pathogen environmental monitoring program (PEM)

Presented by the Almond Board of California

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Almond Board of California

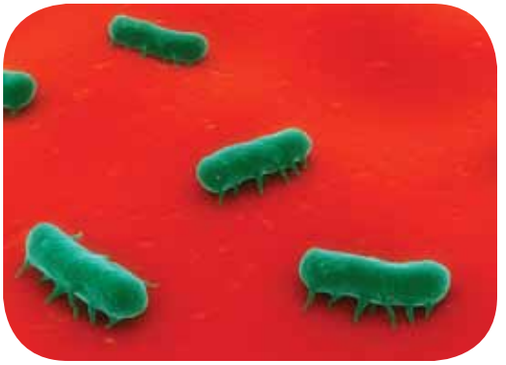

Preventing
Salmonella
Recontamination:
Pathogen
Environmental
Monitoring
Program Guidance
Document

Introduction

A review of the history of the microbiological hazards associated with tree nuts and nut products, including almonds, shows that *Salmonella* spp. is one of the primary target pathogens of concern at all stages of production and handling. The Hazard Analysis Critical Control Point (HACCP) approach is the most widely accepted food safety management framework around the world and is endorsed by the Almond Board of California for use by almond handlers for the production of safe and wholesome products. HACCP is a systematic science-based approach that identifies, assesses and controls the risk of biological, chemical and physical hazards in the product (1). The HACCP approach consists of seven principles, each of which must be followed for successful implementation. The first HACCP principle states that the HACCP team should conduct a hazard analysis that assesses the food safety hazards that are reasonably likely to occur and that must be controlled for the production of safe product. Since history has revealed *Salmonella* spp. to be one of the reasonably likely food safety hazards to occur within the almond production environment, it is critical that an almond facility's HACCP plan identifies, assesses, and seeks to control and mitigate that risk.

An effective mechanism for controlling the risk of *Salmonella* in the almond production environment is the implementation of a Pathogen Environmental Monitoring (PEM) program. As an integral component of an almond facility's HACCP plan, a well developed PEM program will control and mitigate the risk of *Salmonella* spp. contamination proactively in both the production and post-production environment. This document is intended to outline the necessary tools and steps to develop and implement such a program.

Characteristics of *Salmonella*



The genus *Salmonella* consists of rod-shaped, gram-negative, non-sporeforming, predominately motile cells that can grow either aerobically or anaerobically and are members of the family *Enterobacteriaceae*. In nature, they are found in both warm- and cold-blooded animals, humans, and in the general environment, including the soil and water (2). *Salmonella* spp. can grow in the temperature range of 41°F (5°C) to 113°F (45°C) with the optimum growth range of 95°F (35°C) to 109.4°F (43°C). Growth is slow at temperatures below 50°F (10°C), and most strains do not grow at temperatures 44.6°F (less than 7°C). *Salmonella* spp. has a pH range for growth of pH 4 to 9 with an optimum of 7 to 7.5. Almonds fall within this optimum pH range. *Salmonella* spp. is classified according to serotype, and over 2,400 serotypes have been described for the genus.

Since *Salmonella* spp. are vegetative bacteria, they are not as heat resistant as bacterial sporeformers. Strains of *Salmonella* do vary, however, in their ability to resist heat. For example, the strain *Salmonella* Senftenberg 775W is about 10 to 20 times more heat resistant than the average strain of *Salmonella* at high water activity (A_w). A_w is a measurement used to describe the water that is available in a food for the microorganisms to grow. Under favorable conditions, *Salmonella* spp. can grow in the A_w range of 0.94 to more than 0.99, with 0.99 being the optimum A_w for growth. Typically the water activity of almonds under proper storage conditions is below the level required for *Salmonella* growth. However, the addition of moisture or water can create conditions that allow *Salmonella* to grow if it is present on the nuts. Of particular relevance to almonds and other nut products is the ability for *Salmonella* spp. to survive for long periods under dry conditions. Scientific studies have shown, for example, that *Salmonella* Enteriditis Phage Type 30 can survive for up to 550 days on almond kernels held under a variety of common storage conditions (3). Numerous studies have shown that *Salmonella* spp. can survive for long periods of time in foods and in farm/food plant environments, as well, when they become desiccated (4, 5). Although low water activity will inhibit growth, *Salmonella* spp. can also survive for extended periods of time in a low A_w environment. For example, one study has shown that *Salmonella* spp. can survive for up to 24 weeks in peanut butter, with a higher incidence of survivors in product stored at 41°F (5°C) versus 69.8°F (21°C) (6). Furthermore, the A_w of a food product can impact the heat tolerance of *Salmonella* spp. One investigation found that low A_w was detrimental to *Salmonella* survival at 131°F (55°C) or 140°F (60°C), but that temperatures greater than 158°F (greater than 70°C) were always protective—meaning that the pathogen was harder to inactivate at the higher temperature (7). Research has shown that once *Salmonella* spp. contaminates peanut butter, it is not realistically possible to eliminate it with heat treatment—the reduced A_w environment of peanut butter is highly protective of the pathogen (8).

Salmonella and human illness

All serotypes of *Salmonellae* are considered human pathogens. However, the severity of illness varies greatly depending on the strain involved and the susceptibility of the host. Salmonellosis is the leading cause of food-borne illness in the United States, with a reported 16.2 cases per 100,000 population in 2008 reported by the Centers for Disease Control and Prevention (9). Salmonellosis is an infection with symptoms consisting of diarrhea, abdominal pain, chills, fever, nausea, vomiting, dehydration and headache (2). The most susceptible individuals are infants, followed by the elderly and immunocompromised, and then the general population. Symptoms usually appear within 12 to 36 hours with a range of 5 to 72 hours after ingestion of the contaminated food. Symptoms usually resolve in healthy individuals within 2 to 5 days, and the disease is generally self-limiting. In a small percentage of cases, complications can occur, including systemic infection and reactive arthritis, which can have long-term, disabling effects on the patient. Overall, the human mortality rate for salmonellosis is low (less than 1 percent), but can be as high as 20% depending on strain.

The infective dose for salmonellosis is dependent on a number of variables including the strain of *Salmonella* spp. ingested, the susceptibility of the individual and the type of food consumed. However, small numbers, as low as 15 to 20 cells, have been shown to cause illness in humans; therefore, great care must be taken to prevent recontamination of product once it has been pasteurized (10).

Persistence of *Salmonella* in the almond growing and production environments

Research has shown that *Salmonella* Enteriditis Phage Type 30 has persisted in a single almond orchard for over a five-year period and that the same organism can persist and grow in almond orchard soils for extended periods of time (11, 12). *Salmonella* spp. can survive for weeks in aquatic environments, including irrigation water used for crops. And surveys have shown that the organism can survive for months in soils and sediments (13). Research has also shown that *Salmonella* Enteriditis Phage Type 30 can rapidly grow to high levels in wet almond hull and shell slurries and can survive drying of the hulls, which can become a source of recontamination during almond processing if not properly controlled (14). *Salmonella* spp. has been found to colonize and persist on conveyor belts (dependent on type of belt material) and

on various types of fabrics for weeks (15, 16). Various serotypes of *Salmonellae* were found in the production environment of an oilmeal processing plant, including the processing floor, dust samples, employee shoes, brooms, conveyors and other sites (17). Research has also shown that pests and vermin such as rodents, birds, cockroaches and houseflies can harbor, transmit and amplify the presence of *Salmonella* spp. in the environment (18, 19, 20, 21).

Prevalence of *Salmonella* in almonds and other raw agricultural commodities

Almonds, as with most agricultural commodities such as grains, spices and raw cocoa, have been found to harbor *Salmonellae* and other pathogens. *Salmonella* spp. has been isolated from and shown to survive in pecans, peanuts, pistachios, dried edible seeds (sesame, alfalfa, melon, sunflower, flax), Brazil nuts, hazelnuts, macadamia nuts, walnuts and almonds (22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33). One study showed a *Salmonella* incidence of 1.7% in raw almonds, and another study showed an overall isolation rate of 0.87% + 0.2% from raw California almonds sampled over a five-year period (28, 29). The latter study showed that *Salmonella* spp. was present at low levels in positive samples.

Cases of human salmonellosis associated with almonds and other nuts

Given the existence of naturally occurring *Salmonella* spp. in the environment it is not surprising to find the pathogen in raw nuts and similar products. These products need to be handled by the processor as if they are contaminated with *Salmonella* spp., and measures must be taken to prevent recontamination of treated product.

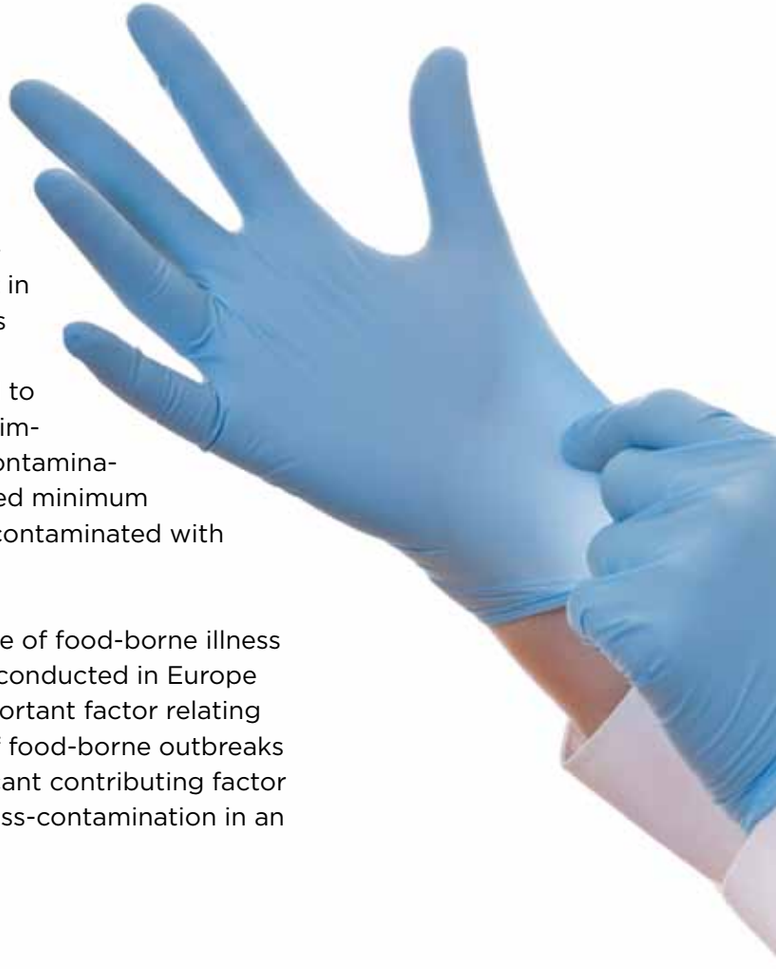
Three documented salmonellosis outbreaks traced to the consumption of peanut butter made with contaminated peanuts have occurred. The first outbreak occurred in 1996 in South Australia and was traced to a single peanut butter manufacturer that used peanuts from an outside supplier that were recontaminated after roasting with *Salmonella* Mbandaka, a relatively rare strain (34, 35). The other two peanut butter outbreaks occurred in the United States in 2006 – 2007 and 2008 – 2009 (36, 37). Over 600 people were sickened in each of these outbreaks. The common theme to all three of these peanut butter outbreaks were multiple major deficiencies in the manufacturing plant that led to recontamination of finished product prior to packaging.

Almonds have recently been the cause of several salmonellosis outbreaks. The first outbreak linked to the consumption of raw almonds occurred in 2000 – 2001 and caused ill-

nesses in Canada and the United States due to a rare strain, *Salmonella* Enteriditis PT 30 (27). The second outbreak traced to the consumption of raw almonds occurred in 2003 – 2004, with illnesses again occurring in Canada and the United States, this time due to *Salmonella* Enteriditis PT 9C (38). Product was recalled from more than 10 different countries. This second outbreak led to the promulgation of the rule for the mandatory treatment of raw almonds to achieve a minimum 4-log reduction of *Salmonella* (39). In 2005 - 2006, a cluster of illnesses caused by rare subtype *Salmonella* Enteriditis occurred in Sweden that was epidemiologically linked to the consumption of raw almonds (40). While the pathogen was not isolated from any of the almonds tested in the investigation, statistically there was a very high matched-odds ratio in the case control study conducted by the Swedish authorities.

