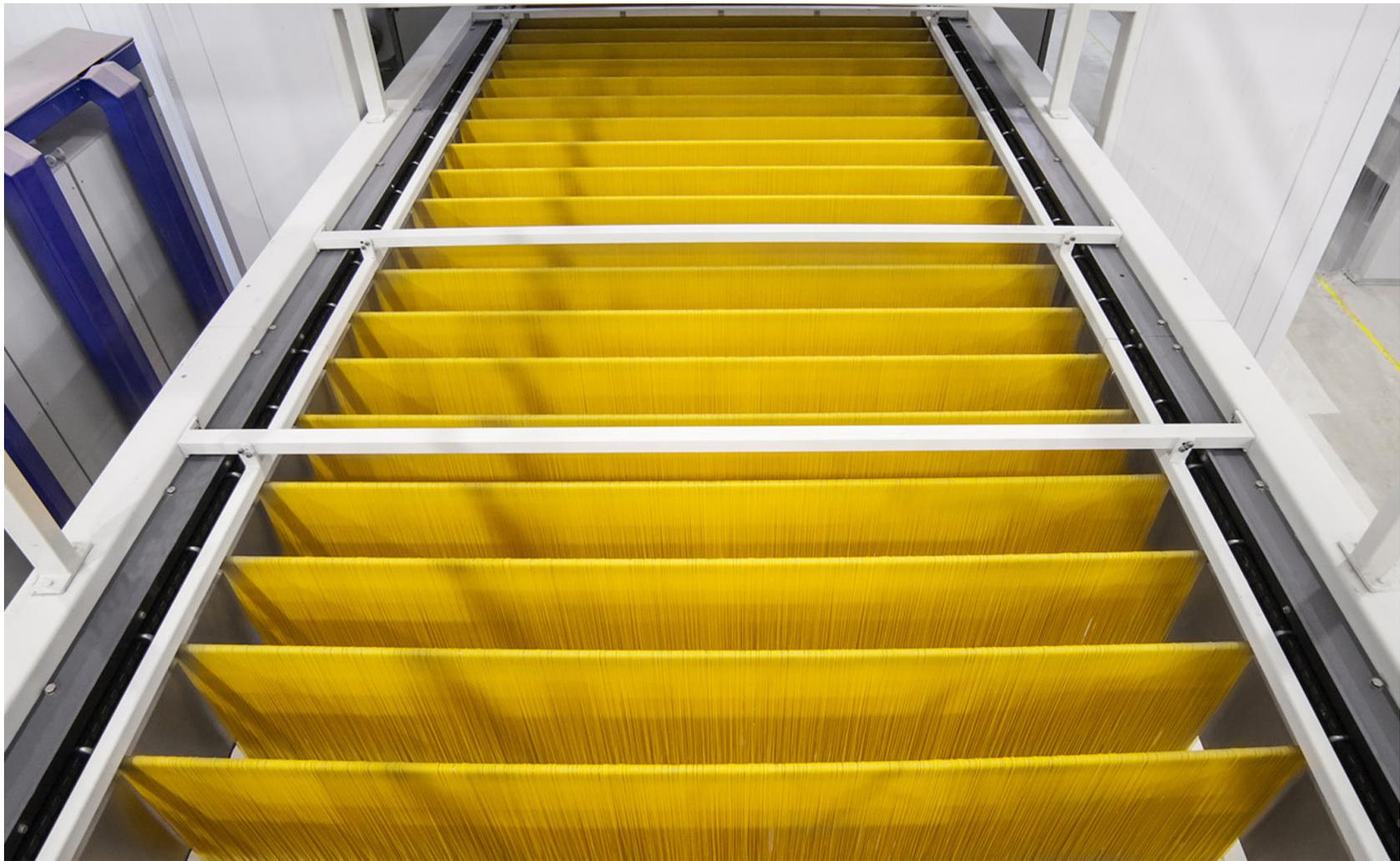


# MITIGATION & CONTROL

OF SALMONELLA IN DRY PASTA // MARCH 2016



Prepared by the National Pasta Association



# MITIGATION & CONTROL OF *SALMONELLA* IN DRY PASTA FACILITIES -- V.1.0

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## INTRODUCTION

Due to the number of foodborne illness outbreaks in recent years, the pasta industry is continually working to improve its processes to provide our consumers with safe and wholesome products. The pasta industry has not been involved in any of these outbreaks and wants to be proactive for food safety.

*Salmonella* is the primary pathogen of concern in our dry pasta products. Pasta is a not ready-to-eat (NRTE) food, where consumer preparation (cooking) achieves adequate lethality for any *Salmonella* that may potentially be in the product. However, it is important to take steps to mitigate the potential for *Salmonella* by controlling for the potential of this pathogen in the food production environment.

*Salmonella* can be difficult to control in a food production environment because it can persist for prolonged periods of time in the dry state and in low-moisture products. *Salmonella* also appears to have increased heat resistance characteristics at reduced water activity in food matrices. Maintaining good hygienic practices, proper equipment design, proper maintenance, and proper ingredient control in the food manufacturing establishment will help prevent the contamination of low-moisture foods with *Salmonella*.

## OBJECTIVE & BACKGROUND

This guidance document was prepared by the Technical Affairs Committee (TAC) of the National Pasta Association (NPA). The objective is to provide guidance to members of the US pasta industry for mitigating and controlling *Salmonella* in their facilities. These practices are recommended as an extension of Good Manufacturing Practices (GMPs).

NPA has identified a valuable reference in the 2009 report, *Control of Salmonella in Low Moisture Foods*, prepared by the Grocery Manufacturers Association (GMA). This document includes content copied and adapted from the GMA report that is used with GMA's permission and, therefore, is not always directly cited or attributed. We recommend review of the GMA report as a complement to this document. This guidance follows the outline of the GMA report, providing the seven key elements of *Salmonella* control, and then sharing how these elements can be applied in the pasta industry. We have added an eighth element covering Good Practices for Training.

Based in Washington, D.C., the Grocery Manufacturers Association is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle.

For more information visit the GMA website, [www.gmaonline.org](http://www.gmaonline.org), or call 1-800-355-0983.

## SCOPE, USE AND DEFINITION

This guidance document is intended only to be a tool to aid pasta manufacturers. Each company needs to make an individual assessment of which practices are applicable and appropriate to follow for their products and facility. This guidance is not all inclusive, nor are these recommendations intended to replace basic good manufacturing practices (GMPs) and other food safety programs (e.g., HACCP plans or food safety plans). Rather, this document serves to highlight practices that the NPA's TAC determined generally to be important for control of *Salmonella* in pasta products. These recommendations may be used to develop a new food safety system or to augment an existing system.

The NPA TAC intends to review this document periodically for accuracy and to include updates from our industry. We encourage the NPA membership to share their practices in order to facilitate food safety in pasta products. After all, food safety is not a competitive advantage.

