CONTROL OF *SALMONELLA* IN LOW-MOISTURE FOODS

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AUTHORS AND ACKNOWLEDGEMENTS

This document has been prepared by Yuhuan Chen (GMA), Timothy Freier (Cargill; chair of Task Force), Jeff Kuehm (Frito-Lay), Mark Moorman (Kellogg), Jenny Scott (GMA), Joseph Meyer (Kellogg and formerly ConAgra Foods), Theodora Morille-Hinds (Kraft Foods), Laurie Post (Mars Snackfood US), Leslie Smoot (Nestlé USA), Scott Hood (General Mills), Joseph Shebuski (Cargill) and Jeff Banks (Cadbury), with assistance from others in the GMA *Salmonella* Control Task Force. Beside the authors, the Task Force consists of Joan Pinkas (McCormick & Company), Karl Olson (Abbott Nutrition), Kurt Deibel (PepsiCo), Dick Smittle (Silliker), Russ Flowers (Silliker), Sterling Thompson (Hershey), Richard Podolak (GMA), Elena Enache (GMA), and Warren Stone (GMA). The input to the guidance document by the GMA Microbiological Safety Committee and the Scientific and Regulatory Affairs Council is also appreciated.

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EXECUTIVE SUMMARY

There is a common misconception that low numbers of *Salmonella* are not a problem in low-moisture foods because these products do not support *Salmonella* growth. However, low numbers of *Salmonella* in foods can cause illness, and the presence of the organism in low-moisture ready-to-eat foods must be prevented.

Over the last several decades, a number of outbreaks of salmonellosis have been associated with the consumption of ready-to-eat low-moisture products, including chocolate, powdered infant formula, raw almonds, toasted oats breakfast cereal, dry seasonings, paprika-seasoned potato chips, dried coconut, infant cereals and, more recently, peanut butter and children's snacks made of puffed rice and corn with a vegetable seasoning. Although *Salmonella* outbreaks from low-moisture products are relatively rare, they often impact large numbers of people. More than 200 cases were attributed to toasted oats cereal in 11 states between April and June 1998, more than 600 cases were attributed to peanut butter in 47 states between August 2006 and May 2007, and more than 500 cases have been attributed to peanut butter and peanut butter-containing products in 43 states between September 2008 and January 2009. Due to the large number of unreported cases of salmonellosis for all types of products, the actual number of cases was likely much higher.

These outbreaks underscore the difficulty in eradicating *Salmonella* from the environment of dry product manufacturing facilities and illustrate the wide diversity of low-moisture products that can be contaminated with *Salmonella* and cause illness. These outbreaks also highlight the need to reinforce industry preventive control measures through guidance based on the best available information.

To address the need for industry-wide guidance, the Grocery Manufacturers Association (GMA) formed a *Salmonella* Control Task Force to develop, through a review and synthesis of industry programs and information from the literature, this guidance document for the control of *Salmonella* when manufacturing low-moisture foods. The guidance is applicable to various products that include, but are not limited to, peanut butter, cereals, dry protein products (such as dried dairy products, soy protein, rice protein), confections (such as chocolate), snacks (such as corn chips), spices, animal feeds (both ingredients and finished products), pet foods and pet treats. Depending on the susceptibility of the product to *Salmonella* contamination, all or selected practices described in this guidance may be applied.

Salmonella Control Elements

To minimize the risk of *Salmonella* contamination the following seven elements should be applied to control *Salmonella* in low-moisture products:

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

   Conduct a hazard analysis to determine potential sources of *Salmonella*, including those associated with facility integrity, air flow, personnel and traffic movement, equipment design and incoming raw materials. Segregate ingredients known to be contaminated with *Salmonella* and establish a program to minimize the risk from water usage. Educate employees on the potential sources of contamination, adherence to traffic patterns, and

proper hygienic practices to follow in order to minimize the ingress or spread of *Salmonella* in the processing area.

2. **Enhance the stringency of hygiene practices and controls in the Primary *Salmonella* Control Area.**

   The Primary *Salmonella* Control Area (PSCA) in a low-moisture product facility is the area where handling of ingredients and product requires the highest level of hygiene control. Establish barriers to separate the PSCA from the rest of the facility. Control all traffic between the PSCA and the rest of the facility, including the movement of personnel and materials. Avoid activities that may lead to contamination of the PSCA.

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

   Building design and layout should be based on hygienic principles, using common practices such as those outlined in the literature. Particular attention should be given to sanitary design, layout and maintenance of equipment located in the Primary *Salmonella* Control Area (PSCA) to ensure that moisture can be excluded from the processing environment, including the utilization of dry cleaning procedures.

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

   Moisture control is critically important in preventing *Salmonella* contamination in low-moisture products. Dry conditions must be maintained at all times in the PSCA, except for the occasions when controlled wet cleaning is deemed essential, e.g., in response to a product contamination incident. Efforts must be made to remove water immediately from the PSCA in the event of water ingress, for example, leaking water or steam valves, infiltration of water following heavy rains (e.g., leaky roofs), etc. in order to keep the plant environment as dry as possible.

5. **Establish a raw materials/ingredients control program.**

   "*Salmonella*-sensitive" ingredients are ingredients that have been historically associated with *Salmonella* (tested positive for the pathogen), have been implicated in past outbreaks, or are used to make products that are intended for at-risk individuals. Obtain sensitive ingredients from an approved supplier (one that can provide a high degree of assurance that *Salmonella* is not likely to occur in the ingredient through the implementation of appropriate process controls). Evaluate the supplier's food safety program with respect to a pathogen environmental monitoring program, sanitation practices, raw materials/ingredients storage, a finished product hold and release testing program, process validation, and a corrective action plan if positive *Salmonella* results are found (with evaluation of the potential significance for other products or ingredients manufactured in the processing facility or on the line being evaluated).

6. **Validate control measures to inactivate *Salmonella*.**

   Determine the target level of *Salmonella* reduction in the product and process under consideration. Determine the adequacy of the selected control measure and associated critical limits for processing, keeping in mind the increased heat resistance reported for *Salmonella* at low water activities. Challenge studies may be warranted. Once the

lethality of the process is validated by scientific data, ensure the operation can deliver the critical limits and that the parameters are consistently met through in-plant validation, which is an integral part of the validation process. Non-thermal control measures can also be used, with validation, to eliminate *Salmonella*.

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

   Verification should focus on implementing a robust environmental monitoring program that has been designed to identify transient and/or resident *Salmonella* in the processing areas. Environmental monitoring for *Salmonella* is generally conducted on non-product contact surfaces, with samples taken primarily in the Primary *Salmonella* Control Area under normal operating conditions. Product contact surface testing may be done as part of corrective actions for an environmental positive. Manufacturers should decide whether or not to conduct finished product testing based on an evaluation of risk. Customer requirements (i.e., Certificates of Analysis) may also dictate the need for finished product testing. Whenever finished product testing is performed, the tested lot should be isolated, placed on hold, and only released into commerce if the product tests negative for *Salmonella*. If a product sample tests positive for *Salmonella*, the tested lot is considered adulterated and should not be released into commerce. Retesting should not be conducted for the purpose of negating the initial test results as this almost always increases the chance of accepting a contaminated lot. Corrective actions must be taken when *Salmonella* is detected in an environmental monitoring or finished product sample.

These seven elements of manufacturing practices are further elaborated in various sections in the guidance. Manufacturers of low-moisture products may consider modifying their programs where necessary based upon this guidance document. This guidance is not intended to be all-encompassing or to replace basic GMPs and the development of a product and process-specific HACCP plan. Rather, the guidance serves to highlight practices important for control of *Salmonella* in low-moisture products. These guidelines may be used to develop a new food safety system or to augment an existing system already employed by a manufacturer or supplier.

INTRODUCTION

Description of the Problem

As a result of an outbreak of *Salmonella enterica* serotype Tennessee infections associated with the consumption of peanut butter in 2006-2007(CDC, 2007a), intensified efforts have been taken to reassess industry practices for controlling *Salmonella* in low-moisture products. These products include those exposed to the processing environment following a final lethality step, products that are not subjected to an inactivation step, or products in which *Salmonella*-sensitive ingredients are added after an inactivation step. *Salmonella* outbreaks from low-moisture products are relatively rare but often impact large numbers of people. In the US between 1996 and 2006, of 64 outbreaks (with 5981 cases) of salmonellosis reported for FDA-regulated foods (excluding eggs), only 2 were from low-moisture processed food products (Zink, 2007a). In addition, one outbreak resulted from cake batter ice cream in which the source of *Salmonella* Typhimurium was the cake batter mix (FDA, 2005), which was not intended for use in a ready-to-eat food such as ice cream. However, the two outbreaks attributed to low-moisture food products (toasted oats cereal and peanut butter) involved a large number of illnesses. During the course of the outbreak investigations, CDC reported 209 cases attributed to toasted oats cereal in 11 states between April and June 1998 (CDC, 1998) and 628 cases attributed to peanut butter in 47 states between August 2006 and May 2007 (CDC, 2007a). These two outbreaks eventually accounted for 1037 clinically confirmed cases of illness (Zink, 2007a). Moreover, a second major *Salmonella* outbreak in the US attributed to peanut butter and products containing peanut-derived ingredients (CDC, 2009; FDA, 2009a) involved more than 500 cases in 43 states between September 2008 and January 2009 and again highlighted the need to address the problem of *Salmonella* in low-moisture products. Due to the large number of unreported cases of salmonellosis for all types of products (Mead, 1999), the actual number of cases was likely much higher.

Over the last several decades, a number of outbreaks of salmonellosis have been associated with the consumption of ready-to-eat low-moisture products, including chocolate, powdered infant formula, raw almonds, toasted oats breakfast cereals, dry seasonings, paprika-seasoned potato chips, dried coconut, infant cereals and, more recently, peanut butter and children's snacks made of puffed rice and corn with a vegetable seasoning (Table I-1). A search of the EU pathogen alert system showed that *Salmonella* has been detected in coriander, dehydrated onions, dried mushrooms, sesame seeds, dried sage, spices, and soybean meal (Betts, 2007). A review of recall records at FDA by Vij and colleagues (2006) showed that from 1970 to 2003 there were 21 recalls involving spices and herbs contaminated with *Salmonella*. Sixteen of these recalls occurred during 2001-2004, and 12 of these recalls involved spices imported from around the world (India, Spain, Turkey, Egypt, Jamaica, Mexico, and Taiwan). The spices in these recalls included ground black pepper, ground cumin, ground oregano, paprika, red pepper powder, ground sage, sesame seeds and ground thyme, and the herb basil leaves (Vij et al., 2006).

The presence of *Salmonella* in low-moisture products is a concern because low numbers of *Salmonella* in foods can cause illness. This is contrary to a common misconception that low numbers of *Salmonella* are not a problem in low-moisture foods because these products do not support *Salmonella* growth. *Salmonella* does not need to grow to cause illness; in some instances infection has occurred from consuming low-moisture products contaminated with less than 1 cfu/g depending on the host, the product, and the *Salmonella* strain. For example,

several incidents involving low numbers of salmonellae in chocolate have been reported over the years (Table I-2). In an outbreak attributed to paprika and paprika-powdered potato chips (Lehmacher et al., 1995), *Salmonella* was found at 0.04-0.05 cfu/g in the snacks. In the 2006-2007 outbreak associated with peanut butter, *Salmonella* was found at 1.5 MPN/g in an unopened jar and a lower level was found in another product sample (Zink, 2008). Chocolate contaminated with low levels of *Salmonella* Montevideo was associated with a number of cases in the UK in 2006 (ACMSF, 2006; FSA, 2006). A chocolate-related outbreak provided the first strong evidence that large numbers of salmonellae were not necessarily a prerequisite for human infection (D'Aoust, 1977; D'Aoust, 1989; D'Aoust and Maurer, 2007) and that the composition of a food ingredient (e.g., high in fat) may protect *Salmonella* against the acidic conditions of the stomach, thus increasing the likelihood of illness from consuming low numbers of the organism. Even small numbers of salmonellae present in the product could colonize the lower gastrointestinal tract and produce clinical symptoms (Waterman and Small, 1998).