In early 2009, the U.S. Food and Drug Administration found multiple samples of pistachio nuts and pistachio-containing products from one specific company to be contaminated with multiple serotypes of *Salmonellae,* including *Salmonella* Montevideo, *Salmonella* Newport, and *Salmonella* Senftenberg (41, 42). While no definitive cases of salmonellosis have been linked to pistachios, the Centers for Disease Control and Prevention reported that one patient in Connecticut with a matching *Salmonella* strain DNA fingerprint reported consuming a pistachio-containing product.

The issue of product recontamination



As discussed, there are many other food-borne illness outbreaks linked to the consumption of low moisture, low A_w foods, including various edible nut and seed products, chocolate and confections, dried dairy powders, and spices. It is indisputable that raw agricultural commodities such as raw almonds occasionally contain various levels of *Salmonellae. Salmonellae* can persist in dry products or in food production environments for long periods of time. It is incumbent on the processor to ensure that lethality steps such as steam or PPO treatments for almonds are validated to achieve a minimum 4-log kill of *Salmonellae*. However, equally as important as the validated kill step is the prevention of product recontamination prior to packaging. It is wasted effort to implement a validated minimum 4-log kill step only to have the treated or pasteurized product recontaminated with *Salmonella* prior to packaging.

Data indicates that post-lethality recontamination is a major cause of food-borne illness and product recalls. A World Health Organization (WHO) survey conducted in Europe found cross-contamination during processing to be the most important factor relating to the presence of pathogens in prepared foods (43). A survey of food-borne outbreaks in the United Kingdom found cross-contamination to be a significant contributing factor in 32.1% of the cases (44). An investigation of *Salmonella* spp. cross-contamination in an

oilmeal processing plant found that controlling traffic flow (personnel and materials), rodents and airborne dust were key factors in reducing contamination rates (17). In two major peanut butter salmonellosis outbreaks, uncontrolled dust in the production facilities was thought to be a major contributing factor (46). Published guidelines for minimizing microbial cross-contamination in poultry feed mills indicate that dust control in the feed milling facility is essential for controlling *Salmonellae* (45). Other key factors include the control of employee traffic patterns to minimize the possibility of cross-contamination and the control of rodents and wild birds. The International Commission on Microbiological Specifications for Foods (ICMSF) recognizes that, while it is not possible to prevent the introduction of pathogens into food processing facilities, it is crucial to minimize their presence (47). The ICMSF stresses a number of potential sources in food-processing areas that must be controlled in order to minimize the potential for product recontamination:

- Raw agricultural commodities, such as raw, unpasteurized almonds, require physical separation through plant design and layout in order to minimize entry of pathogens into processed product areas.
- Food handlers and maintenance personnel can be sources of contamination and must be trained in proper hygiene principles.
- Personal clothing, in particular shoes, can transfer pathogens from one area to another and must be controlled.
- Air and water must be controlled. Compressed air filters, often used for blowing down and cleaning processing equipment, can be a source of contamination if not properly maintained. Water aerosols can disperse microorganisms throughout the facility if not controlled.
- Insects and other pests can act as vectors of pathogen transmission in the food manufacturing plant if not properly controlled.
- Transport equipment such as racks, trolleys, carts, forklifts and similar equipment can he important vectors for transferring microorganisms throughout a facility and should be limited to use in specific areas.

All of these issues are relevant to the production of almonds and almond products. Dust control is a critical factor that must be addressed. The introduction of moisture into the environment should be minimized to the greatest extent possible. The combination of dust and water can lead to the growth of *Salmonellae* and other pathogens to high levels in the environment that can then be subsequently spread throughout the facility. Careful thought and planning must be done in order to control dust and water in the environment.

Salmonella Control Elements in the Almond Production Environment

Each element in the *Salmonella* control equation must be addressed to minimize the potential for product recontamination. Each one of these elements should have a detailed, documented plan to address them. A lapse in any one element increases substantially the risk of product recontamination.

The Grocery Manufacturers Association (GMA) has developed a document for food manufacturers titled the "Control of *Salmonella* in Low-Moisture Foods." This document and its companion annex document provide guidance on the control of *Salmonella* when manufacturing low-moisture foods such as almonds (48, 49). The GMA guidance document outlines seven elements that should be applied to control *Salmonella* in low-moisture products. These seven elements are consistent with the elements of the *Salmonella* control equation and include:

1. Prevent ingress or spread of *Salmonella* in the processing facility.

A hazard analysis should be conducted by a cross-functional team to determine the potential sources of *Salmonella* spp. in the plant. Example of potential sources include incoming raw materials (almonds and other materials), utensils and equipment, personnel and traffic flow, rodents and birds, airflow, and overall facility design and integrity. Ingredients known to be contaminated with *Salmonella* should be segregated. Sanitation and cleaning procedures should be developed that limit the use of water in the production environment. Employees must be educated on the potential sources of contamination, the need to adhere to traffic patterns, and proper hygienic practices and procedures needed to prevent the spread of *Salmonella* spp. in the facility.

key elements

The key elements required for control of *Salmonella* recontamination in an almond production facility can be conceptualized in the *Salmonella* control equation:

TRAFFIC CONTROL (PERSONNEL & EQUIPMENT)
+
DUST CONTROL
+
WATER CONTROL
+
SEPARATION OF RAW & PASTEURIZED PRODUCT
+
EFFECTIVE CLEANING & SANITATION

***SALMONELLA* CONTROL**

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 the handling of ingredients and product requires the highest level of hygiene control. Examples within an almond processing facility include, but are not limited to, sorting and packing lines, finished-goods packaging, and pasteurization equipment and the immediate surrounding areas. The key concept is to, protect product open to the environment prior to packaging. The PSCA should be physically separated from the rest of the facility. Movement of personnel and materials should be controlled between the PSCA and the remainder of the facility. Facility layout should be such that the PSCA is protected from recontamination from the rest of the facility to the greatest extent possible.

3. Apply hygienic design principles to building and equipment design.

Building layout and equipment design should be based on solid hygienic principles (50). In particular, the layout and design of equipment and processes in the PSCA should be well thought out. All efforts should be made to minimize the accumulation of dust and to exclude moisture from the processing environment through the use of proper dry-cleaning practices.

4. Prevent or minimize growth of *Salmonella* within the facility.

The control of moisture in the manufacturing environment is absolutely crucial to the prevention of *Salmonella* contamination in low-moisture products such as almonds. Dry conditions must be maintained at all times in the PSCA, except where controlled wet cleaning is deemed necessary in special cases such as a product contamination issue. If water ingress occurs within the PSCA such as through a drain back-up, roof or wall leak, leaky steam valves, or leaking water pipe, procedures must be implemented to immediately address the problem. Once the leak is repaired, the area must be returned to hygienic condition through proper cleaning and sanitation. If wet-cleaning procedures are used, the area must be thoroughly dry before being put back into operation. Intensive sampling of the environment for *Salmonella* and indicator organisms should be conducted to verify that the cleaning and sanitation procedures were effective in returning the area back to hygienic condition.

5. Establish a raw materials/ingredients control program.

An approved ingredient supplier program should be implemented, particularly for those ingredients that are considered "*Salmonella* sensitive." These ingredients are those that have a known history of association with *Salmonella* spp. "*Salmonella* sensitive" raw materials that have been pasteurized or treated should be segregated upon receipt from other raw ingredients that have not been treated. On-site audits of ingredient suppliers should evaluate food safety procedures in their establishment. This means an implemented and valid HACCP plan with proper prerequisite programs including GMPs, an aggressive Pathogen Environmental Monitoring (PEM) program, sanitation practices, raw materials/ingredients storage, process validation, employee training, a finished-product hold-and-release program (if finished-product testing is performed), traceability, and a corrective action plan if positive *Salmonella* results are found.

6. Validate control measures to inactivate *Salmonella*

By government regulation, almonds must be processed to achieve a minimum 4-log inactivation of *Salmonella* spp. Proper protocols must be followed in order to validate the process. The Almond Board of California has issued several guidance documents on the validation of processes for almonds (51, 52, 53, 54, 55). An external process authority should be used if internal expertise is not available to conduct proper validation protocols of the process. Once a process is validated to inactivate *Salmonella,* the challenge to the processor is to prevent recontamination of that product through subsequent handling and packaging.

7. Establish procedures for verification of *Salmonella* controls and corrective actions.

The most effective verification tool for determining the effectiveness of a facility's *Salmonella* controls is the implementation of an aggressive Pathogen Environmental Monitoring (PEM) program. A PEM program is an ongoing measure of the effectiveness of the overall *Salmonella* control program in the plant. A PEM program, in itself, is not a *Salmonella* control program, but it provides feedback on where efforts need to be directed for the overall control program. The focus of an aggressive PEM program is in the PSCA, but areas remote from the PSCA should be included and will be discussed in further detail.

The most effective verification tool for determining the effectiveness of a facility's Salmonella controls is the implementation of an aggressive Pathogen Environmental Monitoring program (PEM).

Each manufacturer should decide on the value of testing finished product for *Salmonella* spp. Producers need to understand the statistics behind finished-product testing. In general, finished-product testing as a sole measure of product safety is a poor approach in the absence of a robust *Salmonella* control program. If finished-product testing is performed, it is critical that the lots be segregated, placed on hold, and then released into commerce only after a negative result is obtained. If a sample tests positive for *Salmonella* spp., the lot is considered adulterated and should not be released into commerce. In no case should the lot be retested for *Salmonella* spp. with the intention of negating the initial positive result. Corrective actions must be taken and documented when *Salmonellae* are detected in either environmental or finished product samples.

Focusing on the seven *Salmonella* control elements discussed in the GMA guidance document and the elements of the *Salmonella* control equation will significantly reduce risk to the product and the consumer. Conversely, ignoring these principles will greatly increase the risk of a *Salmonella* recontamination event and present increased risk to the business and the consumer. Food recall costs can be astronomical, leading to bankruptcy and closure of the business. It has been estimated that the cost of the 2008–2009 peanut butter salmonellosis outbreak caused by the now defunct Peanut Corporation of America could reach as high as $1 billion in lost production and sales by U.S. peanut producers (56). Clearly, adherence to the guidelines outlined in this document could have avoided such a widespread disaster.

Principles of a Pathogen Environmental Monitoring Program

The International Commission of Microbiological Specifications for Foods (ICMSF) has recognized that even with the optimal application of a HACCP plan or a Good Hygienic Practices (GHP) program, it is no guarantee that recontamination within the processing environment will not occur (47). Despite strict control of all critical control points (CCPs) in a process to ensure destruction of pathogens in raw materials, foods can subsequently become contaminated through one of two ways: 1) the addition of a contaminated ingredient after a kill step, or, 2) recontamination from the processing environment. In the almond-processing environment, recontamination of the product can occur through myriad ways, including contact with raw and untreated materials, processing equipment that is not properly cleaned, manufacturing activities, maintenance activities, sanitation practices, workers, waste, product rework, pests, and microbial pockets embedded in equipment and the structure of the building. Control of recontamination is dependent upon a combination of factors such as those described in the *Salmonella* control equation, and includes the following (57):

- Hygienic design, construction and maintenance of the facility
- Hygienic operation and maintenance of the processes and equipment
- Application of appropriate (e.g., dry vs. wet) cleaning and disinfection procedures
- Training of personnel in food safety and hygienic practices

Microbiological monitoring of the food-processing environment can be performed to meet a number of objectives:

- Verifying the effectiveness of cleaning and sanitation practices
- Determining the frequency required for cleaning and sanitation
- Determining the presence of food-borne pathogens or their indicators in the environment
- Discovering environmental sources of spoilage organisms
- Determining the frequency required for special maintenance procedures (e.g., changing air filters)
- Evaluatiing the hygienic design and fabrication of food-processing equipment and facilities

The focus of this guidance document is on determining the presence of food-borne pathogens including *Salmonellae* or their indicators in the environment of the facility through the development and implementation of an aggressive Pathogen Environmental Monitoring (PEM) program. An effective PEM program is a measure of the effectiveness of the *Salmonella* controls that the facility has in place—proof of how well the facility is managing all of the elements of the *Salmonella* control equation. A PEM program should be thoughtful and aggressively applied. Employees should never be discouraged from finding a positive result. If *Salmonella* is present in the manufacturing environment, finding it through an aggressive PEM program can allow you to do something about it. You want to encourage employees to find it if it is there.