## SECTION I – ELEMENT 1: PREVENT INGRESS OR SPREAD OF *SALMONELLA* IN PROCESSING FACILITY

The GMA guidance document states:

- Facility maintenance, hygiene and pest control are necessary to avoid or minimize the ingress of *Salmonella* into the processing facility. ... Adherence to basic GMPs for the facility, personnel and incoming materials is the foundation for *Salmonella* control.
- Recognized vehicles for ingress and spread of *Salmonella* into the processing plant include sources related to raw ingredients (e.g., raw [ingredients], bottom of pallets, floor of shipping trucks), integrity and design of the facility (e.g., leak from roof, condensation, inadequate separation of pre- and post-processing areas, poor equipment design), personnel (e.g., employee clothing/shoes, improper employee hygiene), and production-related processes (e.g., inadequate sanitation, improper traffic patterns) (Hall, 2007; McNamara, 2007; Zink, 2008). Raw materials used to manufacture low-moisture products, such as spices, [egg ingredients (liquid or dry), dry vegetable powders,] flour and [semolina], may be a potential source of *Salmonella*. (GMA, p.18)

Following are common industry practices specific to the pasta industry for control of *Salmonella*.

### 1.1 Conduct *Salmonella*-Specific Hazard Analysis

Conduct an in-depth assessment of the facility, internally and externally, using a cross-functional team (and outside experts as appropriate) to identify potential problem areas and practices that could lead to *Salmonella* ingress or spread. Efforts should be made to ensure the integrity of the roof, floor, and walls in the processing area and to minimize the use of drain pipes over processing lines (CAC, 2003).

### 1.2 Conduct Self-Inspections for Building Integrity With Quick Action to Fix

- Inspect the integrity of the facility for problems such as the presence of bird nests on the roof, roof overhang over a dock door that may become a place for birds to roost, pests in the facility, storage silos or bins without covers, roof leaks, and faulty sprinklers. Correct these problems in a timely manner and verify the problems have been corrected by conducting enhanced environmental monitoring for the affected area according to procedures outlined in Section VII - Element 7. Also, refer to Figure 1-1, a sample monthly building inspection checklist.
- Maintain a specific outdoor break area that is cleaned regularly to minimize pest attractants such as dropped crumbs, abandoned trash wrappers, etc. and maintain the cleanliness of this area per your sanitation program. Consider in your risk assessment the mitigation of *Salmonella* from transference on your clothes, shoes, work tools, etc.
- Put additional sanitation procedures in place outdoors where product spillage or waste spillage may occur. Vegetation like flowers and trees, if desired around the facility, should be kept at a distance from the building to control bird and pest activity.
- Since it is not possible to entirely prevent *Salmonella* from entering the facility, the raw materials handling area and other areas ideally should be separated from the finished products handling area. A hygienic zoning concept should be applied to separate the facility into different areas, based upon their proximity to the finished product.
- A facility map which outlines and defines these zones should be produced (see Section II - Element 2), reviewed regularly, and outlined with employees, contractors, and visitors.

### 1.3 Scrutinize Your Pest Control Program

- On a routine basis, review and assess adequacy of the pest control program targeting pests such as insects, rodents, birds, reptiles, amphibians, etc. This may include the evaluation of the pest control contractor's program and walking through the facility to verify effectiveness of pest control (e.g., any evidence of pest activities). The building should be sealed to prevent pest entry.
- Pay attention to door and window seals ensuring no gaps or cracks exist. Watch for caulking that has worn away. Ensure that doors are tight fitting and self-closing. If doors need to remain open for periods of time, ensure that they are fitted with a screen or an air curtain to minimize pest entry. Maintain positive pressure in the production area of the facility decreasing the ingress of pests, dust and debris. Look in areas of stored equipment where there is little disturbance, as these can become areas where pests congregate.

For example, holes in the roofs of buildings should be sealed off, bird nests should be removed, and bird deterrent devices should be used whenever necessary such as around dock doors or other areas where

pest entry may occur. Overhang structures outside the facility that may attract birds should be re-designed (Graham, 2007; Silliker, 2002) (GMA, p. 18),

#### **1.4 Develop Standard Operating Procedure (SOP) for Cleaning Equipment Before Bringing it into the Facility**

- Develop a Sanitary Standard Operating Procedure (SSOP) for new or used equipment prior to use. Utilize your Hazard Analysis Critical Control Point (HACCP) Program (or Food Safety Plan) validation process to assess the risks/hazards associated with all equipment prior to bringing it into the facility.
- Develop an SSOP for equipment acceptance and cleaning, sanitizing, and drying of equipment prior to allowing entry into the processing area. This is particularly important for used equipment, which may have been contaminated during its prior use or equipment that is to be stored for long periods of time.
- In addition, establish practices for the transportation of new equipment into the production facility and have a system for monitoring the transportation of such equipment. For example, when equipment must be brought into the production areas on pallets and/or wooden crates, keep that wood to an absolute minimum and remove it immediately after unloading the equipment. To prevent the presence of wood in locations where open product exists, it can be placed in an alternative location, a clearly marked, designated area with a sign stating "no wood beyond this point".

#### **1.5 Segregate Sensitive Ingredients**

Establish controls to segregate ingredients sensitive to potential *Salmonella* contamination such as flour, egg ingredient (dry or liquid), spices, grains, and dry vegetable powder. As elaborated in Element 5, sensitive ingredients also should be addressed through a supplier control prerequisite program to review and approve (raw) material suppliers. More controls may be necessary for ingredients that will be added directly to the finished product without further processing to control the hazards in the ingredient. (GMA, p. 19)

#### **1.6 Implement Water Control Program**

Establish a program for water quality to minimize the risk of water as a potential carrier of *Salmonella*.

- Establish procedures for sourcing and handling potable water within the facility.
- Ensure that the water distribution system is properly maintained to prevent any leakage, especially in the Primary *Salmonella* Control Area (PSCA) (See Section II for further discussion of the PSCA). Use backflow prevention devices where needed.
- Establish verification procedures to ensure that water brought into the facility is of adequate quality (ICMSF, 2005c) and is not a source for *Salmonella*.
- When water usage is necessary in the processing area (e.g., for cleaning and sanitizing equipment), use minimal amounts. In particular, water usage in the PSCA should be avoided or kept to the very minimum. See Element 4 for further discussion.

#### **1.7 Prevent Cross-Contamination Activities**

Prevent or minimize cross-contamination through procedures and activities such as the following:

- Raw or unprocessed foods should be separated from processed foods. Packaging materials should be protected from contamination during shipment, storage and use. Packaging should be inspected immediately prior to use to ensure that it is not contaminated or damaged.
- Wherever possible, use dedicated forklifts, utensils, and maintenance tools for the PSCA; see Section II.
- Outline traffic patterns properly and ensure employee compliance through education and training.
- Inspect pallets and trailers regularly, keep them in good repair, and not stored outside where they may be exposed to bird or pest activity.
- Maintain positive room air pressure in the PSCA and include the air handling system in the master sanitation schedule.

#### **1.8 Contain Construction Areas Properly**

Construction and major maintenance events should be coordinated so that the area under construction is contained.

- Construction includes activities such as layout modifications requiring displacing pieces of equipment, resurfacing floors, cutting drains, cutting through walls, installing or removing exhaust

ducts, etc. Due to the ability of *Salmonella* to survive in dry environments for long periods of time, construction activities may release *Salmonella* from unknown harborage sites and contribute to the spread of the organism throughout the plant (CAC, 2008).

- Control measures during construction may include the following: isolate the construction areas, prevent/minimize dust and aerosols, control traffic patterns, use temporary partitions as appropriate, maintain negative air pressure in the construction area, intensify cleaning procedures, and enhance environmental monitoring during these activities, as described in Section VII.

## 1.9 Train Employees and Contractors

Implement a training program to educate employees on the potential sources of contamination, adhere to traffic patterns, and follow proper hygienic practices in order to minimize the ingress or spread of *Salmonella* in the processing area. Training is particularly important for those who work in the PSCA, including personnel who enter the area on a temporary basis (e.g., maintenance crew, contractors). Also see Section VIII.