Salmonella infections associated with the consumption of contaminated confectionary products such as chocolate, candy and cocoa powder, although rare, have been known since the late 1960s (D'Aoust, 1977). For example, cocoa powder contaminated with *Salmonella* Durham was used in confectionery products that caused an outbreak affecting 110 people in Sweden (Gastrin et al., 1972). Common to all reported chocolate outbreaks is the relatively long duration of the outbreak, wide geographic dissemination, and the large number of affected people, comprised mainly of children (Craven et al., 1975; D'Aoust et al., 1975; Gastrin et al., 1972; Gill et al., 1983; Kapperud et al., 1990). In addition, very small numbers of *Salmonella* recovered from chocolates in these outbreaks indicated a low infectious dose. In an international outbreak associated with chocolate made in Germany, estimates of the numbers of *Salmonella* Oranienburg ranged from 1.1–2.8 cells per gram (Werber et al., 2005). *Salmonella* Nima was found at levels as low as 0.04 cells/g in Belgium-made chocolate coins implicated in an outbreak in Canada (Hockin et al., 1989).

Recommendations for control measures for *Salmonella* in dried milk products were established after outbreaks of salmonellosis traced to these products occurred in the 1960s and 1970s (Mettler, 1994; ICMSF, 2005a). However, outbreaks from low-moisture products have continued to occur periodically (Table I-1). Notably, an outbreak associated with puffed wheat and rice cereal (CDC, 2008a) involved the same strain of *Salmonella* Agona that had been implicated in an outbreak ten years earlier from a toasted oats cereal produced within the same manufacturing facility. Finding the same strain in products produced within the same facility suggests this organism may have persisted within the facility over the 10-year time period. In addition to illnesses associated with the consumption of low-moisture products, a recent multistate outbreak in the US involved the handling of contaminated dry dog foods as the source of human infections of *Salmonella* Schwarzengrund (CDC, 2008b). The dog food manufacturer has since closed the implicated production facility due to a second recall linked to the same organism (CDC, 2008c). These outbreaks underscore the difficulty in eradicating *Salmonella* from the environment of dry products manufacturing facilities and illustrate the wide diversity of low-moisture products that can be contaminated with *Salmonella* and cause illness. These outbreaks also highlight the need to reinforce industry preventive control measures through guidance based on the best available information.

To address the need for industry-wide guidance, the Grocery Manufacturers Association (GMA) formed a *Salmonella* Control Task Force to develop this guidance document through

a review and synthesis of industry programs as well as information from the literature. The industry practices in this document have been collated by the Task Force to provide guidance on approaches to control *Salmonella* and help assure the microbial safety of low-moisture products.

Table I-1. Selected *Salmonella* outbreaks associated with low-moisture products

Year	Product implicated	Etiologic Agent	Country	Reference
1970	Chocolate	*S.* Durham	Sweden	Gastrin et al., 1972
1972	Fishmeal	*S.* Agona	US	Clark et al.,1973
1973	Milk powder	*S.* Derby	Trinidad	D'Aoust and Maurer, 2007
1982-83	Chocolate	*S.* Napoli	UK	Greenwood and Hooper, 1983
1985-86	Chocolate	*S.* Nima	Canada, US	Hockin et al., 1989
1987	Chocolate	*S.* Typhimurium	Norway, Finland	Kapperud et al., 1990
1993	Paprika-seasoned potato chips	*S.* Saintpaul, *S.* Javiana, *S.* Rubislaw	Germany	Lehmacher et al., 1995
1993	Powdered infant formula	*S.* Tennessee	Canada, US	CDC, 1993
1995	Infant cereals	*S.* Senftenberg	UK	Rushdy et al., 1998
1996	Peanut butter	*S.* Mbandaka	Australia	Ng et al., 1996
1996	Peanut-flavored maize snack	*S.* Agona	Multiple countries [a]	Killalea et al., 1996; Shohat et al., 1996
1998	Toasted oats cereals	*S.* Agona	US	CDC, 1998
2000-01	Raw almonds	*S.* Enteritidis	US, Canada	CDC, 2004
2001	Peanuts	*S.* Stanley, *S.* Newport	Multiple countries [b]	Little, 2001
2001	Chocolate	*S.* Oranienburg	Multiple countries [c]	Werber et al., 2002; Ethelberg, 2002; Fisher et al., 2002; Gill et al., 2008
2002	Tahini and Halva	*S.* Montevideo	Australia	Tauxe et al., 2008
2003-04	Raw almonds	*S.* Enteritidis	US, Canada	CDC, 2004
2006	Chocolate	*S.* Montevideo	UK	FSA, 2006
2006-07	Peanut butter	*S.* Tennessee	US	CDC, 2007a
2007	Children's snack	*S.* Wandsworth, *S.* Typhimurium	US	CDC, 2007b
2008	Puffed cereals	*S.* Agona	US [d]	CDC, 2008a
2008	Powdered infant formula	*S.* Give	France	Jourdan et al., 2008
2008-09	Peanut butter, peanut butter-containing products	*S.* Typhimurium	US, Canada [e]	CDC, 2009

[a] Including UK, US, and Israel.

[b] Including Australia, Canada, and UK.

[c] Including illnesses in Germany, Denmark, Austria, Belgium, Finland, Netherlands, Sweden and positive products in Canada, Croatia, and Czech Republic.

[d] Puffed rice cereals and puffed wheat cereals were implicated in the outbreak; the same *Salmonella* Agona strain from the same manufacturer was implicated in the 1998 outbreak involved toasted oats cereals.

[e] One case was reported in Canada.

Table I-2. *Salmonella* levels in chocolate associated with outbreaks [a]

Year	Serovar	*Salmonella* level (cfu/g)	Vehicle [b]	Source of contamination	No. of illness cases	Country	References
1973-1974	*S.* Eastbourne	2.5	Chocolate balls from Canada	Cocoa beans	200	US, Canada	Craven et al., 1975; D'Aoust et al., 1975
1982	*S.* Napoli	2-23	Chocolate bars from Italy	Contaminated water (postulated)	272	England, Wales	Gill et al., 1983
1985-1986	*S.* Nima	0.04-0.24	Chocolate coins from Belgium	Unknown	_	Canada	Hockin et al., 1989
1987	*S.* Typhimurium	≤1	Chocolate products from Norway	Avian contamination (postulated)	349	Norway, Finland	Kapperud et al., 1990
2001–2002	*S.* Oranienburg	1.1–2.8	Two chocolate brands from Germany	Unknown	439	Germany, other European countries	Werber et al., 2005

[a] Adapted from Werber et al. (2005).
[b] In each outbreak, the identified vehicles was traced to a single manufacturer.

A Review of Existing Industry Practices

A survey was conducted in May 2007 to obtain information from GMA members on current practices and measures the industry employs to control *Salmonella* in manufacturing low-moisture products, i.e., foods with water activity (a_w) below 0.85, including products such as cereal, chocolate, spray-dried milk, infant formula, and peanut butter. There were a total of 17 companies/plants that responded to the survey.

All respondents (100%) had standard operating procedures (SOPs) to eliminate or minimize cross-contamination from raw ingredients or from the environment. Sixteen of 17 respondents (94%) required "*Salmonella*-sensitive" ingredients (those that could be potentially contaminated) to be sourced from an approved supplier. While 16 respondents (one did not respond to this question) had an environmental monitoring program for non-product contact surfaces for *Salmonella*, 2 of the 16 respondents (12.5%) monitored *Salmonella* on product contact surfaces on a routine basis. Fifteen of 17 respondents (88%) had an environmental monitoring program for non-product contact surfaces. The majority of respondents (80-90%) had the following practices: test "*Salmonella*-sensitive" ingredients (either in house or by the supplier); include equipment sanitary design review in the *Salmonella* control program; and validate the lethality of thermal processes for *Salmonella*.

Half or more of the respondents (50-70%) routinely analyzed finished products for *Salmonella* as part of quality assurance, established "high hygiene" zones with more stringent hygiene requirements and procedures, and analyzed the air systems (HVAC) for *Salmonella* as part of the environmental monitoring program. Fifty-three percent of respondents had manufacturing periods for the dry portion of their operations that extended 7 days or longer (several companies run production for 28 to 35 days) prior to shutting down for sanitation. Forty-seven percent of respondents had a captive shoes policy (i.e., shoes worn solely within the facility) in place for employees, including temporary contractors. In addition to industry practices, respondents were asked about situations that could introduce water into the facility, and 56% of them had experienced roof leaks or other water leak incidents into the production area.

Another survey was conducted several years ago by the Food Industry Microbiology Round Table (Kuehm, 2002) on industry practices for environmental monitoring for non-meat products. Among 20 respondents with programs to monitor the process environment for pathogens, 15 monitored for *Salmonella* on a weekly or monthly frequency. Four companies monitored daily, two respondents monitored quarterly, and one monitored twice a year. For the number of samples taken at these frequencies, a slight majority (11 out of 20) obtained 10-20 samples, while others took either less than 10 or 21-50 samples. More than half of the respondents (12 out of 20) divided the process environment into zones; and samples were taken during production (6 out of 20), after sanitation (2 out of 20), or after sanitation and during production (6 out of 20 respondents). Some companies preset the sampling sites (8 out of 20), others randomly selected sites (9 out of 20), or did both (3 out of 20). The vast majority of the sampling was done by plant personnel (18 out of 20) and occasionally by corporate personnel (1 out 20) or both (1 out of 20 respondents).

An expert meeting convened by the Food and Agriculture Organization and the World Health Organization (FAO/WHO) issued a report on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula (FAO/WHO, 2006). A detailed description on the management of *Salmonella* and *E. sakazakii* (*Cronobacter* spp.) in powdered infant formula was also

published recently (Cordier, 2008). These reports included a summary of risk-reduction strategies the infant formula industry has taken for the past 30-40 years. Triggered by outbreaks or isolated cases associated with *Salmonella* and *E. sakazakii* in infant formula, the industry has implemented specific control measures to prevent contamination of products with *Salmonella*. The general principles described in the reports are:

1. Avoid entrance of *Salmonella* into the processing facilities, particularly the zones from drying to filling that are considered as high hygiene areas.
2. Prevent *Salmonella* growth in case of entry and prevent the establishment of *Salmonella* niches in the facility.
3. Use hygienic design for high hygiene zones and equipment in these zones.
4. Use "*Salmonella*-negative" dry-mixed ingredients based on a sampling plan such as the ICMSF case 15 (n=60, c=0, m=0, size=25g), recognizing that the absence of *Salmonella* cannot be achieved based on product testing alone.

These general principles are considered applicable to *Salmonella* control for other reduced a_w products such as dried dairy products and dry-mixed ingredients (such as soy-based products) where the organisms is recognized as a significant hazard. Strategies considered effective for controlling *Salmonella* in confectionary products (Williams et al., 2006) include understanding the microbial ecology in the plant, process and production control, moisture control, testing of ingredients to be added after the inactivation step, and environmental monitoring.