Getting started

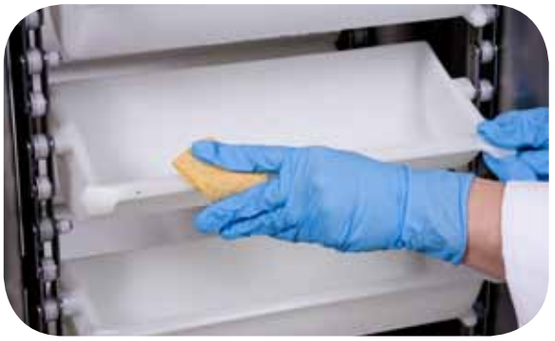
Implementing a PEM program may, at first, seem like a daunting undertaking. However, through the use of a systematic approach, an effective program can be developed in fairly short order. If your company does not have a food safety professional experienced in the development and implementation of a PEM program, it is strongly recommended that you make use of an experienced outside expert or process authority to guide you through it. A PEM program is specific to the individual facility under consideration and specific to the individual operations within the facility. There is no "one size fits all" program that can be used outside of the common principles discussed in this guidance document. The first order of business is to assemble your team that will develop and implement the PEM program. It is desirable to have several individuals familiar with the operation help in identifying potential areas of risk and concern. Examples of such individuals include the plant quality manager, the plant or corporate microbiologist, line supervisors or operators, and sanitation supervisors or workers. If you are using an external process authority or expert to help develop and implement your program, you still should make these individuals available to work with the expert.

Sampling locations: The PEM zoning concept

Once your PEM team is assembled it is important to understand your process flow and emphasize identifying potential points of product recontamination. As discussed in the case of almond and nut processing, *Salmonella* spp. is the target organism of concern. A flow diagram of the process can be very helpful, but it is absolutely essential that you walk the plant floor to determine areas where the product may be vulnerable to recontamination after the lethality step. One useful tool that can help you in site selection and managing your PEM program data is the PEM zoning concept. In the zoning concept, plant operations are divided into four zones based on level of risk. These four zones are illustrated in Figure 1 on page 19 and are defined as follows:

Zone 1—Areas in the plant that are direct product contact surfaces after the lethality or microbial reduction step (e.g., roaster) and before the product is sealed in the primary package. If there is no lethality step in the process, Zone 1 areas are those where the product is exposed to the plant equipment and environment prior to sealing in the primary packaging. Examples of Zone 1 surfaces in the almond production environment include:

- Conveyor belts and buckets
- Utensils
- Employee hands (if touching product)
- Slicers and dicers
- Product hoppers, bins and bin liners
- Discharge chutes
- Fillers








Zone 2—Non-product contact areas in the plant that are closely adjacent to product contact surfaces. Examples of Zone 2 surfaces in the almond production environment include:

- Equipment framework
- Drip shields and housings
- Control panels and buttons
- Overhead pipes directly over Zone 1 surfaces
- Computer screens
- Maintenance tools






Zone 3—Nonproduct contact surfaces that are in open post-lethality product-processing areas, but not closely adjacent to Zone 1 surfaces. Zone 3 surfaces, however, have the possibility of leading to product cross-contamination. Examples of Zone 3 surfaces in the almond production environment include:

- Floors, walls, ceilings
- Hoses
- Air handling units
- Condensate drip pans
- Trolleys, forklifts, walk-alongs, carts
- Trash containers
- Pallets
- Foot mats
- Foot baths
- Drains
- Brooms, mops and squeegees
- Toolboxes








Zone 4—Areas remote from post-lethality product-processing areas. Zone 4 areas, if not maintained in good hygienic condition, can lead to cross-contamination of Zones 1, 2 and 3. Examples of Zone 4 surfaces in the almond production environment include:

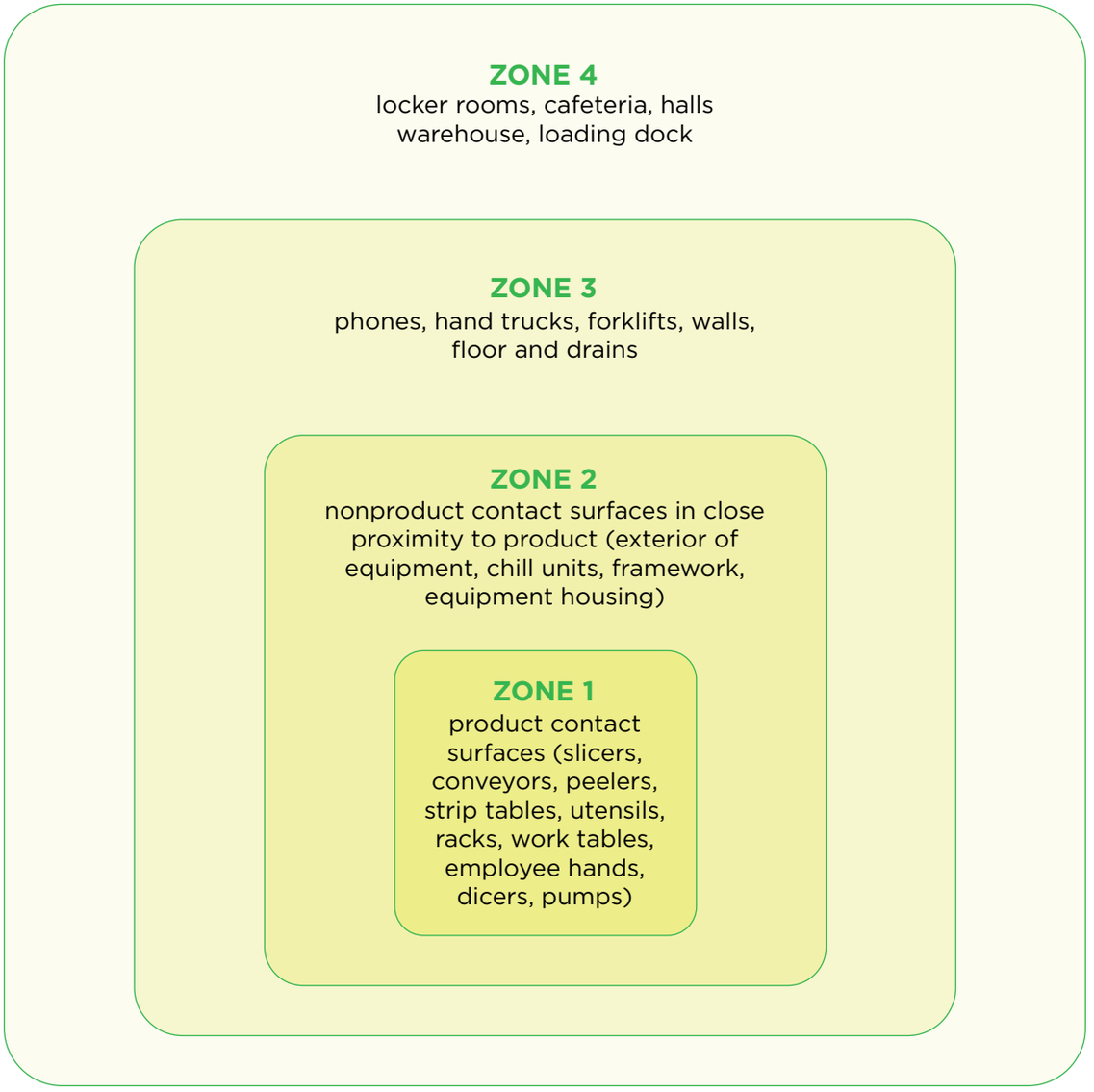
- Hallways
- Loading docks
- Warehouses
- Bathrooms
- Locker rooms
- Cafeteria and break rooms
- Coolers and freezers
- Maintenance shop
- Office areas








Figure 1. Zone Concept to Illustrate Areas of Highest Risk (Zone 1) to Lowest Risk (Zone 4) for Product Contamination.



Following the principles of zoning allows you to take a rational approach to sample site selection and managing the overall PEM program. It can also be used as an effective teaching aid for plant personnel and senior management. It is important for you to define what constitutes Zone 1 to 4 areas in your specific facility and be consistent. Once you have determined Zones 1 to 4 in your facility, you then need to give careful consideration to what specific test methods you are going to employ before you begin testing.

PEM sampling in raw product areas

Raw product areas are not the primary focus of PEM monitoring, since it is assumed that these areas will be contaminated with *salmonellae* from time to time. However, there is value in monitoring these areas because it is not desirable to have high levels of *salmonellae* build up in raw product. The mandatory 4-log *Salmonella* lethality process, as required in the United States, would be inadequate if high levels of the pathogen (greater than 104 CFUs) were present in raw almonds. It is not unexpected to occasionally find *salmonellae* in raw product areas. However, a frequent incidence might suggest that cleaning procedures for those areas are not adequate or that a niche or moisture in the environment may be allowing the pathogen to persist and grow. One recommended approach would be to use total *Enterobacteriacae* (TEB) counts as a quantitative indicator of the potential presence of *salmonellae*. The area should be monitored for both *salmonellae* and TEB counts after cleaning to ensure effectiveness of those areas. If TEB counts exceed 102 CFU per area sampled or per sponge, that suggests cleaning procedures were not effective and need to be repeated (a 102 CFU action limit provides a 2-log margin of safety for almonds that are going to be treated using a 4-log lethality process). The PEM zoning nomenclature can still be used for raw product areas with slight modification to the definitions. Zone 1 areas are those where product comes into contact with processing equipment. Zone 2 areas are those sites that are closely adjacent to Zone 1 areas. Zone 3 sites are those in the open product processing areas, and Zone 4 sites are those remote from Zones 1, 2 and 3 areas. It is imperative that the response team carefully consider what actions need to be taken in the event of a positive result in raw product areas.

Types of testing for pathogen environmental monitoring

There are myriad methods that can be used for your PEM program. The choice of method depends on a number of considerations. The first consideration is to determine which elements you want to include in your PEM program. It is recommended that you include the following components in your PEM program:

- Surface sampling using sponges or swabs
- Product residue scrapings/fines/dust samples
- Water samples
- Air samples

The second consideration is to determine the type of testing you are going to employ. Generally there are two categories of methods you can use: 1) testing for indicator organ-

isms, and 2) testing for the specific target pathogen (*Salmonella* spp.). Indicators are used to measure the potential presence of pathogens and to assess the effectiveness of cleaning and sanitation (58). Food safety indicators should meet the following important criteria:

1. Be easily and rapidly detectable
2. Be easily distinguishable from other members of the food microflora
3. Have a history of constant association with the pathogen whose presence it indicates (e.g., *Salmonella* spp.)
4. Always be present when the pathogen of concern is present
5. Be an organism whose numbers ideally should correlate with those of the pathogen of concern
6. Possess growth requirements and a growth rate equaling or exceeding that of the pathogen
7. Have a die-off rate that at least parallels that of the pathogen and ideally persists slightly longer than the pathogen of concern
8. Be absent from foods that are free of the pathogen except perhaps at certain minimum numbers

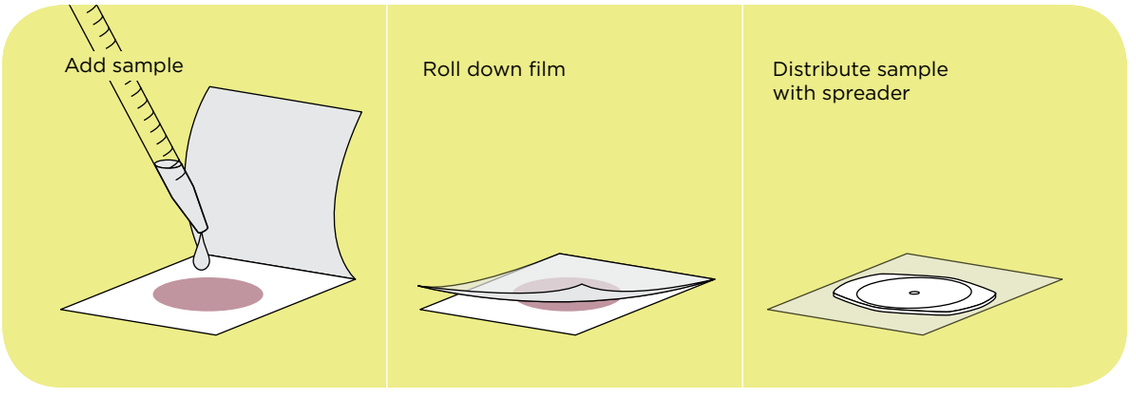
There are a number of indicator tests that can be used for PEM programs in almond-processing operations. One common indicator test is the coliform and *Escherichia coli* group, which is commonly used in the food industry as sanitation and process integrity indicators and for HACCP verification (59). Another highly recommended indicator test is the total *Enterobacteriaceae* (TEB) count, which has been widely used in Europe as a food safety and process integrity indicator test. The *Enterobacteriaceae* group is superior to the coliform group as an indicator of sanitation because this group, collectively, has greater resistance to the environment than the coliforms, can colonize areas where sanitation and cleaning have been insufficient, and members of this group are sensitive to sanitizers. While the coliform/*E. coli* and the total *Enterobacteriaceae* groups are not perfect indicators of the presence of *Salmonella* spp. in the processing environment, they nevertheless are good indicators of cleaning and sanitation practices. Although there is a lack of data correlating TEB counts and *Salmonellae* in environmental samples from almond and nut processing operations, data does exist showing the existence of a loose correlation between TEB counts and the occurrence of *Salmonellae* in environmental samples from a dried-milk processing plant (60):