Maintain an effective, well written uniform and/or shoe policy. Following are some examples from leading industry practices:

- If plant-issued footwear is used in the PSCA to minimize transportation of *Salmonella* (and other potential contaminants) from the outdoors into the production area, they should not be worn in the restrooms.
- For contractors and visitors, shoe covers should be made available and worn over street shoes upon entry into the production area. Each time they re-enter the production area, they should put on a new shoe cover.
- Require a cover or jacket over plant clothing if individuals elect to smoke, or go outdoors to eat lunch or take their breaks. If employees leave the facility grounds, they must dress out of their uniforms.
- Uniforms should not be stored in lockers next to personal clothing, as an additional measure to minimize any potential contaminants from being brought into the production zone.
- These and any other modifications to your specific uniform policy should be fully documented including the risk assessment conducted. All employees must be trained with routine GMP audits performed to verify compliance.

Figure 1-1. Sample Monthly Building Inspection Checklist

MONTHLY BUILDING INSPECTION CHECKLIST				
Month:		Reviewer(s):		
Number	Requirement	Compliant (Yes/No/NA)	Corrective Action Needed (Yes/No/NA)	Comments / Observations
1	Floors, walls and ceilings (including suspended ceilings) are clean and in good repair (e.g., free of cracks and flaking paint). Suspended ceilings need to be inspected for pest infestation.			
2	Floors should be constructed to prevent standing water, be cleanable, and maintained in good repair.			
3	Overhead fixtures, ducts and pipes are reasonably smooth and easily cleaned.			
4	No signs of excessive condensation on equipment or drips to food, raw materials and food contact surfaces.			
5	Plant roof is in good repair and free of potential pest harborage sites and contamination.			
6	City water reports are current.			
7	Hot water for equipment washing and sanitary facilities is 140° F.			
8	Compressed air introduced into the product area is filtered.			
9	Each restroom is equipped with a locker / storage area and changing area, toilets, tissue, hands-free sinks, soap, paper towels, a shower and is well ventilated with self-closing doors.			
10	Outdoor clothing is stored separately from production clothing area.			
11	Hand washing signs are posted in each restroom and upon entering the production floor.			
12	Hands-free sinks, soap, hand dryers and hand sanitizers are located at all employee entrances to the production floor.			
13	There is a designated changing area for visitors or contractors.			
14	There is a designated outdoor smoking area.			
15	There is a lunch room where food can be stored and consumed by employees.			
16	Pedestrian doors are self-closing, tight fitting and of metal construction.			
17	Dock doors are kept closed when not in use. A screening device is used if doors are			

	to be left open.			
18	Overhead and pedestrian doors are maintained with tight (rodent proof) seals.			
19	Dock plates are maintained free of spillage and refuse.			
20	Compactor / dumpster pad is clean.			
21	Exhaust fans and vents are screened or equipped with self-closing devices or shall be of gooseneck design to reduce the possibility of contamination.			
22	Perimeter of building is clean, free of vegetative growth and adequately drained.			
23	Building grounds are maintained to prevent pest harborage and any contamination.			
24	Storage of unused equipment (i.e., angle iron, pipes) is off the ground and 18 inches away from the wall to avoid pest harborage.			
25	Traffic routes onsite are maintained in good repair to avoid contamination.			
26	Building is maintained to prevent pest harborage, water or other contamination.			
27	Ceiling (drop ceilings) and walls clean and in good repair - False ceilings designed with rigid insulating and proper sealing - No signs of leaks, condensate or stains			
28	Note and repair deterioration or missing grout from floors, drains, brick, Cracks or delamination in wall/floor interfaces and along floor expansion joints.			
29	Sewer/drain back-up controls in place starting at the septic system moving to RTE areas (e.g., screens, backflow, prevention device used) - Drain mat covers (if applicable) properly maintained/cleaned/sanitized. - Trench drains adequately flushed and sanitized on a routine basis			
30	HVAC refrigeration units cleaned and maintained on a periodic basis - No signs of leaks or condensate - No food dust getting on cooling or heating coils - Filter replacement SSOP is in place			
31	Condensate adequately controlled in processing zones to prevent product contamination - Condensate piped to a sanitary drain or drip pans in place and maintained			
32	Hoses in ready-to-eat filling areas free from leaks, clean, and kept off the floor during production - No air, water, or electrical hoses hanging over exposed product zones			

33	<p>Equipment food contact surfaces (augers, belts, rollers, conveyors, filler hoppers, nozzles, blenders, cookers, slicers, etc.) free from cracks, chips, poor welds and microbial harborage points</p> <ul style="list-style-type: none"> <li>- No hollow legs, handles, ladders, wheels, tools, in-floor scales, etc. exist which can collect stagnant water</li> <li>- Non-product (framework, insulated lines, control panels, etc.) free of cracks, scratches, or potential harborage locations</li> </ul>			
34	<p>Equipment (pipes, valves, hoses, belts, product &amp; cooling lines, etc.) properly maintained and corrosion-free</p> <ul style="list-style-type: none"> <li>- Unused supply lines removed in production areas</li> <li>- Catwalks above product zones adequately cleaned and with splash guards in place</li> <li>- No cooling water leaks from unpressurized equipment (Chill roll, kettles, etc.)</li> </ul>			

## **SECTION II – ELEMENT 2: ENHANCE THE STRINGENCY OF HYGIENIC PRACTICES AND CONTROLS IN PRIMARY *SALMONELLA* CONTROL AREA (PSCA)**

This section discusses the identification of Primary *Salmonella* Control Areas (PSCA) in a dry pasta manufacturing facility and the risk assessment that accompanies the classification process.

Figure 2.1 at the end of Section II shows a generic pasta manufacturing PSCA layout. This should help the reader better visualize how to prepare a schematic of their own facility and identify the PSCA and general GMP areas.

### **2.1 Defining the PSCA**

- In a low moisture facility, such as a dry pasta manufacturing facility, the PSCA is the area where the handling of ingredients and product requires the highest level of hygiene control.
- Along with the PSCA, a transitional or buffer area and a basic GMP area may be identified. These areas are determined by examining the proximity of the area to the final product and the probability of *Salmonella* being present in the process/product.
- The PSCA should be defined using a risk assessment of each step in the dry pasta manufacturing process.

### **2.2 Establishing Barriers Between Areas or Zones**

- PSCA: The PSCA should be a controlled environment; i.e., some form of barrier should be present to control traffic along with dust or other possible airborne contaminants. This can be accomplished by using plastic curtains and walls or a form of air diversion or filtering.
- Basic GMP areas: Employees may walk through the PSCA to reach Basic GMP areas. They should not walk through Basic GMP areas to reach the PSCA, risking possible contamination of the area. Building design should reflect this concern.
- Non GMP areas: Non-GMP areas such as break rooms, hallways and offices should be segregated from Basic GMP areas and the PSCA.

### **2.3 Risk Assessment of the Pasta Manufacturing Process**

- **Raw Material/Ingredient Receiving and Storage**: This area should be classified as PSCA. Some ingredients (e.g., eggs, spinach) are considered to be *Salmonella* sensitive. Storage areas must be kept clean to avoid contamination from the environment. All raw materials and ingredients must be separated from finished product and finished product packaging and should not be brought to the production floor until needed for processing.
- **Mixing and Extruding**: This area should be classified as PSCA. There is no kill or pathogen inactivation in this step of the process.
- **Drying**: This area should be classified as PSCA.
- **Packaging**:
  - The packaging process generally should be designated as PSCA. In particular, if there is not a separation or divider between production and packing, the packaging area should be classified as PSCA.
  - However, if there is a transitional area or barrier between the production and packaging areas, the packaging floor could be classified as a basic GMP area.
- **Warehousing**: Warehouses and shipping docks should be classified as basic GMP areas.