GMA member companies producing products in the low-moisture product category apply HACCP principles to a wide range of products. HACCP includes seven principles (NACMCF, 1998), which are:

1. Conduct a hazard analysis
2. Determine the critical control points (CCPs)
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record-keeping and documentation procedures

The basic concept underlying HACCP is to prevent the occurrence of food safety hazards in the finished product by building safety into the process. Prevention is a component of the overall food safety management system to control *Salmonella* in low-moisture products. One or more of the HACCP principles may be applied as part of a *Salmonell*a control program, including conducting a hazard analysis on sensitive dry-mix ingredients, establishing critical control point(s) to eliminate *Salmonella,* validating critical limits, establishing verification procedures and assessing the risk of post-lethality recontamination. This guidance document reflects the application of HACCP principles founded on good manufacturing practices and other prerequisite programs to minimize the risk of *Salmonell*a contamination in low-moisture products.

Executive Summary of Literature Review

A comprehensive literature review was conducted to identify sources of *Salmonella*, determine the persistence of *Salmonella* in low-moisture products and in the environment, and assess the relevance of heat resistance studies. The literature review is included as an annex to this guidance document.

Low-moisture products such as peanut butter, infant formula, toasted cereals, and dry aniseed are characteristically low a_w foods that do not support the growth of *Salmonella*. Yet all of these products have been implicated in outbreaks of salmonellosis. Investigations of these outbreaks indicate that *Salmonella* cross contamination in low-moisture foods occurred due to poor sanitation practices, poor equipment design, improper maintenance or poor ingredient control.

Salmonella can persist for prolonged periods of time in the dry state and in low-moisture products. The ability of the organism to survive under dry and other adverse environmental conditions makes it difficult to control. Although some reduction of numbers occurs in low-moisture foods during storage, the degree of reduction depends on many factors such as storage temperature and product formulation. In challenge studies, *Salmonella* was detected in chocolate products after 1-9 month storage at room temperature (Tamminga et al., 1976), in peanut butter products after 6-month storage at room temperature and after storage for more than 6 months at refrigeration temperature (Burnett et al., 2000). *Salmonella* Enteritidis PT 30, a strain associated with an outbreak from raw almonds, was isolated from an almond farm over a period of 5 years (Uesugi et al., 2007). Although storage of high fat low-moisture products at low temperatures (e.g., refrigeration) may be beneficial in preventing oxidative rancidity, low temperatures may enhance the survival of *Salmonella*.

Heat resistance of *Salmonella* is greatly increased at reduced water activities in food matrices (exceptions to this trend observed in laboratory media are discussed in a later section). In molten chocolate, *Salmonella* Typhimurium was reported to have a D-value of 816 minutes at 66 ^{o}C (Goepfert and Biggie, 1968) and it was more heat resistant than *Salmonella* Senftenberg 775W evaluated in the same product. Serovars of *Salmonella* (Agona, Enteritidis and Typhimurium) in peanut butter showed no significant differences in heat resistance (Shachar and Yaron, 2006). When heat resistance parameters were determined based on the linear portion of the inactivation curve for *Salmonella* on oil-roasted almonds, the D-value was 0.85 min at 121 °C and the z-value was 27 °C (Harris, 2008). The nonlinear Weibull model was also used to fit inactivation curves for *Salmonella* in heated peanut butter and on oil-roasted almonds. Based on this model, 42±8 min at 90 °C was needed to give a 5-log reduction of a mixture of three outbreak-associated *S.* Tennessee strains in peanut butter (Doyle and Ma, 2009) and more than 260 min was needed to reduce *Salmonella* by 7 log CFU/g at 70 ^{o}C in peanut butter (Shacher and Yaron, 2006). For oil-roasted almonds, 2.06 ±0.57 min at 121 °C was needed to achieve a 5-log reduction of *S.* Enteritidis PT 30 based on the Weibull model (Abd et al., 2008), in comparison to 4.25 min at 121 °C needed for 5-log reduction based on the D-value (Harris, 2008). Increasing solids level in dried milk increased the heat resistance of *Salmonella* Alachua (Dega et al., 1972). At 57 ^{o}C, the D-value was 38, 12.5, and 1.6 min for *S.* Alachua in 51%, 42% and 10% milk solids concentrate, respectively. The z-value likewise increased as the solids level in the milk was increased. The z-value for *S.* Alachua was reported as 4.1, 6.2 and 6.9 ^{o}C at 10, 42 and 51% milk solids, respectively.

The heat resistance of *Salmonella* is affected by many factors, including strain and serotypes tested, growth and storage conditions, food composition, test media and the media used to recover heat damaged cells. In some cases, setting process parameters based on D- and z-values would be a more conservative approach than based on the nonlinear Weibull model. Due to variations in these parameters, it is important, when using published heat resistance data and applying them to a certain food processes, that the conditions under which the values

were obtained not be significantly different from the product or process parameters used by the processor.

SCOPE

This guidance describes practices for the control of *Salmonella* when manufacturing low-moisture foods with water activity (a_w) below 0.85. The guidance is applicable to various products that include, but are not limited to, peanut butter, cereals, dry protein products (such as dried dairy products, soy protein, rice protein), confections (such as chocolate), snacks (such as corn chips), spices, animal feeds (both ingredients and finished products), pet foods and pet treats. Depending on the susceptibility of the product to *Salmonella* contamination, all or selected practices described in this guidance may be applied.

This guidance is based on the best available scientific data and information, as well as collective industry experiences. It is intended to be a living document that will be updated as new information or scientific data become available.

SALMONELLA CONTROL ELEMENTS

Contamination of low-moisture products with *Salmonella* is of concern in operations without an inactivation step (such as a dry-blending operation) or when it occurs after the inactivation step. *Salmonella* outbreaks associated with low-moisture products may occur due to the inclusion of contaminated (raw) ingredients, insufficient processing, or post-processing contamination (CAC, 2008).

To minimize the risk of *Salmonella* contamination the following seven elements should be applied to control *Salmonella* in low-moisture products:

1. Prevent ingress or spread of *Salmonella* in the processing facility.
2. Enhance the stringency of hygiene practices and controls in the Primary *Salmonella* Control Area.
3. Apply hygienic design principles to building and equipment design.
4. Prevent or minimize growth of *Salmonella* within the facility.
5. Establish a raw materials/ingredients control program.
6. Validate control measures to inactivate *Salmonella*.
7. Establish procedures for verification of *Salmonella* controls and corrective actions.

These seven elements of manufacturing practices are further elaborated in the sections below. Manufacturers of low-moisture products may consider modifying their programs where necessary based upon this guidance document. Basic principles for good manufacturing practices (GMPs; also referred to as good hygiene practices, GHPs) have been outlined elsewhere, e.g., in the FDA cGMP regulations 21 CFR 110 (CFR, 2008b) and the Codex general principles of food hygiene (CAC, 2003), as are HACCP principles and application guidelines (NACMCF, 1998; CAC, 2003; ISO, 2005; Scott and Stevenson, 2006). This guidance is not intended to be all-encompassing or to replace basic GMPs and the development of a product and process-specific HACCP plan. Rather, the guidance serves to highlight practices important for control of *Salmonella* in low-moisture products. These guidelines may be used to develop a new food safety system or to augment an existing system already employed by a manufacturer or supplier.

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

Facility maintenance, hygiene and pest control are necessary to avoid or minimize the ingress of *Salmonella* into the processing facility. Recognized vehicles for ingress and spread of *Salmonella* into the processing plant include sources related to raw ingredients (e.g., raw peanuts, bottom of pallets, floor of shipping trucks), integrity and design of the facility (e.g., leak from roof, inadequate separation of pre- and post-processing areas, poor equipment design), personnel (e.g., employee clothing/shoes, improper employee hygiene), and production-related processes (e.g., inadequate sanitation, improper traffic patterns) (Hall, 2007; McNamara, 2007; Zink, 2008). Raw materials used to manufacture low-moisture products, such as spices, raw cocoa beans, raw nuts, raw peanuts, flour and cereal grains, may be a potential source of *Salmonella*. Surveys reported the incidence of *Salmonella* in wheat flour ranged from 0.14% to 1.32% (Sperber et al., 2007), in 1.5% to 8.2% of untreated spice samples (Pafumi, 1986), and in 1.5% of production samples and 1.1% of retail samples of dried spices and herbs in the UK (Sagoo et al., 2009). Employees may carry *Salmonella* into the facility via shoes or clothing worn outside of the plant. Improper handling practices or traffic patterns, for both personnel and equipment, may also introduce *Salmonella* into the processing environment. Other potential sources of *Salmonella* include pests (e.g., birds, rodents and insects are known to carry and spread *Salmonella* into a manufacturing facility), improper air flow (e.g., air flow from non-ready-to-eat area to ready-to-eat area), and poorly maintained ventilation units and employees with infections.

Adherence to basic GMPs for the facility, personnel and incoming materials is the foundation for *Salmonella* control. For example, holes in the roofs of buildings should be sealed off, bird nests should be removed, and overhang structures outside the facility that may attract birds should be re-designed (Graham, 2007; Silliker, 2002). Since it is not possible to entirely prevent *Salmonella* from entering the facility, the raw materials handling area and other areas prior to inactivation steps should ideally be separated from the finished products handling area subsequent to the inactivation steps. A hygienic zoning concept should be applied to separate the facility into different areas, based upon their proximity to the finished product or relationship to the terminal *Salmonella* inactivation step.

Common Industry Practices:

- Conduct a hazard analysis to determine potential sources for *Salmonella*. Take into consideration potential sources such as those associated with facility integrity, air flow and treatment, personnel and traffic movement, equipment design and incoming materials. For example:
    - Conduct an in-depth assessment of the facility using a cross-functional team (and outside experts as appropriate) to identify potential problem areas and practices that could lead to *Salmonella* ingress or spread. Efforts should be made to ensure the integrity of the roof, floor and walls in the processing area and to minimize the use of drain pipes over processing lines (CAC, 2003).
    - Inspect intake vents to ensure they are of sanitary design and cleanable. They should be fitted with appropriate filters.
    - Inspect exhaust vents to ensure they are hygienically designed to prevent condensate formation and accumulation around the vent exit and to prevent water

dripping back into the facility. Ensure that exhaust ducts are of sanitary design, are cleanable, and that "reverse air flow" does not occur.

- Ensure that fire suppression systems internal to equipment (e.g., roasters, ovens, dryers and venting systems) are supplied with water of potable quality, that activation of suppression systems is logged, and any resulting moisture is removed from internal surfaces of the equipment upon startup. For facility functions where no food contact takes place, "industrial water" (i.e., non-potable) may be utilized.

- Inspect the facility on a regular basis and repair and seal off any openings in a timely manner to ensure sound structure for the facility. An example of a check list for routine facility walk-through inspection is shown in Table 1-1.

    - Inspect the integrity of the facility for problems such as the presence of bird nests on the roof, roof overhang over a dock door that may become a place for birds to roost, pests in the facility, storage silos or bins without covers, roof leaks, and faulty sprinklers. Correct these problems in a timely manner and verify the problems have been corrected by conducting enhanced environmental monitoring for the affected area according to procedures outlined in Element 7.

    - On a routine basis, review and assess adequacy of the pest control program targeting pests such as insects, rodents, birds, reptiles, amphibians, etc. This may include the evaluation of the pest control contractor's program and walking through the facility to verify effectiveness of control (e.g., any evidence of pest activities). The building should be sealed to prevent pest entry.

    - Anticipate potential issues with facility integrity (e.g., a roof leak event) and put in place procedures to correct problems should they arise. To verify that the problems have been corrected, conduct enhanced environmental monitoring for the affected area according to procedures outlined in Element 7.

- Establish procedures to ensure that contaminated equipment is not brought into the facility.

    - Develop a sanitation SOP (SSOP) for new or used equipment prior to use.