Total *Enterobacteriaceae* cfu/g	*Salmonella* positive in 50 g percentage
< 2	0.5
2 - 100	0.9
100 - 500	8.7
> 500	9.0

Note that in the above data *Salmonellae* were detected when TEB counts were at the limit of detection of the method (less than 2 CFU/g). It must be emphasized that it is possible for *Salmonellae* to be present when the TEB counts are negative (the same is true for coliform/*E. coli* counts, as well). This is because enrichment methods used for the detection of *Salmonellae* are more sensitive than quantitative TEB or coliform/*E. coli* counts. However, the loose correlation in the previous table shows that the percentage of positive environmental samples for *Salmonellae* dramatically increase with increasing TEB counts. Therefore the risk of having *Salmonellae* in your processing environment increases with increasing TEB counts. Quantification of TEB and coliform/*E. coli* can be conducted by standard plating or cultural techniques, including Most Probable Number (MPN) methods (57). One convenient method that can be used for quantifying either the TEB or coliform/*E. coli* groups is the 3M Petrifilm™ method (www.3M.com/product/information/Petrifilm-plate.html) as shown in Figure 2 (61).[1] These plates are provided by the manufacturer in sealed foiled pouches that are stored under refrigeration until use or until the end of the expiration date on the label.

A third indicator test that is widely used as a quality indicator for evaluating foods and food-processing operations is the aerobic plate count (APC). APCs cannot be used as safety indicators for pathogens (*Salmonella* spp.) because in almost all cases there is no correlation between APCs and the presence of pathogens or their toxins. There are applications, however, where an APC count can be used as an indication of sanitation effectiveness of a process. APC data from dry processing environmental samples can be difficult to interpret because dry-cleaning procedures will not remove the entire microflora present on equipment, including sporeforming bacteria. Consequently, APCs can vary widely depending on the quality of ingredients or product processed on the line. APCs can be conducted using standard pour-plate methods, the 3M Petrifilm™ methods, or by the Most Probable Number (MPN) technique, among others (62).

Figure 2. 3M Petrifilm™ Plate Method



[1] Mention of commercial names does not constitute an endorsement by the Almond Board of California.

Environmental sampling techniques

Sampling procedures and techniques should be conducted by properly trained personnel, consistent with standard industry practice outlined in this guidance document. Testing of environmental samples, including fines, debris, sweepings, sponges, and swabs, provide critical information and feedback on how effective your measures are in controlling *Salmonellae* in your almond manufacturing operations.

Procedures sampling equipment and environmental surfaces for *salmonellae*

When testing equipment and environmental surfaces for *Salmonellae*, it is important to sample as large an area as reasonably possible. The use of sterile sponges or the 3M™ Sponge-Stick (Figure 3) (http://solutions.3M.com/wps/Microbiology/FoodSafety/) is a very useful means of sampling large areas for *Salmonellae*. Prepared hydrated or dry sponges in sterile Whirl-Pak® bags are available from a variety of vendors. Sterile swabs such as the 3M™ Quick Swab, the 3M™ Enviro Swab or culturette swabs can be used for sampling small areas such as cracks, crevices, holes, and other hard-to-reach areas. If sanitizer is used as part of the normal sanitation procedure in the plant, then sponges or swabs should be placed in sample with neutralizing buffer (for example, D/E neutralizing buffer). This is essential to recovery of sub-lethally injured *Salmonellae* and to ensure that they are able to grow out during culturing of the sponges or swabs in the laboratory. Sponges/swabs with neutralizing buffer are commercially available from many vendors.

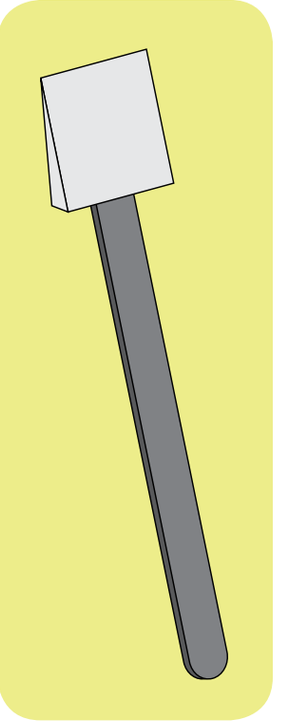


Figure 3. 3M™ Sponge-Stick or equivalent for Sampling Environmental Surfaces

Dust, fines, floor sweepings and vacuum canister debris can be collected with sterile utensils such as scoops, scrapers and spatulas and placed in sterile Whirl-Pak® bags. Such sampling utensils may be purchased from a variety of venders, including eNasco (http://www.enasco.com/page/wp_index). Sample collection should, where possible, proceed throughout the almond-processing plant from Zone 1 to Zone 2 to Zone 3 to Zone 4 using the following procedure as a guide:

1. Prelabel the sponge sample bags using a predetermined coding or numbering system. Make sure site descriptions indicate from which zone each sample is taken.
2. Thoroughly wash and dry hands. Sanitize hands with an appropriate hand sanitizer. Put on sterile gloves.
3. Using sterile gloves, remove the sponge or 3M™ Sponge-Stick from the Whirl-Pak®

bag or container.

4. Grasping the sponge and using constant pressure, sponge an area as large as reasonably possible. Typically, a range of 40 square inches to 400 square inches is used for testing environmental surfaces. Replace the sponge back into the Whirl-Pak® bag or container and seal it.
5. Small areas such as cracks, crevices and screw holes may be more appropriately sampled using sterile swabs. Using sterile gloves, remove the swab from its container and swab the sampling site. Return the swab back to its container.
6. Change gloves between sponge samples and use an alcohol-based sanitizer to minimize the potential for cross-contamination.
7. When Zone 1 sites are sampled with premoistened sterile sponges the site should be wiped down with an alcohol-based sanitizer after the sampling is done. Eco-Wipe™ FCS single-use quaternary/alcohol-based wipes (http://www.ecolab.com) are particularly useful for this purpose. These are approved for nonporous food contact surfaces and are useful in returning the area swabbed back to hygienic condition, including removing any small amounts of residual liquid left by the premoistened sponge.
8. Place the collected, sealed sponge samples into a clean container for transport to the laboratory. Other disposable items such as used gloves, 3M™ Sponge-Stick handles, Whirl-Pak® bag tear strips, used Eco-Wipe™ FCS wipes, and other items should be discarded in appropriate trash containers or another bag or container designated for that purpose. These items should not be placed in the same container used to collect the sealed sponge samples.
9. After sampling, immediately transport the samples to the laboratory and refrigerate until they are tested. Samples should ideally be tested on the same day that they are collected. In the case of shipping samples to an external laboratory, samples should be tested no more than 48 hours after they have been taken. If samples are shipped to an external testing laboratory, they should be appropriately packed with ice packs. The receiving laboratory should check the temperature upon receipt to make sure the samples did not warm up during shipment. Receiving temperatures should be no higher than 45°F upon receipt.
10. A negative control sample should be included with each batch of environmental samples taken. This is done by removing the sponge from the Whirl-Pak® bag or container using sterile gloves and then replacing it back into the bag or container. It should be coded such that the testing laboratory does not know that it is a negative control sample.

Procedures for sampling equipment and environmental surfaces for total *Enterobacteriaceae* counts (indicator organisms)

It is recommended that preoperational Zone 1 surfaces be routinely tested for total *Enterobacteriaceae* (TEB) counts as part of your PEM program in lieu of *Salmonella* testing. Zone 1 surfaces could be tested for *Salmonella* spp. However, if tested, the product made

on that line must be held (if there is no documented sanitation break) until testing results are available. The use of TEB counts obviates the need for hold-and-release testing of product but can yield extremely valuable information regarding the hygienic status of the almond-processing lines and equipment. The following procedure for sampling environmental and equipment surfaces for TEB counts should be used as a guide:

1. Prelabel the sponge sample bags or swab sample containers using a predetermined coding or numbering system. Make sure site descriptions indicate from which zone each sample is taken.
2. Thoroughly wash and dry hands. Sanitize hands with an appropriate hand sanitizer. Put on sterile gloves.
3. Using sterile gloves, remove the sponge, the swab or 3M™ Sponge-Stick from the Whirl-Pak® bag or container.
4. Grasping the sponge or swab and using constant pressure, sponge an area of 200 square inches. If swabs are used, swab an area of 40 square inches. To facilitate accurate coverage of the area, a nonporous plastic template may be used. The template should be sanitized using a suitable sanitizer such as Eco-Wipe™ FCS wipes between sampling sites. Replace the sponge back into the Whirl-Pak® bag or container and seal it. Smaller areas may be sampled with the sponge method if it is not possible to sample a 200 square inch area. The counts per unit area must be adjusted if that is the case.
5. Change gloves between sponge samples and use an alcohol-based sanitizer to minimize the potential for cross-contamination.
6. When Zone 1 sites are sampled with premoistened sterile sponges or swabs, the site should be wiped down with an alcohol-based sanitizer after sampling is done. Eco-Wipe™ FCS single-use quaternary/alcohol-based wipes (http://www.ecolab.com) are particularly useful for this purpose. These are approved for nonporous food contact surfaces and are useful in returning the area swabbed back to hygienic condition, including removing any small amounts of residual liquid left by the premoistened sponge.
7. Place the collected, sealed sponge or swab samples into a clean container for transport to the laboratory. Other disposable items such as used gloves, 3M™ Sponge-Stick handles, Whirl-Pak® bag tear strips, used Eco-Wipe™ FCS wipes and other items should be discarded in appropriate trash containers or another bag or container designated for that purpose. These items should not be placed in the same container used to collect the sealed sponge samples.
8. After sampling, immediately transport the samples to the laboratory and refrigerate until they are tested. Samples should ideally be tested on the same day that they are collected. In the case of shipping samples to an external laboratory, samples should be tested no more than 48 hours after they have been taken. If samples are shipped to an external testing laboratory, they should be appropriately packed with ice packs. The receiving laboratory should check the temperature upon receipt to make sure the samples did not warm up during shipment. Receiving temperatures should be no higher

than 45°F upon receipt.