## 2.4 Product and Personnel Control Measures to Prevent Contamination

- Employees
  - Under FDA's preventive controls final rule, all employees must be trained for Basic GMPs with additional training as appropriate for their responsibilities in the plant. This training must be documented.
  - Employees should be provided with uniforms that remain at the plant and are washed either in house or at a contracted industrial laundry facility.
  - The plant may also consider providing designated shoes or implementing a GMP banning the wearing of outside shoes inside the processing area.
  
- Traffic Control
  - As discussed previously, employees may walk from the PSCA to the Basic GMP area, but they should not walk through the Basic GMP area to the PSCA.
  - Forklifts used to transport raw materials and ingredients into the PSCA should be designated for that use only, and never used for moving finished product or packaging.
  
- Buckets and Waste Disposal
  - Bins, buckets, and other disposal items should be labeled as such and assigned for specific areas. For example, if a bin is used for rework/regrind, it should be labeled as "rework/regrind" and never used for trash, by-products or any other purpose. A color coding and labeling system for all containers is recommended.
  
- Material Control
  - Waste materials should be kept away from the PSCA. This includes trash as well as pasta by-product materials that will be sent for use as animal feed.
  - Product delegated to rework/regrind should be stored in a PSCA and handled with the same amount of precaution as all other ingredients/raw materials.
  
- Utensil Control
  - There should be vacuums assigned for the PSCA and for the Basic and non GMP areas.
  - Brooms, brushes, dustpans, and other cleaning utensils should be identified as PSCA use or non PSCA use. These items should also be specified for food contact or non-food contact surface area use. A color coding and labeling system is recommended.

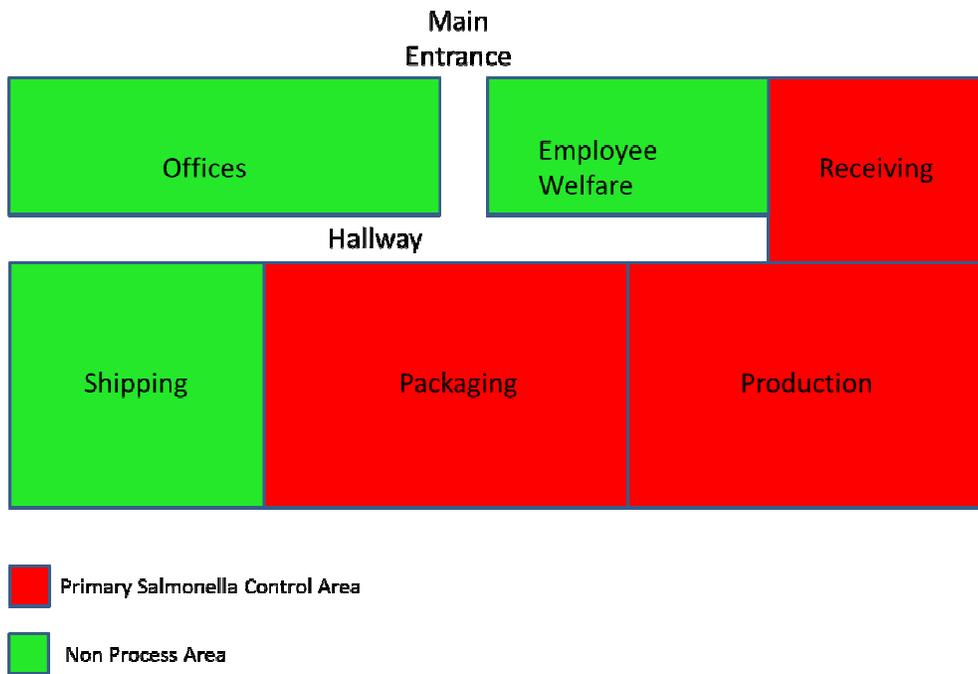
## 2.5 Sanitation Methods to Prevent Contamination

- Cleaning Method
  - Cleaning methods in dry pasta manufacturing can be divided into 3 categories: dry, controlled wet, and wet. There are usually written procedures for these methods.
    - Dry cleaning removes residue (food, dust, etc.) without using water. This includes sweeping, dusting, scraping, and vacuuming. Dry cleaning should be the routine practice in the PSCA.
    - Controlled wet cleaning uses a limited amount of water with a sanitizing step and complete drying occurring after the use of water. Controlled wet cleaning may be used as needed in certain areas or pieces of equipment. If possible, remove equipment from the PSCA, use controlled wet cleaning, sanitize, dry, and then return the equipment to the PSCA.
    - Wet cleaning uses water, but it should only be used as necessary. Areas cleaned with water must be completely dried and verified afterwards for sanitation effectiveness.
  
- Dust

Dust must be managed and removed in an apt manner. As discussed previously, barriers such as a wall or curtain or another method of diverting airborne materials from the PSCA to other areas of the building should be present.

- Sinks  
Hands-free sinks with air hand dryers or hand sanitizing stations should be present at all entrances into the PSCA.
- Water  
The presence of water in the PSCA should be avoided whenever possible. This includes the use of water when cleaning as well as other sources. All employees should be trained to report any incident of leaks or condensate and timely repairs must be made.
- Drains  
When possible, drains should not be present. If drains are present, floors should be sloped to facilitate proper drainage. There should be scheduled annual maintenance and sanitation activities for these areas.

Figure 2.1. Generic Pasta Manufacturing PSCA Layout



### SECTION III – ELEMENT 3: APPLY HYGIENIC DESIGN PRINCIPLES TO BUILDING AND EQUIPMENT DESIGN

Hygienic building and equipment practices are major requirements to control the microbial contamination of dry pasta products. *Salmonella* is inactive in low moisture environments—but although it does not grow, it also does not die. Rather, it can become active later upon rehydration. Process and post-process contamination are significant concerns. Hence, a sound hygienic design, cleaning and sanitation program is necessary to ensure that no microbial load is present on equipment used in the production and packaging process.

#### 3.1 Hygienic Design of Equipment & Facility

- Review equipment prior to purchase for sanitary design and plant layout compatibility
- Project participation and sign-off by Quality Assurance is suggested.
- Optimal design and equipment maintenance should:
  - Keep the design as simple as possible and easy to clean, with a minimum number of parts and all parts and assemblies accessible for inspection, service, maintenance, cleaning and sanitizing.
  - Evaluate the quality of construction at surface finish, joints, crevices, drainage, dead space, doors, covers and panels, controls.
  - Differentiate between food and non-food contact surfaces.
- The type of cleaning will dictate the design; dry versus wet, degree of cleaning and/or inspection.
- Clean at a frequency appropriate to the design.
- Equipment exposed to water has to be designed differently to account for retention of water, corrosion-resistant material, etc.