    - Develop an SSOP for equipment acceptance and cleaning, sanitizing, and drying of equipment prior to allowing entry into the processing area. This is particularly important for used equipment, which may have been contaminated during its prior use.

- Establish controls to segregate ingredients known to be contaminated with *Salmonella* such as raw nuts, flour, baker's yeast, spices, raw cocoa beans, grains, and meat and bone meals. Establish a supplier control prerequisite program to review and approve (raw) material suppliers. For ingredients that will be added to the finished product without a further inactivation step, more controls may be necessary, and these are elaborated in Element 5.

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

    - Raw or unprocessed foods should be separated from processed/ready-to-use or ready-to-eat foods. Packaging materials should be protected from contamination during shipment, storage and use. Packaging should be inspected immediately prior to use to ensure that it is not contaminated or damaged.

- Wherever possible, use dedicated forklifts, utensils, and maintenance tools for the Primary *Salmonella* Control Area (PSCA; see Element 2) or post-lethality area vs. raw or pre-lethality area.
- Outline traffic patterns properly and ensure employee compliance through education and training.
- Inspect pallets and trailers regularly, keep them in good repair, and not stored outside where they may be exposed to bird or pest activity.
- Maintain the highest room air pressure in the PSCA or the post-lethality area and include the air handling system in the master sanitation schedule.

- Establish a program for water quality to minimize the risk of water as a potential carrier of *Salmonella*.
  - Establish procedures for sourcing and handling potable water within the facility.
  - Ensure that the water distribution system is properly maintained to prevent any leakage, especially in the PSCA. Use backflow prevention devices where needed.
  - Establish verification procedures to ensure that water brought into the facility is of adequate quality (ICMSF, 2005c) and is not a source for *Salmonella*. This is also important for water for jacketed temperature controlled equipment, such as holding or mixing tanks that are double walled and filled with water to control temperature in the processing of chocolate, peanut butter, fat-based confections, etc. If the water quality in the system is not adequately maintained, contaminated water leakage through microfractures in the equipment could occur and result in the contamination of product being held or processed in the equipment.
  - When water usage is necessary in the processing area (e.g., for cleaning and sanitizing equipment), use minimal amounts. In particular, water usage in the PSCA should be avoided or kept to the very minimum. See Element 4 for further discussion.
- Construction and major maintenance events should be coordinated so that the area under construction is contained.
  - Construction includes activities such as layout modifications requiring displacing pieces of equipment, resurfacing floors, cutting drains, cutting through walls, installing or removing exhaust ducts, etc. Due to the ability of *Salmonella* to survive in dry environments for long periods of time, construction activities may release *Salmonella* from unknown harborage sites and contribute to the spread of the organism throughout the plant (CAC, 2008).
  - Control measures during construction may include the following: isolate the construction areas, prevent/minimize dust and aerosols, control traffic patterns, use temporary partitions as appropriate, maintain negative air pressure in the construction area, intensify cleaning procedures, and enhance environmental monitoring during these activities, as described in Element 7.
- Put in place a training program to educate employees on the potential sources of contamination, adherence to traffic patterns, and proper hygienic practices to follow in order to minimize the ingress or spread of *Salmonella* in the processing area. Such training is

particularly important for those who work in the PSCA, including personnel who enter the area on a temporary basis (e.g., maintenance crew, contractors).

Table 1-1. Example check list related to potential *Salmonella* ingress and spread in a facility

Subject/Questions	Comments
PHYSICAL FACILITY & PLANT DESIGN	
1. Ceiling (drop ceilings) & walls clean and in good repair? • False ceilings designed with rigid insulating and proper sealing? • Any sign of leaks, condensate or stains?	
2. Deterioration or missing grout from floors, drains, brick? Cracks or delamination in wall/floor interfaces and along floor expansion joints?	
3. Floors constructed to prevent standing water and cleanable? • Floor drains corroded/rusted/joint cracks? • Seepage between rooms/doors noted? • Does the sub-floor have water flow ("aquifer") beneath the current floor?	
4. Sewer/drain back-up controls in place starting at the septic system moving to RTE areas (e.g., screens, backflow prevention device used)? • Drain mat covers (if applicable) properly maintained/cleaned/sanitized? • Trench drains adequately flushed and sanitized on a routine basis?	
5. HVAC refrigeration units cleaned and maintained on a periodic basis? • Any signs of leaks or condensate? • Is food dust getting on cooling or heating coils? • Is there a filter replacement SSOP?	
6. Condensate adequately controlled in processing zones to prevent product contamination? • Condensate piped to a sanitary drain or drip pans in place and maintained?	
7. Hoses in ready-to-eat filling areas free from leaks, clean, and kept off the floor during production? • Air, water, electrical hoses hanging over exposed product zones?	
EQUIPMENT DESIGN & CONDITION	
1. Equipment food contact surfaces (augers, belts, rollers, conveyors, filler hoppers, nozzles, blenders, cookers, slicers, etc.) free from cracks, chips, poor welds and microbial harborage points? • Hollow legs, handles, ladders, wheels, tools, in-floor scales, etc. exist which can collect stagnant water? • Non-product (framework, insulated lines, control panels, etc.) free of cracks, scratches, or potential harborage locations?	
2. Equipment (e.g., pipes, valves, hoses, belts, product & cooling lines, etc.) properly maintained and corrosion-free? • Unused supply lines removed in production areas? • Catwalks above product zones adequately cleaned and with splash guards in place? • Cooling water leaks from unpressurized equipment (e.g., chill roll, kettles, etc.)?	

***Salmonella* Control Element 2:**
Enhance the stringency of hygiene practices and controls in the Primary *Salmonella* Control Area.

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

The separation of one manufacturing area in a facility from another is generally done to minimize contaminant transfer from one area to another, e.g., wet to dry areas, "dirty" (relatively speaking) to clean areas, raw materials to finished products, or a basic hygiene area to a high hygiene area. Compartmentalization or segregation of the facility into specific areas is a common practice in food processing (FAO/WHO, 2006; Holah, 2005). The separation of the low-moisture product manufacturing plant into areas of different hygiene levels with the establishment of a PSCA that is separated from the rest of the processing area is one of the first steps leading to effective *Salmonella* control (Figures 2-1, 2-2, and 2-3). Depending on the product and process and the intended consumer (e.g., general public, infants), the number of hygiene areas established in a facility in addition to the PSCA may vary. The objective is to minimize to the greatest extent the spread of *Salmonella* into the PSCA where preventing product contamination is the most critical.

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

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

The degree of separation between the different hygiene areas within a facility may vary depending on the product and process (Holah, 2005). Barriers are placed between the different hygiene areas to restrict traffic and prevent vectors (potential sources of *Salmonella*) from passing between the basic GMP area to the PSCA. Examples of vectors include dirt on shoes or clothing, pallets and packaging materials, pests, dust, and sometimes water. Examples of physical barriers are walls, doors, split conveyors, filters, etc. Examples of other barriers are pallet exchange, shoe-change, removal of outer bag packaging, marked limits on floors, etc. Whenever possible and necessary, there should be no direct connection between the PSCA and the basic GMP area. Access to the PSCA should ideally be through a buffer area (i.e., a vestibule or anteroom, hygiene juncture) where personnel take steps to minimize carrying contaminants into the PSCA. In addition, hygienic facility design and plant layout to direct the flow of personnel and traffic is another effective control measure to minimize the transfer of contaminants from one area to another (ICMSF, 2002b). The air supply to the PSCA should be suitably filtered to prevent airborne contamination. Ideally, the PSCA should be maintained under positive air pressure to prevent the entry of contaminated air from the outside or surrounding areas of the manufacturing facility (CAC, 2008; FAO/WHO, 2006; Holah, 2005).

The determination of whether a location in the facility belongs to the PSCA, the transitional area or the basic GMP area should be based on an evaluation of risk. An area can be evaluated based on the probability of *Salmonella* being present and the proximity of the area to the finished product. For example, a location that is "medium" or "high" on the probability axis and "near" on the proximity axis would fall into the PSCA (Figure 2-4), while a location that is far away on the proximity axis, or medium distance on the proximity axis and low on the probability axis would fall into the basic GMP area. By using this approach, a facility may be designated into areas with different levels of hygiene control. An evaluation of risk and mitigation strategies can also be used to determine the appropriate control measures for the PSCA. For example, in a facility that uses raw materials known to be contaminated with *Salmonella* presence or in the event that persistent *Salmonella* is found, more stringent controls would be needed.

Common Industry Practices:

- Establish designated areas in the facility with different levels of hygiene controls to minimize the spread of *Salmonella*.
    - Establish a Primary *Salmonella* Control Area (PSCA) within the process area of the facility.
    - Depending on the type of operation, a facility may generally be divided into one, two, or three processing areas (in addition to the non-processing areas). For example, an operation that does not employ an inactivation step may designate the entire

processing area as the PSCA, e.g., a spice blending operation, a snack bar or nutrition bar operation, and other mix and pack operations (Figure 2-1). An operation that employs an inactivation step may designate the processing area after the inactivation step as the PSCA and the rest of the processing area as the basic GMP area, e.g., a corn snack chip operation (Figure 2-2). In addition to the basic GMP area and the PSCA, an operation with an inactivation step may employ a transitional area to further enhance hygiene control in the PSCA, e.g., a powdered infant formula operation (Figure 2-3). In general, the more sensitive the product or the consumer, the more important the separation of the facility into different hygiene areas to facilitate the implementation of enhanced controls in the PSCA.

- Depending on the type of operation and the hazard analysis, it may be desirable to establish a buffer area upon entrance into the facility and/or upon entrance into the PSCA. The buffer area is where traffic restriction can be implemented and different types of hygiene procedures can be applied. The buffer area, if established, should be designed to reduce the potential for introducing contamination into the PSCA, either through workers or through other items such as packaging materials, cleaning tools, and equipment. Examples of desirable features for buffer areas at entrances to the PSCA in an infant formula facility are listed in Table 2-1.

- Establish barriers for the PSCA. Barriers can be established upon entrance and exit to the PSCA, from exiting the basic GMP and transitional areas. The barriers serve to completely or partially separate the PSCA from the rest of the facility. Physical separation between the PSCA and the rest of the processing area is particularly important for operations that use raw ingredients in which *Salmonella* is unavoidable (e.g., raw cocoa beans, raw nuts and grains).

    - Upon entrance to the facility, traffic may move between the basic GMP area and the transitional area without additional barriers. Movement of personnel and materials into the PSCA is controlled to various degrees depending on the type of operation. The riskier the product the greater the need to have a physical separation. For example, in powdered infant formula production, it is desirable to have a physical separation of the PSCA (walled off from the rest of the operation).

    - Another example is peanut processing, where the raw side of the process is separated from the rest of the facility. The area in which raw peanuts are dumped into the roaster is physically separated from the roaster exit. A hygiene juncture is maintained at the entrance of the raw side of the process where gowning and boot changing, which may be color coded, occurs. These are removed when exiting the raw side and a new set of attire is worn on the finished side. This is also the case for cocoa bean handling and processing.

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

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

use in the PSCA. Washing and drying hands prior to entering the PSCA is also important.

