i> |
| <i>When drains are not in use for wet cleaning, they must remain sealed.</i> |
| <i>During cleaning, follow procedures for entering PSCA through buffer area and maintain barriers.</i> |
| After controlled wet cleaning, always apply a sanitizing step. |
| <i>Dry all areas and equipment components promptly and completely after controlled wet cleaning and visually inspect for wet spots.</i> |

5. Establish a raw materials/ ingredients control program:
 - a. List all *Salmonella* sensitive ingredients
 - b. Obtain sensitive ingredients from an approved supplier**
 - c. Provide supplier with ingredient and test method specifications, and audit suppliers' food safety program for pathogen environmental monitoring program, sanitation practices, raw materials/ ingredients storage, finished product hold and release testing program, traceability, process validation, corrective action plans if positive results are found
 - d. If ingredient is added to a food product with no additional lethality step, develop a program for testing prior to approval and use in addition to Certificate of Analysis (COA).
 - implement a hold and release testing program for COA verification or if ingredient received without a COA
 - e. Strongly encourage accepting entire lot rather than split lots
 - f. All materials tested for *Salmonella* should remain under manufacturer's control and released for use only after acceptable test results received

| EXAMPLES OF <i>SALMONELLA</i> SENSITIVE INGREDIENTS USED IN LOW MOISTURE PRODUCTS (This list is not inclusive of all sensitive ingredients): | |
|---|------------------------------|
| Chocolate, chocolate liquor, cocoa powder, chocolate chips, cocoa products | Nuts/nut products |
| Coconuts | Seed/seed products |
| Grains/grain products (excluding starches) | Dried egg products |
| Fruits/fruit products (excluding candied or alcohol packed fruit, jams, or jellies) | Dairy ingredients and blends |
| Spices/herbs (excluding extracts), blended seasonings | Soy products |
| Gums/thickeners (excluding xanthum gum) | Yeasts/yeast extract |
| Gelatin | Dry vegetables |
| Enzymes/rennets | Dry meats or meat products |

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6. Validate control measures to inactivate Salmonella:
 - a. *To validate that Salmonella is inactivated, determine desired target level of log reduction in the specific product and process*
 - b. *Determine if control measure and critical limits for processing use are adequate*
 - c. *Use published data to validate control measure where needed*
 - d. *Consider both thermal and non-thermal validated control measures to eliminate Salmonella*
 - e. *Once process is validated, conduct documented in-plant validation to prove that control measures for the operation can consistently meet critical limits*
 - f. *Ensure that suppliers validate their process and the control measures*

7. Establish procedures for verification of Salmonella controls and corrective actions:
 - a. *Develop a written program for routine environmental monitoring*
 - b. *Increase frequency of environmental monitoring after construction or emergency events*
 - c. *Develop a policy on whether and when to test the product contact surfaces and or finished food product, and a program for testing*
 - d. *Choose the official or validated method used to test samples taken from the environment or finished product*
 - e. **If Salmonella is detected in the environmental monitoring or finished product sample, corrective action must be taken**

(**regulations are **bolded** and best practices are *italicized***)

References and Presentations:

1. GMA, *Control of Salmonella in Low Moisture Foods*, pp 1-81, February 4, 2009