#### 3.2 Equipment Modification/Equipment Installation

- The Quality Manager needs to be involved in the equipment installation process.
- Review the layout of equipment installation conducted by contractors or internal maintenance
  - Protection of adjacent active production areas from construction activities is key.
  - For equipment modifications, ensure they are free from cracks, chips, poor welds and microbial harborage points. For example, hollow tubing which has been drilled creates internal microbial dead spots unless properly sealed.
- Construction area rules must be written, documented, trained and monitored. Verify with spot audits.
- Unused equipment brought from the bone-yard should be cleaned and sanitized outside the PSCA before bringing it into the plant.

#### 3.3 Cleaning/Sanitation of Equipment at Each Stage of the Pasta Process

- Infrastructure and design and installation must avoid microbial growth niches and allow for microbiologically focused sanitation. The following are recommendations for areas and equipment in need of these specific types of cleaning/sanitation:
- Use your existing cleaning standards for these areas.
- Dry Cleaning is utilized for:
  - Primary flour handling areas
  - Cleaning of storage silo – define the methods and their frequency; include transfer hoses from delivery truck to silos.
  - Flour conveying piping system in the plant – document if there is a purge clean protocol
  - For dry sanitation only areas – focus on accessibility for dry cleaning and dust control. Utilize vacuum cleaning as much as possible. Avoid compressed air blowing, as this lifts and settles dirt and microorganisms.
- Wet/Dry Equipment cleaning is utilized for:
  - Mixer/dosing area (use dry and wet methods as documented in your cleaning procedures)
  - Mixers or other dry blending equipment like re-grinders and sifters
  - Press/extruder/screws/dough/sheeters/cutters/equalizer plates
  - Inside of dryer, conveyor belts, dryer walls, etc.
  - Packing room equipment (dry clean product spillage, careful damp cleaning of grease and dirt followed by sanitizer)
- Special/High Risk Area:
  - Wet rooms (e.g., die wash area)
    - Ideally these would be located in a separate room.
    - Sanitation of die washers per SSOPs
    - Die - after-washing protocol alternatives:
      - Use of alcohol spray, or mineral oil spray. This may present an issue with dust sticking on it. Have a contingency plan in case this occurs.

- After cleaning, dry the die and wrap it in plastic.
  - Clean, dry and sanitize the die before next use.
- Die storage and soak tanks in a wet environment
- Prevent the exit of water from the wet room into surrounding processes or into a dry processing area.
- Drying room (pre-shaker, pre-dryer, continuous and static dryers, coolers, accumulators) – Follow documented protocols based on risk
- Vacuum/Dust Collector – Dry clean and inspect at a documented risk-based frequency.
- Finished product holding bins, fillers, hoppers, conveyors, metal detectors, check-weighers, palletizer, tote dumpers, tables, etc. – Follow written cleaning protocols for each based on risk.
- Warehouse equipment – Forklifts, other transfer machinery and equipment should be clean. Forklifts should be designated exclusively for their intended use – for example, only for use outside the plant or only for use in the PSCA.
- Water drainage must ensure rapid drying. Floor drains should not contain stagnant water. If no floor drains, vacuum or mop, then air dry low spots on floor.
- All cleaning and frequencies should be fully documented, with risks evaluated. Employees must be trained on proper use of chemicals and concentrations.

#### 3.4 Emergency Breakdowns in Facility and Equipment

- During an unscheduled maintenance activity, hygienic procedures should be strictly followed.
- Ensure protection of adjacent production areas.
- Follow cleaning and sanitizing procedures, post verification and validation.

#### 3.5 Accessory Tools Clean-up and Sanitation

- Equipment and accessory tools (vacuum cleaners, valves, hoses, belts, tools) should be properly maintained and corrosion-free.
- Tools and supports and ladders should be of hygienic design, with no hollow bodies, loose parts, or uncleanable surfaces.
- Stick washing and cleaning protocol should be established and documented.
- Bucket elevators – frequency of cleaning and how to clean should be established within SSOP.
- Plastic tubs for rework – FDA approved tubs and totes, cleaning procedures for tubs and totes should be established within SSOP.
- Cleaning tools should be color-coded for allergen use only, product contact area cleaning, and non-product area cleaning.
- Catwalks and step-over platforms should be impervious material with sealed toe-kicks.

#### 3.6 Employee Education/Training Specific to Building, Equipment and Design

- Train maintenance and all other employees that their regular activities should be conducted with hygiene in mind
- Cleaning procedure training should be conducted whenever new or old equipment is brought in.
- Elaborate on the difference between:
  - Resident *Salmonella* – That which has not been effectively removed and will come back until properly identified and eliminated.
  - Transient *Salmonella* – That which occurs as the result of an isolated event.
- Active spot audits by the food safety team must be conducted to verify the effectiveness of cleaning protocols.

Additional training procedures are found in Section VIII.

## SECTION IV – ELEMENT 4: PREVENT OR MINIMIZE GROWTH OF *SALMONELLA* WITHIN THE FACILITY

This section covers the prevention or minimization of *Salmonella* within the facility. Water in a dry processing environment is one of the most significant risk factors, as it allows *Salmonella* to grow. Therefore, a pasta facility should focus on the control of water and moisture accumulation in order to prevent or minimize *Salmonella* growth.

### 4.1 Minimization of Water Use

- *This is one of the most critical elements in preventing growth of Salmonella.*
- Implement regular cleaning and monitoring procedures. If wet area is adjacent to high risk area, utilize sanitizing procedures (SSOPs).
- Maintain effective segregation of die room (wet) from press area (dry).
- Consider dry sanitizer for entrance/exit to die room or other wet wash areas.
- Utilize dry cleaning method wherever possible, particularly in PSCA.

### 4.2 Selection and Method of Cleaning for Various Hygiene Areas

- Create plant layout identifying hygiene areas with designated cleaning methods for each. Color code to create easy reference for training.
- Three types of cleaning methods are to be employed (Also refer to GMA, Table 4-1, p. 42)
  - Dry cleaning
  - Controlled wet cleaning
  - Wet cleaning
- Color code cleaning tools to match the cleaning method (additional colors may be necessary due to allergen control requirements).
- Assure written procedures for each method are in place and employees are properly trained on these methods.
- Older facilities may require special attention, as they may not be designed based on current sanitary principles. There is a higher potential for cracks and other niche points in older facilities.
- Dry clean niche points even if they still appear dusty after cleaning. Once they become wet, niche points present more of a microbial risk even if they appear to be clean. This applies to all facilities.

### 4.3 Elimination of Water in PSCA

- Create a separate wet cleaning room for Clean-Out-of-Place (COP) items outside of the PSCA.
- Use *textured* sanitizing wipes in lieu of the handwash sink, if necessary.
- Assure a robust air filter maintenance program is in place to prevent condensate in lines.
- Assure proper balance of air handling systems to prevent condensate at dryer entrances/exits (hot/cold interface).
- Perform thorough inspection of dryer interiors during preventive maintenance and sanitation to identify potential moisture accumulation points, as these points are not visually apparent during production. Look for clumps of product accumulation or water stains.
- Assure that a procedure for reporting food safety issues, particularly leaks and condensate, is in place and that employees are properly trained.

### 4.4 Controlled Wet Cleaning

- Assure a high-risk incident sanitation procedure is in place (for example, roof leaks, drain back ups).
- Describe in written format how to contain water; color code cleaning tools; sanitize area and tools after cleaning; increase environmental monitoring to verify risk assessment and corrective actions, and capture all of at-risk product from potential contact with this water source.