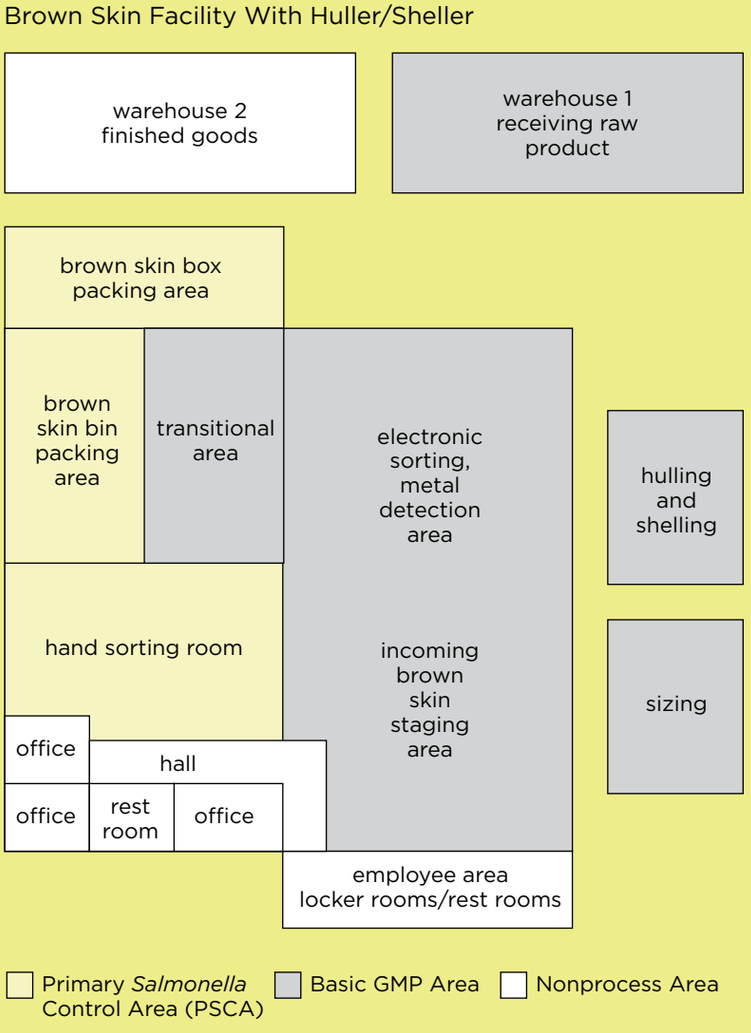
9. A negative control sample should be included with each batch of environmental samples taken. This is done by removing the sponge from the Whirl-Pak® bag or container using sterile gloves and then replacing it back into the bag or container. It should be coded such that the testing laboratory does not know that it is a negative control sample.
10. Samples should be quantitatively sampled for TEB counts per the procedures outlined in the Compendium of Methods for the Microbiological Examination of Foods (57). One convenient method is to employ the use of the 3M Petrifilm™ method for conducting TEB counts.
11. Sponge samples are analyzed by adding 100 ml of sterile diluent (e.g., letheen neutralizing broth) to the sample bag. Vigorously massage the sponge for one minute or more to release the microorganisms and plate according to the TEB method used. If swab samples are taken, vigorously shake the container holding the swabs by making 50 complete cycles of 15 cm in 10 seconds, striking the palm of your other hand at the end of each cycle. Plate according to the TEB method used. Counts should be calculated and reported per unit area sampled (e.g., TEB count per 200 square inches or TEB count per 40 square inches).
12. When unmeasured surface areas such as pipe interiors, nozzles, valves or gaskets have been swabbed, the results should be reported on the basis of the entire sampling site and reported as TEB count per swab or sponge.

Conduct a hygiene zone assessment

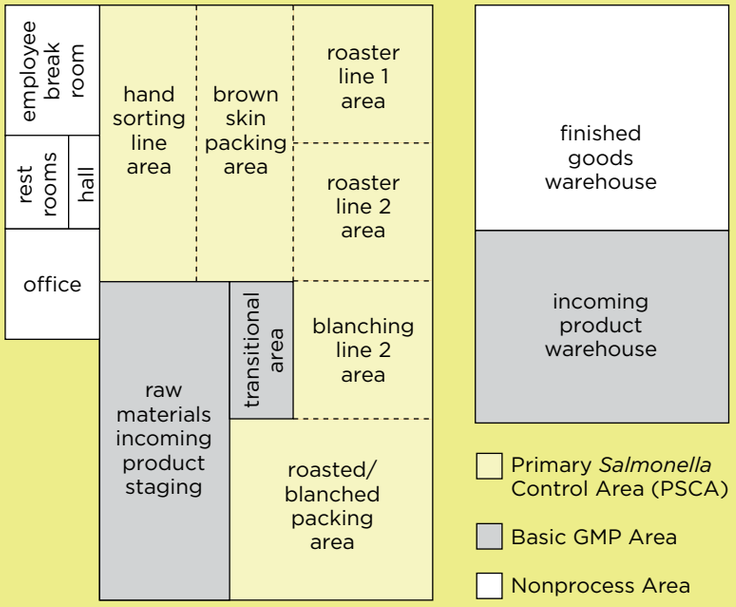
A team knowledgeable with the layout of the manufacturing operation should walk the plant floor to determine sampling locations. As discussed in section 2, the plant should be segregated into hygiene zones based on the Primary *Salmonella* Control Area (PSCA) concept. In almond-processing facilities, the PSCA is the area where the post-lethality-treated product is exposed to the environment, such as sorting and packing lines, and final packaging areas. These areas are sometimes referred to as the ready-to-eat (RTE) area, the critical side of the operation, or the high-hygiene or high-risk area. Examples of almond plant layout with different levels of hygiene zones are shown in Figure 4. The objective of hygiene zones is to identify areas of high and low risk within the manufacturing operation. Once these hygiene zones have been identified, specific pathogen control measures and monitoring programs can be developed. The focus is to prevent the spread of *Salmonellae* into the PSCA where protection of the exposed post-lethality treated-product is critical.

Depending on the type of operation, an almond-processing or manufacturing facility can be divided into one, two or three hygiene zones in addition to the nonprocessing areas. These areas would typically be the PSCA, the basic GMP area and a transition area between the two. An example of a transition area might be between a PSCA and pre-lethality step processing as a basic GMP zone.

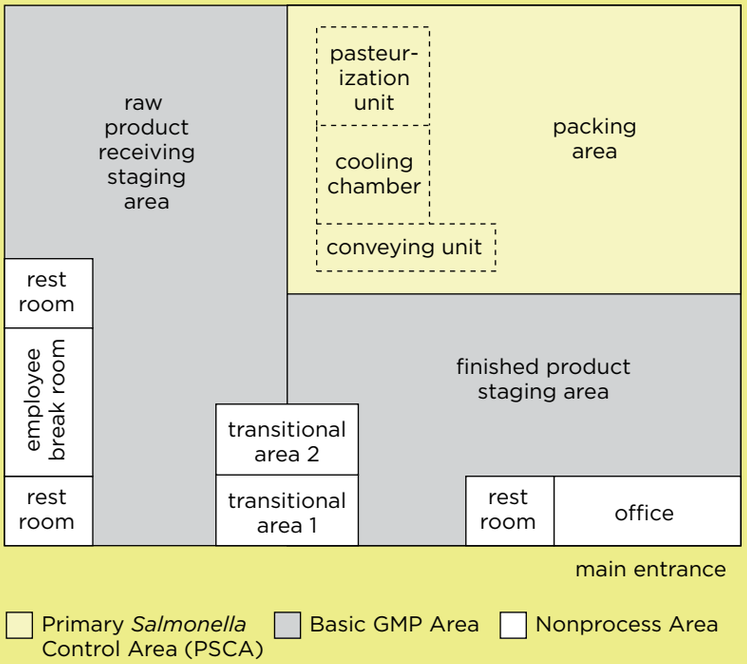
Figure 4. Examples of Almond Plant Layouts layout With Different Levels of Hygiene Control. Primary *Salmonella* Control Area (PSCA) in yellow and basic GMP area in gray. White areas are non-process areas (adapted from Reference 48).



Handling Facility With Treatment/Pasteurization



Custom Pasteurization Facility



The team should conduct a hygiene zone assessment of the entire facility and create a color-coded map of the facility using the following procedure:

- Survey the entire facility, including all production areas, storage, receiving, warehousing and loading docks, as well as employee facilities such as cafeterias, break rooms, locker rooms, washrooms, maintenance areas, offices and conference rooms, and others.
- Designate the PSCA, basic GMP areas, transition areas (if any) and nonprocessing areas.
- Pay particular attention to areas within the facility where ingredients, products or the environment could be a potential source of pathogen contamination and have a high risk to cross-contaminate post-lethality-treated product. Also pay attention to non-process areas such as refuse and recycling, restrooms, forklift battery charging stations, boiler rooms, and others that could impact the PSCA.

PEM sampling site selection and frequency of monitoring

Once the team has mapped out the hygiene zones within the manufacturing facility, it is now time to select the specific sampling sites within each area using the zoning concept discussed in section 3.2. Environmental sampling for *Salmonella*e is routinely conducted in Zones 2, 3 and 4. Zone 1 surfaces are normally tested for indicators such as TEB counts. Only under special situations are Zone 1 surfaces sampled for *Salmonella*e, such as investigational sampling due to a potential contamination events such as a roof leak or a finished-product *Salmonella*-positive result. Zone 1 surfaces could be routinely sampled for *Salmonella*; however, any Zone 1 testing for *Salmonella* or other specific pathogens necessitates a stringent product hold program until results are received. Testing Zone 1 surfaces for TEB counts or other appropriate indicators obviates the need for a finished-product hold program.

Table 1 summarizes examples of sampling sites, type of microbiological test and minimum recommended frequency of testing by zone. Also note that a Zone 1 designation may be given to equipment surfaces and building structures (e.g., beams, catwalks, overheads, ceilings, covers, conduit, HVAC units, pipes, etc.) that are directly above product-contact surface. The assessment team, working together, should determine whether a surface above a direct product contact surface constitutes a Zone 1 surface. This determination will depend on a number of factors including the likelihood the surface will contaminate the product immediately below it (e.g., and condensate formation, dust collection, etc.), the ability to effectively clean and sanitize the surface on a regular basis, among others.

The number and location of environmental samples taken is determined by the risk levels inherent to the product and process. Areas with water use, high traffic patterns, a history of positive pathogen results, and areas where microbiologically sensitive raw materials are handled or stored should be sampled at a higher frequency. Focus should be given to post-lethality-treated open product areas (PSCAs) since this is where the risk of product recontamination is highest. In general, this will equate to a greater number of samples collected in

Zone 2 and Zone 3 areas than are taken in Zone 4 areas. Sample sites should be identified and rotated weekly according to shift and the day of the week. A rotation schedule should be developed to allow all locations within Zones 1, 2 and 3 to be covered within a month. Zone 4 sites should be rotated so that all sites are covered within a quarter. The sampling plan must be flexible to allow for additional samples to be taken, as determined by the team. The overall number of PEM samples taken each week depends on the size of the facility and on the historical data from the facility.

Establishing your baseline: investigational sampling

Once potential areas for sampling are identified, it is useful to conduct preliminary intensive investigational sampling with the purpose of finding the target pathogen if it is there. In the preliminary investigational phase, environmental samples are collected at a higher frequency and number than is done for the ongoing PEM program. The selection of samples is typically based on the experience of the investigator and the type of process under consideration. Depending on the size and complexity of the operation, it is not uncommon to take 25 to 50 samples or more per zone per day for the first month (rotating shifts in a multiple shift operation), then moving to a weekly schedule with the same number of samples for the next two to five months. It is highly recommended that you use a combination of indicator organisms and *Salmonella*e testing as part of your PEM program. There are a number of indicator tests that you can use for your PEM program. As previously discussed, it is recommended that you use total *Enterobacteriaceae* (TEB) counts as your indicator test for evaluating Zone 1 and other surfaces. Whether you use TEB counts or coliform counts as your quantitative indicator method, it is very important to determine the baseline counts that would be expected under normal operating conditions and what counts that would be unacceptable. This entails doing work to establish your baseline counts and action levels for counts that deviate from the baseline.

Zone 1 sites are normally tested for TEB counts preoperationally, before sanitizing and prior to start-up of the production line. Sampling after cleaning but before applying sanitizer is a good measure of cleaning effectiveness. If Zone 1 sites are sampled after the sanitizer step, then be sure to use a neutralizing buffer for the sample sponges or swabs, as previously discussed. Zone 1 sites should be tested individually and never composited. Zone 1 sites may be sampled during production, but this will require careful analysis and establishment of baseline data. This requires collecting TEB count data on your post-lethality-treated product to determine the expected baseline TEB level. One approach would be to sample Zone 1 sites intensively for six months to establish baseline levels (preliminary investigational sampling). Any significant deviation (e.g., 1 log) above the baseline level constitutes a special cause for corrective action. The team needs to take into consideration variables such as seasonality, geographic differences and supplier source that can impact the baseline. In general, depending on the degree of post-lethality treatment, the TEB levels should be very low in the product. The team needs to decide if it adds value to sampling Zone 1 sites during production, versus taking more Zone 2 and 3 samples during

TABLE 1: PEM sampling site examples, type of microbiological test, minimum sampling frequency, and typical number of samples by zone.