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

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

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

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

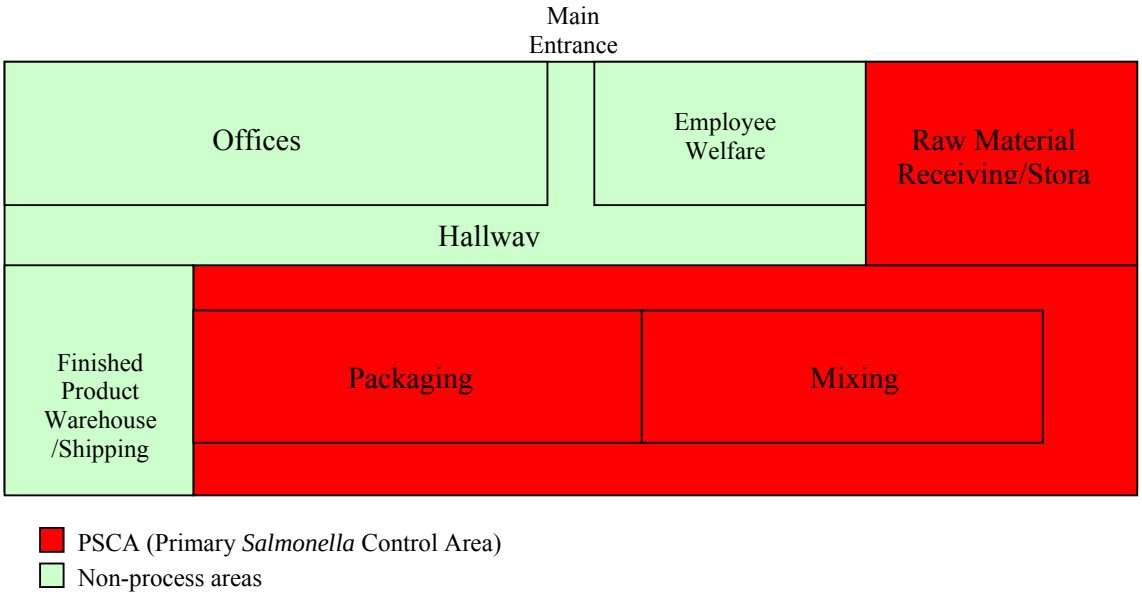

Figure 2-1. Example of a conceptual plant layout showing the entire process area as Primary *Salmonella* Control Area (PSCA) in red. The non-process area (e.g., warehouse and office) is in green. This layout may be applicable to products such as dry blends and snack bars.

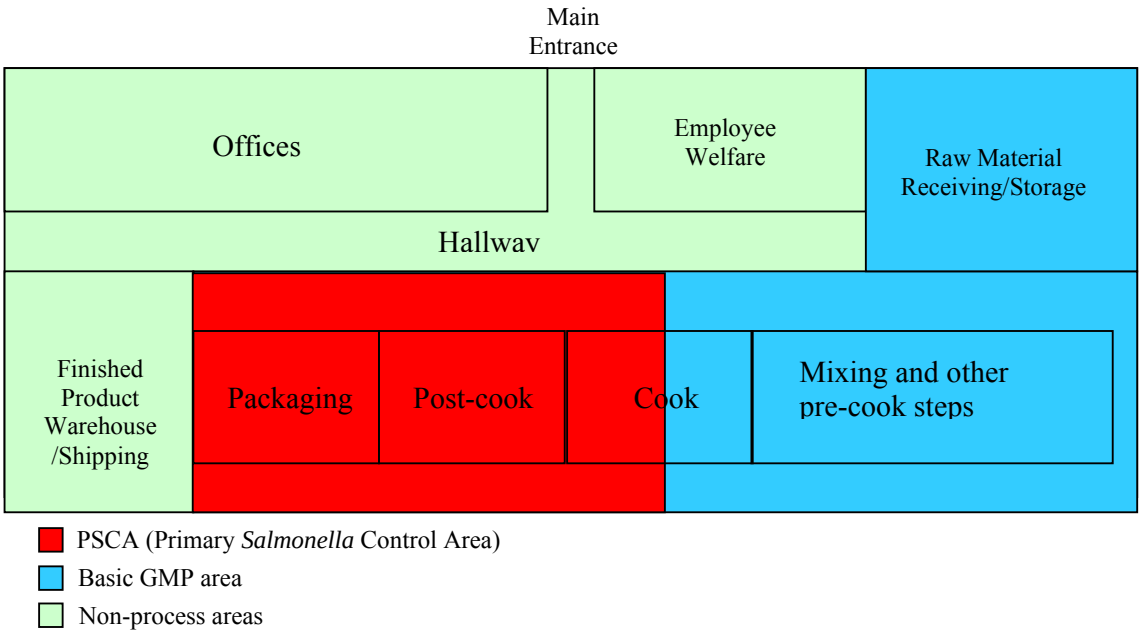

Figure 2-2. Example of a conceptual plant layout showing two process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red and a basic GMP area in blue. This layout may be applicable to products such as corn snack chips, cereals, and peanut butter.

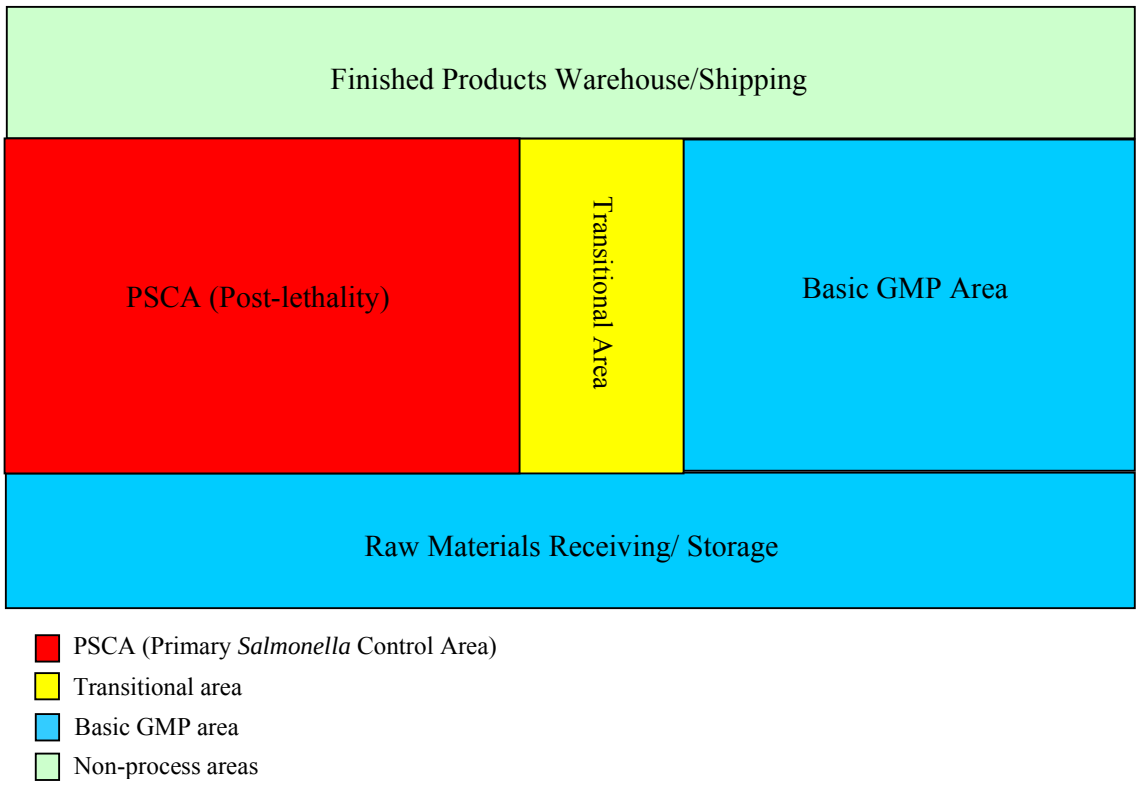

Figure 2-3. Example of a conceptual plant layout showing three process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red, a transitional area in yellow, and a basic GMP area in blue. The non-process area (e.g., warehouse, shipping) is in green (offices and employee welfare areas are not shown). This layout may be applicable to products such infant formula.

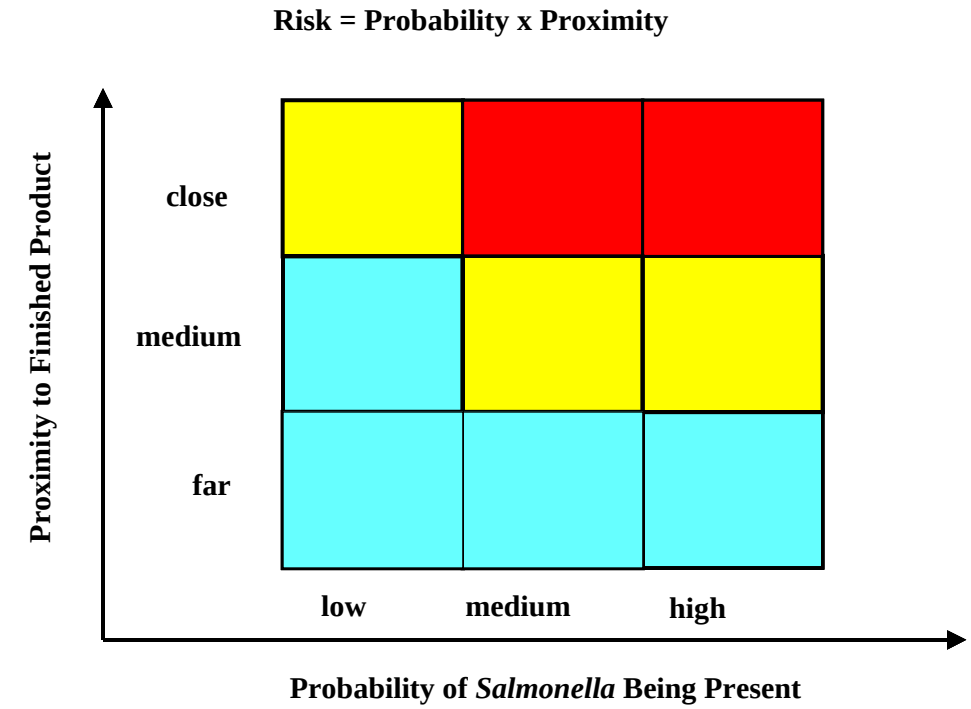

Figure 2-4. An example of using a risk evaluation approach for determining hygiene areas in a facility. In this approach, the risk of *Salmonella* contamination in finished product is proportional to the probability that *Salmonella* is present in the process area and the proximity of the area to the product before packaging.

Table 2-1. Example of desirable features for a buffer area at the entrance to the Primary *Salmonella* Control Area (PSCA)

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

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

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

***Salmonella* Control Element 3:**
Apply hygienic design principles to building and equipment design.

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

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

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

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

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

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

Common Industry Practices:

- Building design and layout should be based on hygienic principles, using common practices such as those outlined in the literature (CAC, 2008; EHEDG, 2001, 2003 and 2008; Graham, 2005).
- A common approach should be applied to sanitary design that keeps the equipment design as simple as possible and strives for a minimum number of parts, with all parts and assemblies accessible for inspection and cleaning. A program should be established for design review of equipment based on sanitary design principles, including some or all of the principles outlined in Table 3-1 as appropriate.
    - Review new equipment prior to purchase for sanitary design and layout. The proposed layout and placement in the facility should be evaluated to confirm that access necessary for proper cleaning is not compromised. The presence of the new equipment should not compromise the cleanability of existing machinery.
    - A similar review should be conducted for equipment that is relocated from one facility to another.
    - Plans to modify existing equipment should be reviewed by the plant food safety team prior to beginning the alteration.
    - Existing equipment should be periodically reviewed to verify that it still meets sanitary design principles and has not been altered in a manner that would compromise the sanitary design or cleanability of the equipment. Existing equipment should be modified when necessary to eliminate difficult-to-clean areas (such as unsealed hollow components, scratched surfaces, crevices, poor sanitary welds, etc.) and design features that may lead to residue build-up or stagnant products. Examples of poor design features are shown in Figures 3-1 and 3-2.
- If water will be used, the infrastructure and equipment must be designed to accommodate water. Development of microbial growth niches must be prevented. Water drainage from the process in the facility must ensure rapid drying. Additionally the infrastructure must be designed to prevent entry of unwanted water from surrounding processes or from outside the facility.
- Particular attention should be given to sanitary design, layout and maintenance of equipment located in the Primary *Salmonella* Control Area (PSCA) to ensure that moisture can be excluded from the processing environment, including the utilization of dry cleaning procedures (see more details in Element 4). Conditions leading to the formation of condensate should be eliminated or minimized to the greatest extent possible.