### 4.5 Establishment of Dry Cleaning Procedures for the PSCA

- Identify each piece of equipment in the PSCA.
- Utilize photos as a job aid to point out critical areas and assure effective cleaning.
- Eliminate or seal off all drains not necessary in this area.
- Have a procedure in place to ensure new or used equipment is properly cleaned *before* assembling in GMP area or PSCA (possibly include this as part of contractor policy).

## SECTION V – ELEMENT 5: ESTABLISH A RAW MATERIALS/ INGREDIENT CONTROL PROGRAM

### 5.1 Obtain Ingredients from an Approved Supplier

A supplier approval program should be developed to assess the adequacy of control measures the supplier has implemented to mitigate the risk of *Salmonella* in sensitive ingredients (e.g., eggs, spinach). Supplier verification is important because the absence of *Salmonella* in sensitive ingredients, dry-mixed ingredients, or finished products cannot be assured through testing alone (FAO/WHO, 2006; EFSA, 2008). (GMA, p. 46) FDA's final rule on preventive controls for human food contains detailed regulatory requirements for a supply-chain program that companies must follow as part of their food safety plan. (21 C.F.R. Part 117 Subpart G.). The recommendations herein are intended to complement the regulatory requirements, but companies also should recognize their obligation to comply with the supply-chain program regulation.

- Supplier Approval Program: Develop a written program with flow charts to outline the approval process including which corporate and facility functions are involved and who signs off (e.g., R&D, Purchasing, QA).
- Supplier Information Form: Develop a detailed form asking appropriate questions to include technical data about the ingredient, significant hazards, chemical make-up, *Salmonella* sensitive, contact name, etc. An example of those questions is included at the end of this element in Figure 5.1.
- Samples Received and Reviewed
  - Ensure Quality Dept. is involved in the ingredient approval and decision process. Review the technical data sheets when received by Purchasing, R&D, and Quality. Have a mandatory sign-off by all departments on final formulas and ingredients.
  - Write into the supplier specification that if they use or switch to any other supplier or facility (such as to obtain cost savings or increase availability) you must be notified beforehand. At that point you will want to evaluate the risk of the new supplier or facility.
  - Review ingredient technical data sheets and supplier information annually to ensure nothing has changed.

### 5.2 Evaluate the Supplier's Food Safety Program

Include in your supplier approval program mechanisms to ensure the adequacy of the supplier's food safety programs; risk assessment matrix, on-site audits, existing audits by qualified third party auditors. (GMA, p. 46)

- Risk Assessment Matrix
  - Maintain a Vendor/Supplier Contact Information list with risk assessments determining the audit frequency of each supplier. Review annually to ensure contacts have not changed. Provide comments on each risk assessment as to why frequencies of audits are chosen.
  - Include whether a supplier is from a high-risk country (e.g., China) and who is auditing that supplier.
  - If you source an ingredient from a broker, you will need to identify the actual product manufacturer so that you can conduct supplier verification directly. Note that you can rely on the broker to conduct supplier verification on your behalf, but the broker's needs to provide you with adequate documentation. Also, if you rely on the broker to verify the actual manufacturer, do not just accept the broker's assurance of ingredient safety. You still need to approve the supplier. How is the broker verifying/validating the supplier's food safety program?
- On-site audit
  - If an on-site audit is warranted from your risk assessment of the ingredient or supplier, you can either conduct the audit yourself (using an employee who is appropriately qualified) or use a qualified third party.
  - If you elect to do the audit yourself, use an audit template with probing questions about their food safety (*Salmonella* mitigation) and supplier programs. See Vendor Approval Program Highlights, Figure 5.1, below. Send this prior to the on-site audit and verify the responses when on site.
  - If an audit conducted by a third-party, including under an approved Global Food Safety Initiative (GFSI) audit scheme, is acceptable to you in lieu of an on-site audit conducted by your company, ask for the complete audit report, not just the certificate. You may have to sign a confidentiality agreement which states you will not circulate the document without the owner's permission, but should bear in mind that some of this information is available to FDA. Review the deficiencies and corrective actions closely. Follow up with the supplier for more detail if needed.
  - Be comfortable and confident any identified risks from the audit were mitigated and verified.

### 5.3 Incoming Ingredient Testing

- Testing Protocols
  - For ingredients requiring *Salmonella* testing, push to have them tested prior to arrival at your facility. Have the supplier send samples to an independent lab with results to both you and the supplier. (You should expect to pay for these tests.)
  - If testing must take place after receipt of the ingredient, provide clear communication to the supplier of your intent. Failure of pathogen testing could result in notification to the FDA through the Reportable Food Registry (RFR).
  - If testing must take place after your receipt of the ingredient, ensure that the entire lot remains “on hold” pending receipt of the testing results.
- Tolerances and Frequencies
  - Establish and follow set frequencies of tests
    - Test each lot based on risk assessment.
    - **Never retest a lot if it tests positive for *Salmonella* for the purpose of releasing the product.**

#### 5.4 Corrective Actions for Non-Conformance if *Salmonella* Found

- Develop a written corrective action program with step-by-step instructions of what to do if *Salmonella* is detected through product testing. Hold the ingredient or product, segregate the lot, and notify the supplier for immediate pick up or destruction.
- Reportable Food Registry (RFR) notification
  - Be prepared to notify the FDA through the RFR if incoming ingredients test positive for *Salmonella*. Be prepared to show that the affected lot is locked down and will be removed immediately, as well as to demonstrate that no other product in your facility is affected.
  - This notification is required within 24 hours.

#### 5.5 Hold and Release Program

- Raw Material Receiving
  - Have a written protocol for receiving loads of sensitive ingredients.
  - If you require pre-testing, ensure test results are received prior to unloading transport or that raw material is held in a designated, segregated hold area until results are received. Have qualified personnel meet the transporter and verify lots and counts are accurate and match the testing results.
- Tags and Electronic Holds
  - If testing will be done in house, tag ingredients and store in a designated, segregated hold area apart from other, similar approved ingredients to prevent use prior to approval.
  - Once testing results are received and approved, release the lot immediately and move it away from hold stock.
- FIFO (First In, First Out)
  - Use the first in, first out protocol to keep from pulling ingredients out of rotation and to aid lot bracketing.
  - If another company receiving these same ingredients from the supplier tests the lot and finds positive results, your lots may become involved. Insist the supplier provide you with dedicated lots in proper sequence, when possible.

**Figure 5.1. Vendor Approval Program Highlights**

- Review the results of supplier visits /audits (both when conducted by your company or a 3<sup>rd</sup> party)
- Maintain sound ingredient specifications (review periodically; establish clearly detailed specs and testing requirements)
- Review of operations and QA programs of all suppliers (HACCP / Pest Control Program / Environmental Management Program (EMP) / Audits of their suppliers / ethical sourcing statements and follow up)
- Review microbiological environmental data from suppliers (detail frequencies / zones monitored / indicator organisms tested / pathogens and lots locked down)
- Review of sampling and testing programs and data from ingredient and finished good suppliers (Certificates of Analysis)
- Review sanitation practices of suppliers (Master Cleaning Schedules / frequencies / allergen control / validation [e.g., Neogen style quick tests])
- Review supplier's traceability program (review last 2 test traces; one forward, to the customer, and one back, to the supplier, as a minimum)
- Review supplier's process validation step (review testing done, plus results; review Corrective Action Response (CAR) if positive results are found.)
- When possible, it is best to purchase entire lots of material and not split lots. This keeps items in proper rotation and minimizes exposure to lots being sent to several customers if an issue develops or another customer decides to test the lot out of their control. If another company receives a positive pathogen test for the same lot, your product may be implicated and a recall may be necessary.
- Have alternate suppliers when possible to ensure availability of ingredients or in case other issues arise.
- If supplier is a broker ask the same questions: who is auditing their suppliers?