Zone	Examples of Sampling Sites	Microbiological Test	Minimum Frequency of Sampling	Typical Number of Samples[1]
I	Direct or indirect product contact surfaces[2], e.g., sorting lines, product conveyors product discharge chutes, pipeline interiors, storage hoppers, filler hoppers, nozzles, product scrapers/utensils, employee hands handling product	Indicator organisms, e.g. Total Enterobacteriaceae Counts (TEB), total coliform counts. *Salmonella* testing normally only under special situations	Weekly, post-cleaning prior to sanitizer application and start-up. Also, as needed for investigational, validation and/or verification purposes	Line Dependent
II	Environmental surfaces immediately adjacent to product contact surfaces, e.g., equipment framework/supports, outside of tunnels or filling cabinets, below filling equipment, control panels, motor housings, catwalks, scales, scrap containers, drains near zone 1 surfaces, HVAC vents	*Salmonella*	Weekly	10 - 15
III	Environmental surfaces further removed from product contact surfaces in open product areas, e.g., hand trucks, forklifts, walls, ductwork, drains, floors, ceilings, equipment legs, tools, brooms, squeegees, floor scrubbers, trash containers, pallets, floor debris, ceiling drain pipes, wash stations, ingredient storage areas, wall/floor junctures	*Salmonella*	Weekly	10 - 15
IV	Areas remote from the processing area, e.g., warehouses, bathrooms, locker rooms, maintenance areas, cafeteria/break rooms, loading docks, boiler room, offices, plant entrance, refuse/recycle areas	*Salmonella*	Monthly	5 - 10

[1]In general, the same or greater numbers of samples are taken in zone 2 than zone 3, and in zone 3 than zone 4. Larger or more complex operations may require more samples taken per zone than shown here.
[2]Direct product contact surfaces (PCS) are surfaces exposed to product during normal equipment operation. Indirect product contact surfaces are surfaces from which liquids or dust or other material may drain, drop, diffuse, or be drawn into the product or into the container, and surfaces that touch product contact surfaces or the product container

production, combined with a finished product testing program. In some cases, processing equipment such as sorting lines and conveying systems can contain harborage niches that can be detected only while in operation. If this is a concern, an alternative would be to run operational Zone 1 testing as part of a periodic verification program rather than part of the routine PEM program. Also, consideration must be given to weighing the potential risk of inadvertent cross-contamination of Zone 1 sites via sampling during production against the insights gained from the data through collecting operational Zone 1 samples. Factors such as ease of collecting the sample, implications of temporarily shutting down the line for sample collection and others must be considered before implementing Zone 1 sampling during production.

Zones 2 and 3 samples should be collected both preoperationally and operationally for *Salmonella*. Operational samples should be taken throughout the production run (for example, just after start-up, three or four hours after start-up, and at the end of the run).

These sampling times and sites can be rotated from week to week.

Zone 4 samples should typically be collected monthly. The focus should be on sites that are adjacent to open product areas or where traffic (people and materials) flows into or out of open product areas (PSCAs). Remote locations such as locker rooms, loading docks, warehouses, cafeterias and break rooms, and other areas should also be included. Employee lockers, if not properly cleaned and maintained, have been shown to be a source of *Salmonella* contamination. The intent of Zone 4 sampling is to identify potential harborage sites of the pathogen that could ultimately become a source for spreading it throughout the production facility.

Once swab locations are selected, a master list can be compiled by zone throughout the facility. Each zone can be mapped for tracking purposes and entered into a master database. A generator of random numbers can be used to select swab locations to be sampled each week; however, you should ensure that each location is sampled rotationally so that they are sampled at least four times, minimum, within a year. The same exact location within a zone should not be sampled each time samples are collected unless data has shown it to be a chronic problem location. The sampling plan needs to be flexible, allowing for additional sample collecting based on the data obtained. The concept of "follow the data" should be practiced at all times. A PEM program is dynamic and should be responsive to the data generated by sampling.

Microbiological methods available for testing PEM samples

There are myriad microbiological methods available for the analyses of PEM samples. Whatever method is selected, it is absolutely imperative that you validate the method on your samples for your specific applications. It is recommended that you use an official or industry-recognized method for testing samples. In the United States, the methods in the FDA's Bacteriological Analytical Manual (BAM) are considered official methods for the testing described in this guidance document (63). Other official and/or industry-recognized methods include:

- ISO 6579 methods, which are considered official methods in Europe, but are increasingly recognized around the world (64)
- American Public Health Association's Compendium of Methods for the Microbiological Examination of Foods (57)
- AOAC International's Official Methods of Analysis (65)

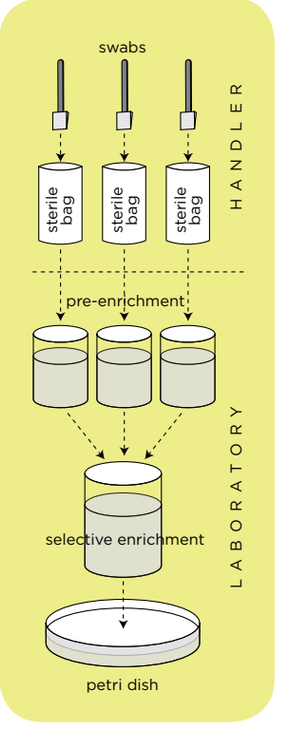
There are also country-specific and industry-specific methods published, but most of the above-cited method references are universally recognized and accepted. Methods that have been validated and found to be equivalent in specificity and sensitivity to these officially recognized methods may be used; however, you need to make sure the methods are properly validated.

There are a number of rapid methods available for the detection of *Salmonellae* in environmental, ingredient, and in-process or finished-product samples. Many of these methods are immunological-based Enzyme Linked Immunosorbent Assays (ELISAs) that utilize specific antibodies for capture of the *Salmonellae*, modified cultural methods that often utilize selective and differential media for the isolation and identification of *Salmonellae*, and genetic-based methods such as the Real Time Polymerase Chain Reaction (RT-PCR) assays that target gene sequences specific to *Salmonellae*. All of these methods have advantages and disadvantages and must be carefully considered and thoroughly validated before being used for your samples. A validated rapid method is generally considered a screening method, where negative results are accepted as such, but positive results need confirmation (either cultural or by some other recognized method). It's advisable to proceed based on a presumptive Zone 1 positive result from an environmental sample from a cleaning, sanitation and product disposition perspective. This approach is the most conservative, gaining you time for cleaning and sanitation and other interdictive steps if, indeed, it turns out to be a confirmed positive result.

Never composite environmental samples by combining multiple sponges or swabs into one pre-enrichment. This practice may make it difficult to detect low levels of *Salmonellae* present in one sample because of increased background competitive microflora leading to a false negative result. Also, a positive result on a composited sample does not allow you to identify the specific location(s) that are positive for *Salmonellae*. This makes troubleshooting more difficult and results in broader corrective actions than otherwise would be needed.

Environmental samples may be pooled by combining up to 10 post-enriched samples into one sample to run a rapid method such as RT-PCR or ELISA. The Pathatrix® Auto is a commercially available system from Matrix MicroScience (www.matrixmsci.com) and approved by the Association of Analytical Communities Research Institute (AOAC RI). It's based on recirculating immunomagnetic separation and allows for the efficient pooling of environmental samples. If pooled samples yield a *Salmonella*-positive result, the individual pre-enrichment samples comprising the pooled sample are run individually to identify the positive sample(s). Sample pooling has the advantage of significantly reducing the per-assay cost of running samples. It is recommended that only samples from the same zone be pooled for testing purposes. As with most rapid methods, the ability to pool samples is method-dependent and must be thoroughly validated for your specific applications.

It is highly recommended that all *Salmonella* isolates be serotyped and characterized by a genetic typing method such as pulsed-field gel electrophoresis (PFGE), ribotyping, or another validated and recognized method. Genetic typing methods are very useful in troubleshooting and tracking data from your PEM program. Genetic typing maps can be developed showing "hot spots" or problem areas in the plant. These maps are usually set up using blueprints or diagrams of the relevant areas according to zones. It should be understood that it is possible for multiple strains of *Salmonella* to be isolated from an en-



Sample pooling

vironmental sample. Multiple strains of *Salmonella* have been isolated from raw nuts and from production areas (33). Therefore, the presence of one strain of *Salmonella* in product and a different strain in the production environment does not necessarily mean they have no commonality.

If your operation does not have its own microbiological testing laboratory, you should use a reputable accredited independent testing laboratory. There are a number of resources available to help you choose a properly accredited independent food microbiology testing laboratory. The AOAC's Analytical Laboratory Accreditation Criteria Committee (ALACC) has published "Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals" (ALACC Guide) which are guidelines based on the ISO 17025 requirements. Up-to-date information on these requirements may be found at http://www.aoac.org/accreditation/faq2.htm. Other valuable resources that can be used in helping you find accredited food microbiology testing laboratories include the American Association for Laboratory Accreditation (A2LA) (http://www.a2la.org/appsweb/food.cfm) and the American Council of Independent Laboratories (ACIL) (http://www.acil.org/). The value of using accredited laboratories is to ensure that they are producing accurate, reliable and consistent results using properly validated methods. There are also a number of independent expert consultants that can be used to help you find and qualify a properly accredited laboratory.

Data interpretation and corrective actions

Once preliminary investigational data is collected, it must be analyzed and interpreted. Intensive data from the preliminary investigational phase is used to set up the ongoing PEM program. Data, during the preliminary investigational phase, should be continually monitored and used to guide ongoing sampling during that phase. If an area shows repeated positives, then that area should be considered a potential harborage or problem area that warrants continued attention. Once the ongoing PEM program is initiated, based on the intensive data analyzed from the preliminary investigational phase, the frequencies and typical number of samples per zone outlined in Table 1 may be implemented. It is critical that corrective actions be implemented and documented whenever a *Salmonella* positive occurs. With most environmental samples it is recommended that corrective actions be initiated when a presumptive *Salmonella* result occurs. As discussed previously, this is the most conservative route, gaining time in the event the sample is confirmed positive for *Salmonella*. Confirmation can take up to a week; therefore, taking action on a presumptive positive minimizes your risk exposure while you wait for confirmed results.

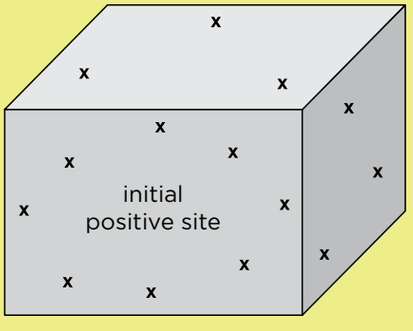
The following are key considerations relative to taking proper corrective actions:

- Your facility should have a predetermined action plan that would be implemented in the event of a *Salmonella*-positive environmental sample result. The action plan should be specific for each of the four zones and include protocols for:
  - The type of immediate corrective actions to be taken by zone

- Actions taken to verify that *Salmonella* has been eliminated from the area in question
- An analysis to find the root cause of the contamination so that it can be prevented in the future

- All corrective actions, including additional sample results, need to be properly documented. It is extremely useful to have a computer-based spreadsheet for tracking results and documenting corrective actions.
- If a positive result is found in any sampling zone, the area needs to be thoroughly examined both visually and through vector swabbing to determine the extent of the contamination and to ascertain potential causes of the problem. Vector swabbing entails taking additional multiple environmental samples around the initial positive site. Vector sampling is usually done in a typical "star-burst" pattern around the initial positive site as shown diagrammatically in Figure 5. Typically, 10 to 15 additional sponge or swab samples are taken around the initial positive sites. Sampling, where possible, should radiate out from the initial positive site in all directions, including up and down, if appropriate. Troubleshooting samples are usually run as separate samples and not pooled as discussed in section 3.8.
- The specific corrective actions taken are based on an assessment of the likelihood of finished-product contamination based on the location of the initial positive site. A positive finding in Zones 2, 3 or 4 does not necessarily implicate finished product. That decision should be made by the team and appropriate management personnel.

Figure 5. Vector Sponge/Swab Sampling Starburst Pattern Around the Initial *Salmonella* Presumptive Positive Site.