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

Table 3-1. Sanitary design principles for equipment [ξ]

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

[ξ] Adapted from an American Meat Institute document (AMI, 2002) targeted to *Listeria* control in high-moisture products. In many cases the general principles for sanitary design for high moisture are appropriate to low-moisture products.

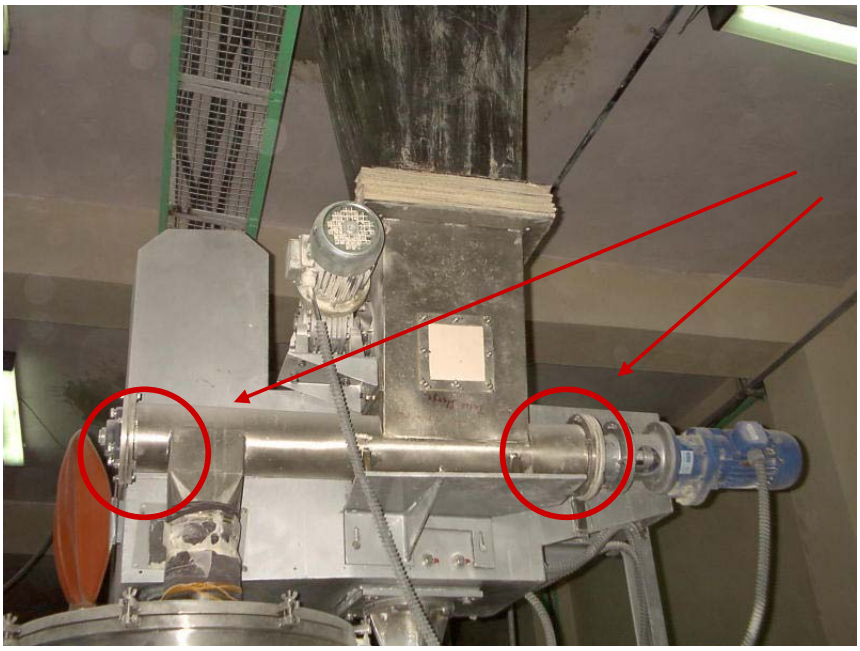

Figure 3-1. Ends of a horizontal screw conveyor – always a potential area of stagnant product build-up.

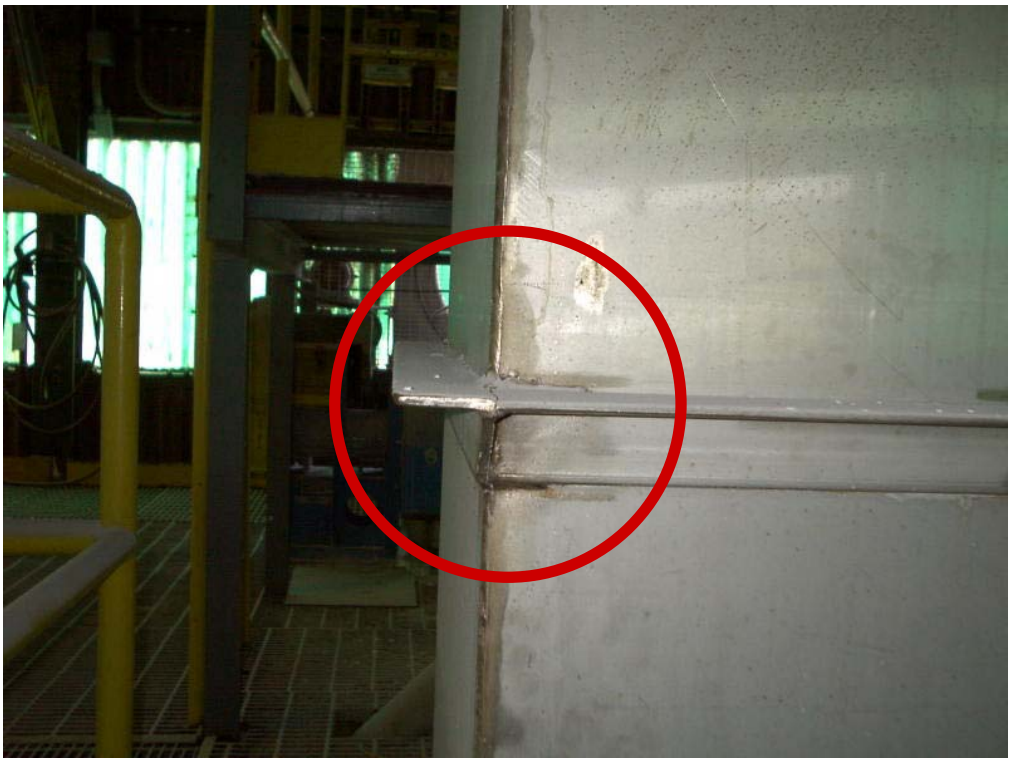
Figure 3-2. A flat surface that can collect product (This should be eliminated or sloped).

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

Moisture control is critically important in preventing *Salmonella* contamination in low-moisture products (ICMSF, 2005b). Water in the dry processing environment is one of the most significant risk factors (perhaps the single most important factor) for *Salmonella* contamination, as water allows for pathogen growth, significantly increasing the risk for product contamination. Industry experience indicates that the presence of water, even in very small amounts present for short, sporadic time periods, may allow *Salmonella* to grow in the environment. At times, moisture is obvious in the form of water droplets or puddles; or it may be from sporadic sources such as roof leaks. However, many sources of moisture, such as high relative humidity or moisture accumulating inside of equipment, are not visually apparent.

Salmonella can, to varying degrees, be introduced into low-moisture product manufacturing facilities and become established in those environments. Harborage sites may develop and become a source of product contamination unless these sites are identified and eliminated (CAC, 2008). A harborage site, or niche, is a site in the environment or on equipment (junctions, cracks, holes, dead-end areas, etc.) that enables the accumulation of residues (food debris, dust, and water) and permits the growth of microorganisms such as *Salmonella.* These sites may be difficult to inspect or access and therefore can protect *Salmonella* during routine cleaning and sanitizing.

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

The presence of water in the dry processing environment can result from improper use of water during cleaning, which has been linked to the occurrence and spread of *Salmonella* (CAC, 2008; see Annex). Other events resulting in the presence of water in a dry area include condensate formation, leaking water or steam valves, infiltration of water following heavy rains (e.g., leaky roofs), the use of water showers in the case of fire emergencies, etc. (CAC, 2008). Efforts must be made to remove water immediately from the PSCA in such events in order to keep the plant environment as dry as possible. Dry conditions must be maintained at all time in the PSCA, except for the occasions when controlled wet cleaning is deemed essential. Potential problems arise when there is visible water present in the dry areas or when there are areas in which standing water has dried out. *Salmonella* may be found not only in wet spots but also spots where standing water has dried (Zink, 2007a). The latter situation may present an additional risk of spread via the generation of airborne contaminated dust**.**

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

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

Product accumulation should be removed as soon as possible (ICMSF, 2005b). Occasionally there are special circumstances, such as finding environmental sites positive for *Salmonella*, which requires that equipment not designed for wet cleaning be wet cleaned. Extreme care must be taken to understand the risks and to formulate a plan that will successfully eliminate the contamination without spreading and enhancing the problem. Dry and controlled wet cleaning may be required, including clean-out-of place with disassembly, cleaning and sanitizing, drying and reassembly. It is recommended that a multidisciplinary team be formed that has the appropriate expertise to plan and oversee this type of high-risk operation.

Common Industry Practices:

- Minimize the use of water in the entire plant environment.
- Specify the type of cleaning practices to be used in different hygiene areas, i.e., the basic area, transitional area, and PSCA. There are three types of cleaning (Table 4-1): dry, controlled wet and wet cleaning. Dry, wet and controlled wet cleaning in the different hygiene areas should be used at appropriate frequencies, which may be modified based on the specific product and process.
- Choose dry cleaning as the routine cleaning practice in the PSCA. Use controlled wet cleaning infrequently in a prudent manner and on an as-needed basis. Do not use wet cleaning or only use it in very rare cases in the PSCA, e.g., in response to a product contamination incident.
- When controlled wet cleaning is necessary care must be exercised such that only the minimum amount of water is used. Table 4-2 lists common procedures for controlled wet cleaning. It is recommended that the environment of the wet-cleaned area be tested for *Salmonella* to verify sanitation effectiveness (see Element 7). Areas/situations where controlled wet cleaning may be necessary include the following:
    - In the case of an unusual event, such as a roof leak or a faulty sprinkler that may lead to potential product contact surface contamination in the PSCA, production should be stopped. The leak should be fixed, and the area cleaned, sanitized, and dried before production resumes.
    - Wherever possible, remove parts of equipment and conduct controlled wet cleaning on them in a room dedicated to cleaning.

- When controlled wet cleaning is done in a certain area of the PSCA, the area should be segregated and care must be taken so that the cleaning activities do not adversely impact the adjacent areas.
- Other examples of situations where controlled wet cleaning is needed include when the buffer area upon entry to the PSCA becomes dirty and requires cleaning, when there is a need to remove sticky build-ups and to remove allergens, etc.

- Eliminate water in the PSCA. Water distribution systems (piping, etc.) should also be limited to the greatest extent possible.
  - In order to maintain the PSCA as dry as possible, the use of "dry drains" (i.e., drains that are physically capped with an impermeable barrier when not being used to collect water) is recommended.
  - In production where hygroscopic products are made, procedures should be in place to remove as soon as possible accumulated product to avoid moisture build-up and localized condensation.
- Establish appropriate dry cleaning procedures for the PSCA.
  - The goal of dry cleaning is to collect, remove and dispose of residues without redistributing them or cross contaminating the environment. Examples of dry cleaning tools and their uses are described in Table 4-3. Personnel responsible for maintenance, cleaning and checking the tools should be designated and properly trained.
  - In addition to tools such as brushes and scrapers, vacuum cleaners are useful for dry cleaning. When vacuum cleaners are used, it is desirable to dedicate individual vacuum cleaners to specific areas, so that vacuumed material can be tested as part of the environmental monitoring program (see Element 7). If the material tests positive for *Salmonella*, there is a limited area to search for the source of the contamination. In addition, the contaminated vacuum has not been used in other areas around the plant and the contamination is confined. Desirable design features for vacuum cleaners are described in Table 4-4.
  - The objective of dry cleaning is to remove residues without the use of water by using tools or cleaning aids that do not entail the application of water or other aqueous solutions. Where appropriate, "blasting" with dry CO_2 pellets or other dry abrasives can be an effective method for removing stubborn residues on equipment or facility surfaces without introducing water. Hot oil may also be used to flush the interior of equipment used to handle low-moisture products such as peanut butter or chocolate.
  - Sanitizers that will rapidly evaporate after contact, such as alcohol-based sanitizers, provide a means to spot-sanitize equipment with a very minimal introduction of water. For example, critical or sensitive spots (such as electrical equipment control panels) can be dry-cleaned and then sanitized with an alcohol-based sanitizer. However, it is not possible to sanitize a dirty surface, such as an area with dry soils that cannot be removed effectively. These sanitizers are flammable; caution should be taken to prevent explosion or fire during application.