## **SECTION VI – ELEMENT 6: VALIDATE CONTROL MEASURE TO INACTIVATE *SALMONELLA***

“Determine the target level of *Salmonella* reduction in the product and process under consideration. Determine the adequacy of the selected control measure and associated critical limits for processing, keeping in mind the increased heat resistance reported for *Salmonella* at low water activities. Challenge studies may be warranted. If the lethality of the process is validated by scientific data, ensure the operation can deliver the critical limits. Non-thermal control measures can also be used, with validation, to eliminate *Salmonella*.” (GMA, pp. 5-6)

### **6.1 Literature Review**

A very low incidence of *Salmonella* contamination has been directly linked to dry pasta in the US. There is still the potential, as evidenced by the Sperber study (Sperber et al, 2007), that our primary raw material, flour, could support very small quantities of *Salmonella* after milling.

### **6.2 Validation for Dry Pasta**

The NPA has worked with outside consultants to develop a validation study for pasta. It is a given in our industry that manufacturers operate different equipment in their pasta plants. Equipment manufacturers, age of the equipment, and varying time/temperature profiles make it difficult to apply one set of dryer profiles to eliminate any potential presence of *Salmonella*. Time and temperature ranges vary widely, and different combinations may or may not completely reduce the bacterial load in dry pasta. In light of this variation and the inherent challenges of validating the wide range of processes used throughout the industry, NPA efforts currently are focused on validating the cooking process as a validation step. Because dry pasta requires consumer preparation and is a not ready-to-eat food, it is appropriate to validate consumer preparation as a kill step.

We have relied upon the fact that our products are being cooked (boiled) before consumption and that provides a final thermal kill step if there was any remote chance of *Salmonella* making it through our process. Literature supports the effectiveness of a thermal kill when *Salmonella* is subjected to boiling water. The research question we want to answer is at what hydration ratio this occurs (i.e., yield vs. cook time).

- Because of various cook times, NPA’s research effort will compare microbial log reduction to pasta hydration ratios which could be applied to any thickness of pasta. NPA is utilizing an outside food laboratory to validate the effective thermal kill of *Salmonella* during the cooking process.
- The research will also verify the use of the hydration ratio in determining effective cook times.
- Test results are pending study completion.

### **6.3 Clean Break: Importance of Lot Control in Bracketing a Positive *Salmonella* Event**

In the event of a positive *Salmonella* finding in finished product, establishing a clean break can help bracket the scope of product affected by the incident. In 2011, NPA solicited experts in the field of microbiology to advise on the role of microbial clean breaks in the pasta making process. The experts independently evaluated separate facilities and advised the industry that certain sanitation steps can constitute a clean break, but the analysis is facility specific. They also emphasized the importance of implementing robust GMPs and SSOPs in order to mitigate the potential for *Salmonella* contamination. In particular, emphasis was placed on building upon prerequisite programs to minimize the probability of an event through post-process contamination.

### **6.4 Prerequisite Programs to Eliminate *Salmonella***

The fact that all drying processes may not reach the necessary time and temperature to achieve a thermal kill supports the need for a strong focus on prerequisite programs to minimize the introduction and proliferation of *Salmonella* in the process.

We have many non-thermal programs at our disposal to be used in conjunction with the GMA’s seven key elements, including: Master Sanitation, Integrated Pest Management, Water Testing, Good Manufacturing Practices, Inspections and Preventive Maintenance, to list a few.

## **SECTION VII – ELEMENT 7: ESTABLISH PROCEDURES FOR VERIFICATION OF *SALMONELLA* CONTROLS AND CORRECTIVE ACTIONS (ENVIRONMENTAL MONITORING PROGRAM)**

The adequacy of the *Salmonella* control program should be verified on an ongoing basis to assure effectiveness and drive continuous improvement. Verification should focus on implementing a robust environmental monitoring program that has been designed to identify transient and/or resident *Salmonella* in the processing areas, even though such environmental monitoring may not be part of the facility's Food Safety Plan. (GMA, p.59)

### **7.1 Development of Environmental Monitoring Program (EMP)**

- An effective EMP must be robust, meaning that personnel must actively search to test areas susceptible for positive *Salmonella*. Risk assessments of the plant should be completed to determine the sampling sites based on risk to finished product exposure. (See Section II, above)
- Testing procedures must be scientifically valid.
- Recommended practices include a “seek and destroy” methodology that includes a risk assessment and protocols for finding the highest risk areas within the manufacturing environment while also routinely scanning the peripheral, lower risk areas.
- Emphasis should be placed on areas with raw, unprocessed materials (especially those with high moisture exposure) and zoning outward, following high foot and forklift traffic patterns throughout the facility.
- Emphasis in the program should be placed on Zone 3 areas within a processing environment and expand outward to Zone 4 areas based on risk of transmission through the plant.
  - Zone 3 Areas (Also refer to GMA , Table 7-1, p. 64,)
    - Raw material processing areas. Examples include receiving areas and processing rooms and drains in these areas (first point of entry into the plant/process)
    - Floors, structures, drains, and high traffic areas around mixing and extruding processes
    - The floor decking around an egg dump
    - Floor drains in that area
  - Zone 4 Areas (Also refer to GMA, Table 7-1, p. 64,)
    - Employee entrances, contractor or maintenance entrances, dock doors (receiving and shipping)
    - Threshold of doors leading outside from maintenance or employee smoking areas which could be tracked into the plant during normal operations
    - Remote areas in the plant such as warehouse exterior perimeters or areas with limited traffic should be cycled into the program at a lower frequency.
    - Any peripheral locations that appear to possess a risk or are not considered normal, such as roof leaks, product spillages in hard to clean areas, excessive debris accumulation, etc.
- Testing for indicator organisms, such as *Enterobacter*, should be used as a recommended practice. Presence of indicator organisms will indicate the conditions necessary for *Salmonella* to grow and sanitary measures should be taken to eliminate these conditions before *Salmonella* can grow. The presence of indicator organisms does not necessarily mean that *Salmonella* is present, but rather they predict conditions that are favorable for *Salmonella*. Therefore, sanitary measures should be taken to prevent *Salmonella* ingress.
- Zone 1 and Zone 2 monitoring is not mandatory for the program to be effective but is a recommended practice to control conditions necessary for *Salmonella* to grow. (Also refer to GMA, Table 7-1, p. 64) Companies engaging in Zone 1 testing should have procedures in place that address how they would respond to a positive test result and should strongly consider implementing a “test and hold” program.
- Specific high-risk areas within a plant should be assessed by a cross-functional plant team that would include QA, Sanitation, Operations, and Maintenance to determine environmental swabbing locations and frequency.
- A plant cross-functional team should assess the swabbing locations determined from the risk assessment and assign swabbing frequency based on the risk assessment. Testing in lower risk areas should be less frequent and higher risk areas should be more frequent.
- *Salmonella* testing should never be completed in a laboratory within a processing facility due to potential cross-contamination risk from the growth of *Salmonella* from swabs and the presence of positive controls for verification. The recommended practice would be to use either an off-site internal lab with proper laboratory Good Laboratory Practices or a contracted third-party laboratory that is certified for this testing.