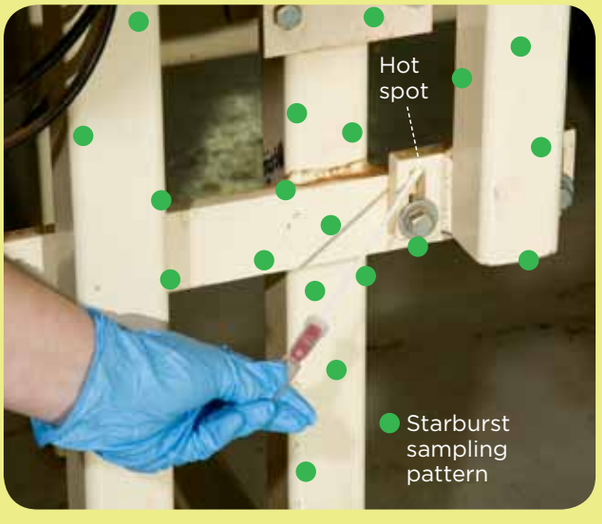


Table 2 provides some examples of corrective actions following the initial positive *Salmonella* result in the plant environment. You should have a predetermined cross-functional response team in place to conduct follow-up investigations on *Salmonella* positive findings. The response team should consist of members from Microbiology/Food Safety, Quality Assurance, Sanitation, Operations, Engineering, Maintenance, Management and other disciplines, as appropriate. All key personnel that can help troubleshoot find the root cause of the problem and correct it should be part of the response team. The focus is on finding and eliminating all potential sources of environmental contamination to the greatest extent possible.

The response team should conduct a preliminary investigation into any positive *Salmonella* finding to determine potential sources of contamination. A report should be compiled that details all maintenance disruptions and activities, in-plant construction, unplanned line downtime or other nonstandard production activities (e.g., plant R & D trials) in the area from the last full microbiological cleanup or sanitation to the current positive finding. Immediate actions should be taken to correct any obvious GMP or other deficiencies based on the findings including:

- Quarantine the suspect area and limit access to minimize spreading the contamination to other parts of the plant.
- Reinforce hygienic practices among employees, outside contractors and others, and retrain in GMPs and principles of food safety, if necessary.
- Assess and adjust the type and frequency of cleaning and sanitation procedures, if needed.
- Eliminate sources of water and water accumulation, if found.
- Repair structural damage (e.g., on floors, walls and other structures) as necessary.
- Reexamine traffic patterns (both personnel and materials) and redirect them, if feasible.
- Audit handling practices (production, sanitation, maintenance and material handling) and make adjustments where necessary.
- Redesign and/or perform equipment maintenance as necessary.
- Conduct interdictive cleaning such as floor scrubbing and sanitation, or cleaning of overhead pipes and equipment.

TABLE 2: Examples of corrective actions by zone that should be taken after initial *Salmonella* positive environmental result

Zone I Corrective Actions
Product should always be placed on hold if zone 1 *Salmonella* testing is to be done
Quarantine the suspect area and limit access to that area
Break down the line from the initial positive site on for visual inspection, additional vector sponge/swab sampling, and cleaning and sanitation activities
Conduct vector sampling in zones 1, 2, and 3 around the area of the initial positive result prior to cleaning. Precaution should be taken not to spread contamination to other areas of the plant
Thoroughly clean and sanitize the line and surrounding area using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments (47, 49)
Conduct pre-operational inspections on the line equipment and area prior to start-up and take additional vector samples of the area prior to start-up. It is highly advisable not to start-up the line until all vector sampling results are obtained (if the line is started prior to obtaining all vector sampling results, then product must be put on hold until negative results are obtained)
Increase the frequency of intensive sampling of the line and adjacent areas from weekly to daily (zones 1 – 3). After three consecutive days of negatives are obtained, the normal routine PEM sampling plan may be reinstituted
The response team should make a careful decision on disposition of finished product that is put on hold as a result of a zone 1 positive *Salmonella* finding. All finished product from full microbiological clean-up/sanitation to full microbiological clean-up/sanitation must be addressed by the team. Product should be re-worked, if possible, or condemned according to all legal and regulatory statutes. It is not an acceptable practice to test lots of finished product for *Salmonella* in response to a confirmed zone 1 result for the purposes of releasing product.

Zone II Corrective Actions
Stop production and prepare the system for cleaning and sanitation
Quarantine the suspect area and limit access to that area
Break down the line from the initial positive site on for visual inspection, additional vector sponge/swab sampling, and cleaning and sanitation activities
Conduct vector sampling in zones 2, and 3 around the area of the initial positive result prior to cleaning. Precaution should be taken not to spread contamination to other areas of the plant
Thoroughly clean and sanitize the line and surrounding area using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments (47, 49)
Conduct pre-operational inspections on the line equipment and area prior to start-up and take additional vector samples of the area prior to start-up. Do not restart the line until satisfactory vector swab results have been obtained.
Increase the frequency of intensive sampling of the line and adjacent areas from weekly to daily (zones 2, 3). After three consecutive days of negatives are obtained, the normal routine PEM sampling plan may be reinstituted

Zone III Corrective Actions
The response team should make the decision whether or not to stop production based on the proximity of the initial positive site to product contact areas
Quarantine the suspect area and limit access to that area, if feasible
Visually inspect the area and conduct additional vector sponge/swab sampling prior to cleaning and sanitation activities
Conduct vector sampling in zones 2, and 3 around the area of the initial positive result prior to cleaning (zone 2 sampling is done to ensure that contamination has not spread closer to open product areas). Precaution should be taken not to spread contamination to other areas of the plant
Thoroughly clean and sanitize the area (at least a 50 foot radius, if possible) using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments (47, 49)
Conduct pre-operational inspections on the line equipment and area prior to start-up and take additional vector samples of the area prior to start-up. Do not restart the line until satisfactory vector swab results have been obtained.
Increase the frequency of intensive sampling of the line and adjacent areas from weekly to daily (zones 2, 3). After three consecutive days of negatives are obtained, the normal routine PEM sampling plan may be reinstituted

Zone IV Corrective Actions
A *Salmonella* positive finding in a zone 4 location does not implicate finished product, but it does provide information on non-production areas and the potential for spread of contamination throughout the facility
Quarantine the suspect area and limit access to that area, if feasible
Visually inspect the area and conduct additional vector sponge/swab sampling prior to cleaning and sanitation activities
Conduct vector sampling in selected zone 3 areas adjacent to the location of the initial zone 4 positive location, if appropriate, and zone 4 sites around the area of the initial positive result prior to cleaning (selected zone 3 sampling is done to ensure that contamination has not spread closer to open product areas). Precaution should be taken not to spread contamination to other areas of the plant
Thoroughly clean and sanitize the area (at least a 50 foot radius, if possible) using dry, controlled wet, and/or wet cleaning procedures appropriate for low moisture environments (47, 49)
Take additional vector samples of the area after cleaning and sanitation to verify effectiveness of those procedures
Increase the frequency of intensive sampling of the areas from monthly to daily (zone 4 and selected zone 3 areas adjacent to the location of the initial zone 4 positive). After three consecutive days of negatives are obtained, the normal routine PEM sampling plan may be reinstituted.

It would not be unexpected to occasionally find a *Salmonella*-positive result in Zone 4 areas such as high-traffic hallways and employee locker rooms. However, a positive finding needs to be aggressively addressed in order to minimize the potential for spread of the pathogen to other parts of the facility. A Zone 3 positive in the absence of any Zone 2 positives should be considered as an early indication of the need to make the cleaning and sanitation program more robust or to address other potential issues in the plant like traffic flow, and structural or maintenance issues.

If vector samples test positive for *Salmonella* in any zone, then additional samples must be taken to define the scope of the problem. Additionally, aggressive actions must be undertaken to eliminate the problem. The finding of persistent problem areas or "hot spots" over time is an indication that the primary contamination source may be a harborage site where the pathogen has established itself and may be multiplying. In the case of repeated or persistent problem areas, aggressive corrective actions must be taken to contain and correct the problem. The following steps should be taken as part of the root cause analysis by the response team:

- Map the locations of positive samples on a facility diagram to help define the scope of the problem.
- Implement daily vector sampling of the environment until the situation is corrected.
- Restrict traffic flow in these areas to the extent possible.
- Visually inspect areas for potential harborage sites and intensify cleaning efforts in these areas
- Reinforce GMP and food safety practices with line operators and other personnel.
- Visually monitor handling practices (production, sanitation, maintenance, material handling) and make adjustments where necessary.
- Scrutinize equipment cleaning and preventive maintenance practices, then modify if necessary.
- Repair structural damage (e.g., floors, walls, other structures) as necessary.
- Redesign and/or perform equipment maintenance as necessary.
- Zone 1 sampling or finished-product testing may need to be implemented or intensified in the event of persistent Zone 2 positives.

In extreme cases where a hot spot cannot be eliminated or contained, serious consideration must be given by the response team to taking that production line or piece of equipment out of service and physically restricting or segregating that area from the rest of the plant until a permanent solution can be found.

When using a quantitative indicator such as TEB or coliform counts, none of these organisms should be present on equipment after cleaning and sanitation activities. Table 3 lists recommended guidelines for aerobic plate count coliform and TEB counts on clean equipment surfaces before and after application of sanitizer. Typically, preoperational sampling is done after cleaning but before application of sanitizer. This gives a better in-

dication of the effectiveness of cleaning. Samples that are taken after application of sanitizer must include the use of proper neutralizing solutions as discussed in section 3.4.1 to ensure that residual sanitizer does not inhibit recovery of injured cells, if present.

If operational samples are collected for TEB or coliforms, it is critical that a baseline be established under normal operating conditions, as discussed in section 3.7. An upward trend or a sudden deviation from the established baseline would be cause to initiate an investigation and corrective actions. The response team must carefully evaluate trend data over time to establish what constitutes a significant trend.

Table 3. Recommended Microbiological Indicator Limits for Equipment Cleaning Before and After Application of Sanitizer

Quantitative Microbiological Indicator Test	Target/ Acceptable Limits	Post-Heat Treatment Taken Before Sanitizer (cfu/40 in^2)	Post-Heat Treatment – Pre-op Taken After Sanitizer (cfu/40 in^2)
Aerobic Plate Count	Target	< 100	< 10
	Acceptable	< 500	< 100
Coliforms	Target	< 10	< 10
	Acceptable	< 100	< 50
Total Enterobacteriaceae	Target	< 10	< 10
	Acceptable	< 100	< 50

Plant construction, equipment installation, and major repairs

It is well documented that activities such as plant construction, equipment installation and major repair work can lead to increased recontamination risk to the product if not properly managed. In the event of such activities, increased control procedures are required, including:

- Setting up temporary control barriers within the plant, as appropriate. This may include physically separating the area through the use of temporary walls, ceiling-to-floor plastic curtains or other suitable containment barriers.
- Modifying traffic flow in the area to minimize the risk of spreading contamination throughout the rest of the facility.
- Increasing the amount of cleaning and sanitation during construction or equipment-related activities.
- Reinforcing GMP and hygiene practices with plant personnel and, especially, outside contractors.
- If used equipment from outside the plant is installed, it is highly recommended that the equipment be cleaned and sanitized before it enters the plant. The effectiveness of the cleaning and sanitation should be verified through sponge or swab sampling before

installation.
- Airflow and air pressure in the area should also be evaluated and adjusted if necessary to minimize airborne transmission of dust and contaminants.