- Compressed air should generally not be used for dry cleaning except in special situations (e.g., to dislodge dust from inaccessible points). Moreover, if and when compressed air is used, it should be dried and filtered to exclude microorganisms and moisture prior to use. Water traps in compressed air systems can be included as part of the environmental monitoring program and be tested for indicator organisms (e.g., Enterobacteriaceae), as well as *Salmonella*.
- Dry cleaning should be monitored and verified by visual observations and environmental monitoring.

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

Table 4-1. Types of cleaning in a low-moisture product manufacturing facility

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

Table 4-2. Examples of common industry procedures for controlled wet cleaning

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

Table 4-3. Examples of tools for dry cleaning and their uses

Tools	Design features and usage
Brushes, scrapers	- Choose tools with sanitary design that do not create hygienic problems. These tools should be cleanable, durable and without loose parts. The handles and supports should have no spaces where residues can accumulate. If the handle is hollow (e.g., to control weight for practical reasons), it should be sealed. - A tool that is used for cleaning product contact surfaces should not be used for cleaning floors, drains, and ceilings. - Provide a designated area to store cleaning tools not in use, e.g., hooks, hangers, storage cabinets, etc. - Check all brushes and scrapers regularly and replace them as needed. Do not use tools that are worn and could become potential sources of foreign materials and contamination. - Dry clean the tools. Wet cleaning is done only in designated areas and only if the tools can be dried promptly and completely; it must be done using controlled wet cleaning.
Vacuum cleaners	- Portable vacuum cleaners with appropriate design features are recommended for dry cleaning to avoid or limit the spread of dust. A vacuum cleaner has the advantage of collecting and retaining residues in a dust container. They can also reach difficult-to-reach places. For example, a vacuum cleaner is preferred to remove residues on overhead structures such as wiring supports and pipes (using a brush in this case would create and spread dust). - Desirable design features for vacuum cleaners are described in Table 4-4. - A vacuum cleaner used in the PSCA should not be used outside the area. A vacuum cleaner that is used for cleaning inside equipment should not be used for cleaning the floor. Dedicated accessories should be used accordingly. The dust bag should be removed in an area isolated and as far away as possible from the process line (but still in the PSCA). The vacuum cleaner dedicated to the PSCA should not be taken outside the PSCA for emptying because it could transport contaminants on its return. - A vacuum cleaner will only be an efficient tool if it is well maintained in such a way that it does not become a carrier of contamination, e.g., protected against water and moisture, making sure attachments are well fitted. If a vacuum cleaner used in the PSCA needs cleaning or maintenance, it can be done in a dedicated/isolated area in the PSCA or it can be protected by a plastic cover and transported on a pallet to a dedicated area outside the PSCA. After maintenance, the vacuum cleaner should be dry-cleaned. On rare occasions when necessary (e.g., when contamination is detected), the exterior of the vacuum cleaner can be subjected to controlled wet cleaning, sanitizing, and drying prior to use again. - Filter(s) should be properly maintained on a regular basis and replaced when necessary. - Central vacuum cleaners, if they are used, should be used with caution because these tend to have lengthy pipes that are difficult to clean and maintain. They can also harbor insects.

Table 4-4. Desirable design features for vacuum cleaners based on the location of use

For use outside the PSCA:

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

For use inside the PSCA:

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

***Salmonella* Control Element 5:**
Establish a raw materials/ingredients control program.

Low-moisture products may be manufactured in a way that some ingredients are added after an inactivation step in the process or none of the ingredients are subjected to an inactivation step. For example, seasoning may be added to an extruded product after the heating step, ingredients for fortification may be added after milk pasteurization and spray drying, or products such as cold-pressed bars (e.g., nutrition bars) or dry blends may be produced by combining ingredients without an inactivation step. In order to prevent finished product contamination, it is essential not only to protect products from environmental contamination after the *Salmonella* inactivation step, but it is also essential to avoid introducing *Salmonella* from ingredients that are added without an inactivation step.

The addition of contaminated ingredients after the inactivation step has contributed to *Salmonella* contamination in finished products. For example, according to results from investigations of the 2007 *Salmonella* outbreak (CDC, 2007b) associated with children's snacks, FDA found *Salmonella* Wandsworth in the broccoli powder used for seasoning the product after the inactivation step. Product samples obtained from the processing plant also tested positive for *Salmonella* Wandsworth and *Salmonella* Typhimurium, while samples taken from the plant environment tested negative (Liang, 2008; Zink, 2007b). The manufacturer sourced ingredients from both domestic and international suppliers. An outbreak associated with potato chips in Germany (Lehmacher et al., 1995) was traced to the use of contaminated paprika seasoning added after the inactivation step. In another instance, contaminated dried milk powder added to chocolate liquor after the *Salmonella* inactivation step (cocoa bean roasting) contributed to *Salmonella* in the finished milk chocolate. In the 2008-2009 outbreak of *Salmonella* Typhimurium attributed to peanut butter and peanut butter paste originating from a single processing plant (CDC, 2009; FDA, 2009a), the potentially contaminated peanut butter and paste were distributed to more than 70 companies for use as an ingredient in hundreds of different products, including low-moisture products such as cookies, crackers, snack bars, cereal and candies. Because the peanut butter or paste was used in many products without a further inactivation step (e.g., peanut butter crackers, peanut butter snack bars) or the inactivation step was not fully validated (such as in peanut butter cookies subjected to baking), hundreds of product recalls by dozens of companies ensued (CDC, 2009; FDA, 2009a). The latest outbreak and its cascade effects clearly illustrate the need to have knowledge about ingredient suppliers and their control programs and the need to verify that these programs are effective in controlling *Salmonella*.

FDA's inspection of the processing facility implicated as the source of the *Salmonella* Typhimurium outbreak found a number of deficiencies (FDA, 2009b), including deficiencies in process control, e.g., lack of validation of roasting step, and GMPs, e.g., deficiencies in facility integrity and maintenance, plant construction and design, protecting equipment/containers/product against contamination, separation of raw and finished products, pest control, sanitation program. Notably, FDA indicated that the plant did not clean a peanut paste line after *Salmonella* Typhimurium was isolated from the product, and continued manufacturing on the line for over three months (FDA, 2009b). FDA inspectors found that, in approximately a dozen instances, the plant released a product that initially tested positive for *Salmonella* after it was retested and found negative. Environmental samples collected by FDA inspectors at the facility tested positive for *Salmonella* Senftenberg and Mbandaka (FDA, 2009b). Such deficiencies can be uncovered by a robust supplier qualification and requalification process. Common industry practices outlined in the seven *Salmonella* control

elements in this guidance may be used in evaluating whether a supplier has a comprehensive *Salmonella* control program in place.

"*Salmonella*-sensitive" ingredients are ingredients that have been historically associated with *Salmonella* (tested positive for the pathogen), have been implicated in past outbreaks, or are used to make products that are intended for at-risk individuals. When such ingredients are added to the finished product without further lethality, procedures should be in place to assure the control of *Salmonella* in these ingredients to avoid finished product contamination.

A supplier approval program should be developed to assess the adequacy of control measures the supplier has implemented for *Salmonella* control in sensitive ingredients. It is well known that the absence of *Salmonella* in sensitive ingredients, dry-mixed ingredients, or finished products cannot be assured through testing alone (FAO/WHO, 2006; EFSA, 2008). Absence of *Salmonella* cannot be assured through acceptance or rejection of a lot according to requirements stated in a specification. The supplier approval program may include initial approval of the supplier; supplier audits; periodic requalification that takes into consideration key factors such as whether the supplier has a validated process and conducts microbiological monitoring of their process environment; and periodic raw material/ingredient testing upon receipt.

Common Industry Practices:

- Create a list of "*Salmonella*-sensitive" ingredients, with an emphasis on those that are used without a further inactivation step in the finished product. Table 5-1 shows a list of "*Salmonella*-sensitive" ingredients commonly used in low-moisture products.
    - Sensitive ingredients should be held under adequate hygiene conditions to avoid recontamination. Where feasible, sensitive ingredients should be stored in a segregated area.
    - Before sensitive ingredients are brought into the PSCA, procedures should be in place to minimize cross contamination from packaging materials or containers used to transport bulk ingredients. For example, removal of the outer layer of multiple-layer bags prior to bringing the bags into the PSCA may be employed.
- Obtain sensitive ingredients from an approved supplier. An approved supplier is one that can provide a high degree of assurance that *Salmonella* is not likely to occur in the ingredient through the implementation of appropriate process controls. Establish a supplier approval program to ensure the adequacy of the supplier's food safety programs. The approval program should include components such as the following.
    - Conduct an initial comprehensive audit of a supplier's food safety program.
    - Use common practices outlined in the seven elements of this guidance where applicable as a basis for supplier approval. Industry practices from the GMA's Food Supply Chain Handbook (GMA, 2008) can also be applied as appropriate.
    - Evaluate the supplier's food safety program for areas that include, but are not limited to, the following:
        - A pathogen environmental monitoring program.
        - Sanitation practices.
        - Raw materials/ingredients storage.

        - A finished product hold and release testing program.
        - Traceability.
        - Process validation.
        - A corrective action plan if positive *Salmonella* results are found, and an evaluation of the potential significance for other products or ingredients manufactured in the processing facility or on the line being evaluated.
    - Supplier approval should be specific to an individual facility or processing line.
    - Supplier requalification should be conducted at a frequency based on risk. Consider that the supplier's history may not be a guarantee of future product safety and quality.
    - Develop guidelines for adding and removing a supplier from the approval list based on the adequacy of their food safety program and their compliance to the program.
    - Provide the supplier with ingredient specifications and ensure the supplier is in agreement with the requirements. The specification should be lot-specific and include a requirement that the lot be *Salmonella*-negative. A complete microbiological criterion (sampling plan, methodology, etc.) should be defined. ICMSF or FDA BAM sampling plans (ICMSF, 2002a; FDA, 2003 and 2007) are commonly used as part of a criterion. Samples taken should be as representative as possible of the entire production lot.
- Develop a program for testing and using sensitive ingredients to be added to products without a lethality step or ingredients added after lethality step. This is particularly important for situations involving new or unknown suppliers or where there is a lack of confidence in the supplier's *Salmonella* control program. The program should include components such as the following:
    - Wherever possible, obtain a Certificate of Analysis (COA) from the supplier that includes results of *Salmonella* testing and sample size analyzed.
    - Implement a hold and release testing program for COA verification or for ingredients that were obtained without a COA.
    - Use approved testing labs (in-house or external). Laboratory approval should evaluate the ability of the laboratory to conduct *Salmonella* tests for the food(s) of interest. It may be of value to conduct this evaluation as an on-site laboratory audit. The laboratory must follow Good Laboratory Practices, which ideally should include proficiency testing (e.g., for *Salmonella* testing). Laboratories may or may not be certified (e.g., ISO 17025). These considerations should also be extended to the supplier's laboratory to ensure their COA results for sensitive ingredients are reliable.
    - The FDA BAM or an ICMSF sampling plan (e.g., cases 10-15) may be used, depending on the ingredient and the robustness of the supplier's food safety program. The frequency of sampling may vary, e.g., once every lot (such as for a new ingredient from a new and unknown supplier), once every 6 lots, or less frequently, depending on the supplier.

- Make clear in the program that if a product sample tests positive for *Salmonella*, the tested lot is considered adulterated and it should not be released into commerce. It is important to note that retesting should not be conducted for the purpose of negating the initial test results (Rainosek, 1997; ICMSF, 2002c; see further discussion in Element 7). Conduct an evaluation of risk for *Salmonella* contamination to determine disposition of adjacent lots.