## 7.2 Corrective Actions for Suspect Result

- If you are going to test, you need to have corrective action protocols in place for how you will respond to positive findings. Sanitize the area immediately after swabbing so if there is a positive, then you know it has been killed before the results came back.
- If you find *Salmonella*, swab out further from the positive test area to see if the *Salmonella* was localized or coming from another source, etc. (use a ring target approach with the positive site as the bulls eye and vectoring out in three different directions within 4 to 6 feet of the original positive site). If another positive result is received, sanitize entire area then continue to vector out into the next ring of the target until all negative results have been obtained. The section that follows discusses a root cause analysis to address the underlying cause of the problem.
- Recommended practices typically would be three consecutive negative result sets within a two-week timeframe to consider an area controlled.

## 7.3 Results: Tracking and Trending

Results should be recorded into tracking software that allows for trending analysis of results over time. Data should be reviewed by QA and Sanitation to determine if further root cause analysis is needed to find and eliminate repeat positives or patterns in the data.

- Use trends to identify “hot spot” areas where repeat positives/suspect results are occurring.
- Assemble necessary plant resources to review if short-term corrective actions (e.g., re-rerouting traffic patterns or foot sanitation improvements) are needed, or if long-term corrective actions are needed (e.g., drain repairs, drain relocations, processing changes where moisture accumulates) are needed.
- Recommended practices for a Pathogen Environmental Monitoring (PEM) program will also include a hygienic restoration program. Hygienic restoration is required when an insanitary condition is created within the plant with non-potable moisture from a high risk area. This would include, but not be limited to: roof leaks, air conditioner condenser leaks inside the facility, drain backups, fire sprinkler system discharge, etc. When a hygienic event has occurred, the following practices should be followed:
  - Step 1: Repair the root cause immediately (if capital investments are required, determine short-term corrective actions and monitoring plan until long-term corrective actions can be completed)
  - Step 2: Clean and sanitize the areas affected.
  - Step 3: Complete pathogen swabs of the area affected and area around where the event occurred.
  - Step 4: If any positives are found, re-evaluate root cause then follow corrective actions in Step 2 until three consecutive negatives are achieved in the area with positives.
- Annual review of PEM program should be completed by a cross-functional team to determine effectiveness of the plan, corrective action effectiveness, and overall health of the program and plant.

## 7.4 Documentation

Documentation is critical to prove the rationale behind the program and its effectiveness to control the pasta plant environment. Maintain documentation of the following, at a minimum:

- Environmental monitoring procedures that (1) identify the test microorganism(s), (2) identify the locations where samples will be collected and the number of sites to be tested, (3) identify the timing and frequency for collecting and testing samples, (4) identify the test(s) conducted, including the analytical method(s) used, (5) identify the laboratories approved to conduct testing, and (6) set forth corrective action procedures.
- Process mapping and risk assessment/rationale
- Log of results and any trending data analysis
- Thorough corrective actions taken as a result of a positive/suspect, including post restoration follow-up swabbing
- Hygienic restoration corrective actions and results, including any post restoration follow-up required
- Annual review of the program and any corrective actions or changes to the program from this review.

## 7.5 Finished Product Testing

If finished product or any internal product testing is conducted, make sure the entire lot is locked down until the testing results are received. Have an action plan established in the event a positive is found.

- Be careful to only sample finished goods after a sanitation step so you have a “clean break” to limit the scope of affected product.
- If you find a suspect or positive, product must be destroyed or diverted for animal consumption (if appropriate). Product that tested positive must not be sampled further to obtain different results.

## **SECTION VIII -- ELEMENT 8: TRAINING AND EDUCATION PROGRAMS**

Effective training and educating at all levels of our organizations is key to understanding and implementing the above recommendations. Training and education also presents a challenge for all of us. Finding training methods that not only are effectively retained, but that can be passed on as “just the way we do things”, is ideal in creating a food safety culture where new processes are welcomed as improvements rather than inconveniences. This element addresses training techniques to achieve this goal.

### **8.1 Training Within Industry (TWI)**

TWI uses a learn-by-doing approach. It provides teaching essential skills for all types of industries. It is different from the training systems we are using now and can require a mind shift to be effective. This can be the missing link in making training effective.

TWI consists of four basic training programs: Job Instruction, Job Methods, Job Relations and Program Development. This guideline will concentrate on Job Instruction.

### **8.2 Job Instruction**

“If the worker hasn’t learned, the instructor hasn’t taught.” Having a training program, but not teaching the instructors how to train, will result in failure. Once in place, this program teaches instructors to train inexperienced workers and get them “up to speed” faster. The instructors are taught to do the following:

- Break down process into closely defined steps (See Figure 8.1, below)
  - Prepare the students by putting them at ease
  - State the process and find out what they already know about it
  - Get the students interested in learning more about it.
  
- Show the procedures while explaining the key points and the reasons for the key points.
  - Present the operation through one important step at a time
  - Stress each key point
  - Instruct clearly, completely and patiently
  - Utilize one-point lessons with pictures to supplement written materials.
  
- Watch the student attempt under close coaching (This can include the traditional “testing” section.)
  - Try out what has been learned
  - Have them do the process and correct errors
  - Make sure they understand by having them explain each key point as they do it (demonstration and/or testing).
  
- Wean the student from the coaching.
  - Put the students on their own
  - Designate who they should go to if they need help
  - Check frequently with encouragement
  - Taper off the coaching and provide them with a standard work for reference
  - Ask for volunteers to assist in the next training session of the same process.

### **8.3 Delivery Methods**

- PowerPoint presentation with applicable pictures/photographs delivered by a live trainer or through an online system (such as Protrain)
- One-on-one sessions with a trainer (mostly on the job)
- Group sessions with a trainer.
- Train the trainer documentation should be maintained showing what credentials the trainer has and where they were received.

### **8.4 Training Frequencies**

- Each new or transferred employee
- Refresher training should be conducted every six months to a year
- Build training to your audience; bilingual if needed
- Document training and keep a matrix of employees ensuring those not trained due to absence are picked up on another schedule.

**Figure 8-1. Example of Job Instruction Breakdown Sheet**

**Operation:** Changing an insert  
**Parts:** Tool holder, new insert  
**Tools & Materials:** 5/32" hex key, 1/4" hex key

<b>STEPS</b>	<b>KEY POINTS</b>	<b>REASONS</b>
<i><b>What is done</b></i> A logical segment of the operation when something happens to advance the work.	<i><b>How it is done</b></i> Anything in a step that might: - Make or break the job - Injure the worker - Make the work easier to do	<i><b>Why it is done</b></i> The reason for the key points.
1. Remove insert & seat	Swing clamp off insert first	Easier to remove parts
2. Inspection	Insert: no chips, burns Seat: no wear, cracks Tool Holder: no wear, burrs, cracks	Any defects will result in poor part quality, longer cutting times, or excess tool and machine wear
3. Install new insert	Seat: keep loose with tip-to-tip centering Insert: snug down Clamp: snug Insert: loosen Clamp: tighten	Insert/Clamp: sequence allows insert and seat to be flat and secure The insert won't cut correctly, resulting in tool and part damage

**8.5 Training Shortfalls**

- Failure to understand your audience
- Death by PowerPoint – slide after slide of just text
- Complicated language that is unclear/confusing
- Directions to just “read and sign” that you were trained
- Lack of verification of effectiveness; verify comprehension using short quizzes and/or trainer observed sign-offs
- Sessions longer than an hour without a break
- Exceeding the scheduled training time.

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