Sampling the environment for *Salmonella* should be performed during construction or other major activities at an increased frequency and number to ensure that no problems are being created. Sampling sites and frequency should be determined by the team based on an evaluation of:

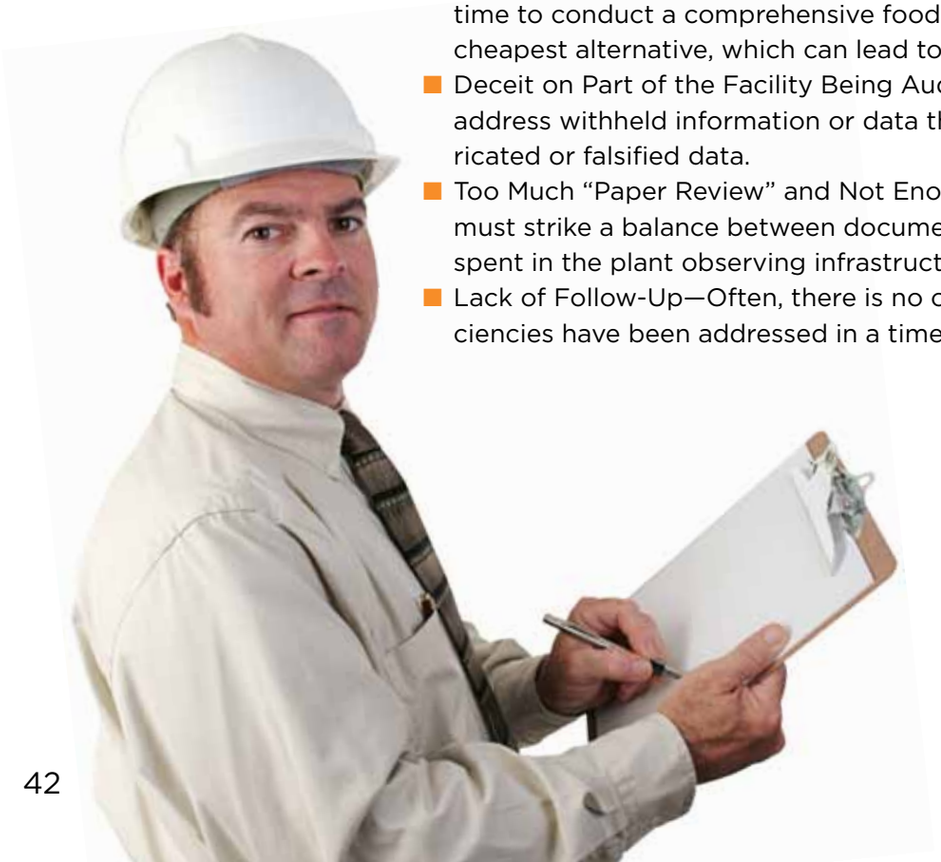
- Location of construction or other activities.
- Type of construction or activity (e.g., demolition, installation, major repair, material removal).
- Time duration of the activities.
- Types of environmental controls implemented.

Once construction or major equipment-related activities are completed, the area needs to be thoroughly cleaned and sanitized. Verification of cleaning and sanitation effectiveness must be performed by intensively sampling the area for *Salmonella* contamination before the area is released for production activities. An aggressive PEM protocol should be followed during commissioning of the area or equipment. Depending on the magnitude of the construction or major activities, this often entails taking hundreds of sponge or swab samples of the environment. If positive results are obtained, then the area or equipment must be recleaned/resanitized and resampled until negative results are obtained.

The Role of Audits in Managing a PEM Program

The food industry has become increasingly reliant on independent third-party audits and certification to ensure that their processes, personnel and establishments conform to food safety and other standards. However, third-party audits have recently come under fire due to several large-scale food-borne outbreaks linked to establishments that have received high scores from third-party auditing firms including the 2008–2009 peanut butter outbreak caused by the Peanut Corporation of America (37, 66). There are a number of factors that have led to this variability in the quality and consistency of food safety audits:

- Differences in Experience Levels of Individual auditors—Even though auditors may be specific to a segment of the food industry (e.g. almond handling and processing), their experience level can vary greatly. This can lead to difficulties in asking the right questions or in focusing on the right issues.
- Auditors Are Not "Jack-of-All-Trades"—It is very rare to find an auditor experienced in all the various aspects of engineering that are germane to food processing, including process, packaging, mechanical, electrical, and design or system engineering. Most auditors are not experts in product formulation, food processing, sanitary design, microbiology and food safety, or other relevant disciplines. Many auditors come from a quality-assurance background rather than a food safety background.
- Time and Cost—Many audits are done in one day or less. This is definitely not enough time to conduct a comprehensive food safety audit. Some companies look for the cheapest alternative, which can lead to glaring mistakes.
- Deceit on Part of the Facility Being Audited— It is extremely difficult for auditors to address withheld information or data that is pertinent to the audit or to pick up on fabricated or falsified data.
- Too Much "Paper Review" and Not Enough Time Spent on the Plant Floor—Auditors must strike a balance between documentation review (which is important) and time spent in the plant observing infrastructure and practices (which is crucial).
- Lack of Follow-Up—Often, there is no or little followup by auditors to ensure that deficiencies have been addressed in a timely manner.



- Lack of Audit Depth—Virtually all audits do not encompass on-site audits of suppliers providing ingredients and materials to the facility being audited. The same is also true for external testing laboratories that the facility being audited may be using for microbiological and other critical testing.
- Over-Reliance on Audits by the Facility—Some companies believe that if they "pass" an audit, everything must be in order, and they become complacent—until the next audit.
- Announced vs. Unannounced Audits—Most third-party audits are announced, giving the facility time to prepare for the audit. Some certification bodies and auditors provide advice to the facility on how to prepare for the upcoming audit. The audit is not reflective of the true operating conditions in the facility.
- Implicit Versus Explicit Conflict of Interest—Both accreditation bodies that set the audit standard and the auditing firm that certifies the facility conforms to the auditing standard go to great lengths to try to ensure impartiality and prevent explicit conflict-of-interest issues with auditors. However, most accreditation bodies and auditing firms are "for-profit" entities; therefore, issues with implicit conflict of interest may persist, since the facility undergoing the audit pays for the audit. Some auditors may tend not to be as tough in their evaluation as they otherwise might be for fear of losing the business.
- Companies Do Little or Nothing With Audit Results—Some companies do not react with a sense of urgency in addressing audit results, particularly on those items that are characterized as "minor deficiencies." Some companies even address major deficiencies such as roof leaks with only temporary or stop-gap measures and do not devote the proper investment and resources to the correct long-term solution.

Some skeptics believe that third-party audits are not truly independent and, by nature, are suspect and of minimal or no value. In fact, however, third-party audits do provide value, but you must recognize they are not infallible. The value your company gets out of third-party audits is directly proportional to your commitment to aggressively following through on audit findings, including minor deficiencies. You must recognize that minor deficiencies, if not addressed in a timely manner, at some point will become major issues. It is much better to address them when they occur rather than let them become major problems for you. There are a number of resources available to you to use in developing or strengthening your third-party certification program. The U.S. FDA has issued a guidance document on voluntary third-party certification programs for foods and feeds (67). This document describes the general attributes that FDA believes a certification program should include to provide high-quality verification of food safety. This document outlines the attributes of a strong third-party certification program. including:

- Authority of the certification body to perform audit activities
  - Authority to examine and gather records and other information
  - Authority to collect and analyze samples
  - Authority to assess and report on compliance with certification criteria
- Qualification and training of auditors

- Effective audit program elements
  - Risk-based
  - Written policies and procedures
  - Verification that the establishment meets certification criteria
  - Process for addressing establishment complaints about audits
  - Documentation and recordkeeping
- Quality assurance program for audits and auditors
  - Field evaluation of audits to verify audits are consistent
  - Audit report evaluation
  - Sample report evaluation
  - Individual auditor performance
- Compliance and corrective actions
  - Apply a risk-based approach to determine when an investigation, followup and re-audit are necessary
  - Evaluate whether the establishment has executed proper corrective actions
  - Withdraw certification if the establishment fails to take corrective actions
- Industry relations
  - The certification body (auditing company) should provide establishments seeking certification with information about current FDA requirements and guidance
  - It is preferable that the certification body be actively involved in regulatory, scientific, industry and other external activities
- Resources
  - The third-party certification body should have sufficient resources to accomplish the elements of the certification program
- Self-assessment of the overall certification program
  - Assesses performance and identifies strengths and weaknesses
- Laboratories
  - The certification body should have access to the appropriate laboratory services needed to support the audit
- Ability and willingness to notify the FDA
  - Product safety issues
  - Certification withdrawal
  - Changes to the certification program
- Attention to conflict of interest
  - The certification body and its auditors should be free of any conflicts of interest that threaten impartiality

An in-depth evaluation of your PEM program and data should always be a part of an overall independent third-party audit. This also includes an in-depth review of all documented corrective actions, procedures and other information discussed in this guidance document. The PEM program is a major tool that is critical to demonstrating the effec-

tiveness of your facility's GMPs, hygienic practices and food safety plan. Therefore, it is crucial it be part of every third-party food safety audit that is conducted.

A strong third-party auditing and certification program, if conducted properly, can be a meaningful investment and tangible evidence of your company's commitment to food safety. In the end, the rewards you get from a strong program are directly related to the time, diligence and commitment you put into the program.

Personnel Education and Training and Management Commitment

It is incumbent upon the company to ensure that employees are properly trained in effective GMPs, hygienic practices, food safety principles, and other practices and procedures that enable them to do their job in an effective manner that will not jeopardize the product or the consumer. Plant personnel can have a direct impact on the safety of the foods produced in the facility. The risk of product recontamination within the facility can be significantly reduced with effective training and monitoring of ongoing employee practices.

The FDA's GMP regulations stipulate that "Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices" (68). The FDA also states, as part of its GMP modernization initiative, that ineffective training of employees is a problem at the food manufacturer level relative to controlling microbiological hazards in foods (69). In their analysis, the FDA states that it is not clear that current training methods are sufficient and that the training many companies conduct may be too generic. They also believe that other impediments to effective training may include training the wrong people not training enough people or not providing enough training. The FDA has articulated the following beliefs about training (70):

- Food production workers should have appropriate training in the principles of food hygiene and food protection, and this training should include the importance of employee health and personal hygiene.
- Training must be delivered in a form that is readily understandable to all personnel and delivered in a manner that is easily understood by the trainee.
- Food processors must maintain a record of this training for each employee.
- Certain core principles of food safety, equipment sanitation and regulatory compliance must be included in the training of all food workers and supervisors.

The FDA's focus on the importance of employee health and personal hygiene is supported by the fact that many food-borne outbreaks and illnesses, including those caused by *Salmonella*, have been traced to recontamination of the food directly by food handlers. The Center for Disease Control (CDC) publishes an annual list of infectious and communicable diseases that are transmitted through handling foods (Table 4) (71). Stressing the importance of complying with good personal hygiene and hygienic practices, including proper hand washing, is critical in any employee GMP training program.

Table 4. CDCs List of Pathogens Transmitted by Food Contaminated by Infected Handlers or From Food That is Cross-Contaminated During Processing or Preparation

Pathogens Frequently Transmitted by Food Through Infected Handlers	Pathogens Occasionally Transmitted by Food Through Infected Handlers or Through Cross-Contamination During Processing/Preparation
Noroviruses	Campylobacter jejuni
Hepatitis A virus	Cryptosporidium spp.
Salmonella Typhi	Entamoeba histolytica
Sapoviruses	Enterohemorrhagic Escherichia coli
Shigella spp.	Enterotoxigenic Escherichia coli
Staphylococcus aureus	Giardia intestinalis
Streptococcus pyogenes	Nontyphoidal *Salmonella*
	Taenia solium
	Vibrio cholerae
	Yersinia enterocolitica

Effective training is also a key part of a successful PEM program. Employees must understand that effective monitoring of the environment is a critical measure of the success of the company's food safety commitment. Employees should never be discouraged from aggressively trying to find the pathogen in the plant's environment. If *Salmonella*e are present in the plant environment, you want to find it. Only if you can find it can you control it and reduce the risk to the franchise and your consumers. The FDA also believes that third-party validation of test results can be useful to further establish confidence in your environmental sampling results (69). It is highly recommended that your company have a qualified outside expert validate your PEM program.

Effective training is also a key part of a successful PEM program. Employees should never be discouraged from aggressively trying to find the pathogen in the plant's environment.

You must also understand that education and training go hand-in-hand. Food safety education focuses more on the *why* food safety is important, and food safety training focuses more on the *how* to do food safety (72). The reason food safety education and training are stressed so much is that they focus on influencing the employee's behavior. Research has shown that if education and training materials can be personalized, then they are much more effective in influencing behavior than by just showing facts or statistics.

Overall, the success of any PEM program is directly dependent on support and commitment throughout the organization, starting with top management and cascading down. If management does not provide sufficient resources, both in terms of capital and personnel to do an effective job, then it will ultimately fail. If management is more worried about "meeting the numbers" than supporting a robust food safety culture throughout the organization, then it will fail. In high-performing, successful companies, food safety is not considered just a "program"; it is a pervasive part of the company's culture. The leaders in successful companies take a systems-based, behavior-based approach to creating a food safety culture throughout the organization (72, 73). Food safety should not be viewed as a cost. Sure, there are costs associated with a commitment to food safety, but senior management must realize that investing in food safety, including investing in a solid PEM program, is a smart investment. It is an investment no different than in investing in sales and advertising, production and distribution, or new product development. Research shows that companies that are dedicated to food safety and those that instill a culture of food safety throughout the organization are big winners in the marketplace. The company wins, the employees win, and the consumer wins.

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