- Wherever possible, source an entire lot and strongly discourage being supplied with a split lot that has been distributed to multiple customers or multiple manufacturing plants. (This has the potential for one company's verification test to implicate another company's products.)
- All materials being tested for *Salmonella* should remain under manufacturer's control and be released for use **only** after acceptable test results are received.

Table 5-1. Examples of "*Salmonella*-sensitive" ingredients used in low-moisture products*

Chocolate, chocolate liquor, cocoa powder, chocolate chips, cocoa products
Nuts/nut products
Coconuts
Seeds/seed products
Grains/grain products (excluding starches)
Dried egg products
Fruits/fruit products (excluding candied or alcohol-packed fruits, jams or jellies)
Dairy ingredients and blends
Spices/herbs (excluding extracts), blended seasonings
Soy products
Gums/thickeners (excluding xanthan gum)
Yeast/yeast extract
Gelatin
Dry vegetables
Enzymes/rennets
Dry meat or meat byproducts

* This list is not inclusive of all sensitive ingredients.

***Salmonella* Control Element 6:**
Validate control measures to inactivate *Salmonella*.

When a lethality step is needed to inactivate *Salmonella* in a low-moisture product or ingredient, the processing parameters used should be adequate to inactivate the level of the organism likely to be present. According to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), validation encompasses collecting and evaluating scientific data and technical information to demonstrate that the control measures and associated critical limits at the lethality step, when followed, will result in a safe product (NACMCF, 1998). In addition, it is necessary to demonstrate that the chosen control measure and critical limits can be applied in production at a critical control point. Validation of lethality steps for low-moisture foods involves determining an appropriate log reduction for *Salmonella*, determining the critical limits in the process required to achieve the reduction, and confirming the process equipment consistently delivers the critical limit parameters in the operation (NACMCF, 1998; Scott et al., 2006).

In general, NACMCF's definition for pasteurization (NACMCF, 2006) can be used to guide the determination of an appropriate level of log reduction. With respect to a low-moisture product, NACMCF's definition translates into applying any process, treatment, or combination thereof, to reduce the most resistant *Salmonella* serotype "to a level that is not likely to present a public health risk under normal conditions of distribution and storage." NACMCF also indicated that a control measure aimed at inactivating the target pathogen does not protect the consumer if the product is subsequently recontaminated during manufacturing. The effective approach to prevent recontamination is through good hygiene practices verified by environmental monitoring (see Element 7) to ensure that recontamination is not likely to occur.

The level of reduction required will depend on the potential levels of *Salmonella*, if present, in the raw ingredients. Efforts have been made to set an appropriate level of log reduction for a specific low-moisture product based on a risk assessment. For example, a risk assessment (Danyluk et al., 2006) conducted to assess the risk of salmonellosis from almond consumption was used to determine that a 4-log reduction of *Salmonella* in raw almonds is adequate to ensure safety of the finished product (AMS, 2007). In some instances, historical knowledge is used as the basis for validation (Scott, 2005). For example, pasteurization at 72 °C for 15 sec is considered adequate to inactivate expected levels of vegetative pathogens of concern in raw milk. These parameters may be used as the critical limits or the basis to establish other process parameters as critical limits at the lethality step to inactivate *Salmonella* in the fluid milk ingredient for a dried milk product; preventing recontamination after pasteurization during drying and subsequent handling would be essential to protect the finished dried product from recontamination. Both industry guidelines (Froning et al., 2002) and FSIS regulations in 9 CFR 590.575 (CFR, 2008a) set parameters for the pasteurization of dried egg white, which include heating the product in a closed container to at least 130 °F (54.4 °C) for 7 days or longer until *Salmonella* is no longer detected (As a practical matter, the egg industry routinely uses a more severe heat treatment in order to eliminate the avian influenza virus as well as *Salmonella*).

Both thermal and non-thermal control measures can be used for *Salmonella* inactivation to achieve the target log reduction. Various processing steps (e.g., cooking, frying, roasting, baking, heat extruding, fumigation) may be used to inactivate *Salmonella* in a low-moisture product. Thermal processing is the most commonly used control measure to inactivate

Salmonella. For example, the Almond Board of California's Technical Expert Review Panel (ABC TERP) determined that oil roasting at or above 260 °F (126.7 °C) for 2 min will result in a 5-log reduction of *Salmonella* on the surface of whole almonds (ABC, 2007). The ABC TERP also provided minimum time and temperature combinations required for blanching processes to deliver a 4 or 5-log reduction of *Salmonella* on almonds (ABC, 2007). These parameters were determined based on heat resistance data for *Salmonella* Enteritidis PT 30 as the target organism.

It is useful to review available scientific data for the processing method of interest, including high temperature short time or low temperature long time when desirable for maintaining product quality. In order to assure appropriate validation, it is also necessary to evaluate scientific and processing equipment data and information specific to the processing technology under consideration. A process authority should be consulted where necessary. For example, the ABC TERP, which consists of experienced microbiologists and processing experts, evaluates the adequacy of various treatments to inactivate *Salmonella* in raw almonds and develops guidelines for validating individual processes, including propylene oxide (PPO) treatment for raw almond kernels, PPO treatment for in-shell almonds, blanching, oil roasting, dry roasting and other processes that may be proprietary (ABC, 2007).

Heat resistance of *Salmonella* is affected by factors during heating, as well as the *Salmonella* strains used (Harris, 2008). Heat resistance observed in an aqueous system may not be applicable to a low-moisture product. For example, a study by Ng and colleagues (1969) found that *S.* Senftenberg 775W was the most heat resistant among 300 strains evaluated in an aqueous solution, while this strain was found to be less heat resistant than *S.* Typhimurium in chocolate (Goepfert and Biggie, 1968). *S.* Enteritidis PT 30, the target organism for raw almonds, was implicated in a foodborne illness outbreak and was found to be more resistant to dry heat than many of the strains evaluated on almonds (ABC, 2007; Wang, 2008).

A number of studies have been published on heat resistance of *Salmonella* in various low-moisture products (see Annex section on heat resistance). Available D- and z-values for heat resistance of various *Salmonella* strains in low-moisture matrices are shown in Table 6-1 for food matrices and in Table 6-2 for model systems. These data indicate that heat resistance in a product with low a_w is much greater than that in a high-moisture product. For example, while reaching an internal product temperature of 160 °F (71.1 °C) without a hold time would eliminate *Salmonella* in raw poultry (FSIS, 1999), the same temperature would result in little inactivation of *Salmonella* in milk chocolate, in which the D-value for *S.* Typhimurium has been reported as 816 min at 71 °C (Goepfert and Biggie, 1968).

Table 6-1 shows D-values for *Salmonella* in wheat flour (Archer et al., 1998), milk chocolate (Barrile and Cone, 1970; Goepfert and Biggie, 1968), almonds (Harris, 2008), corn flour (VanCauwenberge et al., 1981), and dry animal feeds (Liu et al., 1969). In addition, recent research (Doyle and Ma, 2009) found that, based on the non-linear Weibull model, 42±8 min at 90 °C achieved a 5-log reduction of a mixture of three outbreak-associated *S.* Tennessee strains in peanut butter (49±12 min were needed to inactivate a composite of other *Salmonella* isolates). Liu et al. (1969) determined the heat resistance of *S.* Senftenberg 775W in meat and bone meal and chicken starter at moisture levels from 5% to 30%, where the investigators found that the method used to prepare the inoculum (growing the cells in a laboratory medium vs. in meat and bone meal suspension) affected the heat resistance. Akinleye (1994) reported that D- and z-values were affected by water activity of a salt

solution model system. D- and z-values relevant to low-moisture heat conditions from this study are shown in Table 6-2, along with data from another study using sucrose as a model system (Sumner et al., 1991). It should be noted that comparison of inactivation kinetics data from different studies can be difficult and it is crucial to review the raw data and experimental procedures, as well as the D- and z-values reported, so as to apply the data appropriately.

Heat-inactivation of *Salmonella* in low water activity matrices was found be non-linear in many cases, such as in peanut butter (Ma et al., 2008), oil-roasted almonds (Abd et al., 2008), flour (Archer et al., 1998), and in laboratory media (Mattick et al., 2001). The *Salmonella* inactivation curve in low water activity foods can be complex, often showing a concave upwards curvature, and significant tailing has been observed (Mattick et al., 2001; Harris, 2008; Marks, 2008). Thus, the rate of inactivation may not be constant throughout the heating process and caution needs to be taken when interpreting and using heat resistance data to support the adequacy of the process parameters.

In a study by Archer et al. (1998) on the heat resistance of *Salmonella* Weltevreden in wheat flour, the investigators observed that death kinetics were non-linear, with approximately a 1-log reduction in the first 5-10 minutes of heating, followed by a slower, linear decrease in survivors. To be conservative, the investigators calculated the D-value based on the second, slower phase of the inactivation curve. Sumner et al. (1991) reported the D-value of *Salmonella* Typhimurium ATCC 13311 increased by more than 100-fold as the a_w was reduced from 0.98 to 0.83 in sucrose solutions; this trend was observed in the treatment temperature range of 65 to 77 °C (149-170.6 °F; the study did not investigate temperatures below 65 °C for *Salmonella* inactivation). In laboratory media with a_w adjusted using glucose and fructose, Mattick et al. (2001) reported that *Salmonella* Typhimurium DT104 inactivation was non-linear in the range of 55 to 80 °C (131-176 °F). At temperatures ≥70 °C (158 °F) the heat resistance increased as the a_w decreased from 0.90 to 0.65; however, this trend was not observed for heat treatment at 65 °C (149 °F) or below, where decreasing a_w from 0.90-0.65 either had little effect or slightly decreased the heat resistance of the *Salmonella*.

Some studies have also been published on the inactivation of *Salmonella* by non-thermal processing. For example, the efficacy of low-energy X-ray irradiation was examined for inactivating *S.* Enteritidis PT 30 on almonds at different water activities (Jeong et al., 2008). The organism was found to be more resistant at a_w 0.65 (D_{10}-value ~ 0.34 kGy) compared to a_w 0.23 (D_{10}-value ~0.26 kGy). Irradiation, for products where its use has been approved, can also be an effective control measure. Irradiation with a dose up to 30 kGy (21 CFR 179.26) has been approved for use to inactivate microorganisms in dry aromatic vegetable substances such as herbs, spices and vegetable seasonings (CFR, 2008c). Danyluk et al. (2005) reported that a greater than 5-log reduction of *S.* Enteritidis PT 30 on almonds occurred after the product was treated with PPO (0.5 kg/m^3) for 4 hours followed by storage for 5 days. Ethylene oxide is effective for treating spices and herbs to eliminate *Salmonella* (Pafumi, 1986; Vij et al., 2006). While its application as a control measure is being phased out in some cases (such as for basil), it remains an effective measure to eliminate *Salmonella* in spices and herbs where approved, especially for treating high risk ingredients that otherwise would not receive a lethality treatment for *Salmonella*.

Validation testing can be carried out using *Salmonella* (appropriate strains), using a surrogate organism that has been validated for the product and process under consideration, or using a

non-microbial method such as an enzyme that has been validated for use in such applications. When the time and temperature profiles of a process can be mimicked in the laboratory (e.g., oil roasting), a challenge study with appropriate *Salmonella* strains can be conducted in the laboratory to validate the process (Larkin, 2008). This approach has been used to validate a dry-air roasting process for peanuts, where a lab-scale roaster was used to mimic the actual processing times and temperatures and the process was found adequate to deliver a 4-log reduction of several *Salmonella* strains (Tuncan, 2008).

When it is difficult to mimic the processing conditions in the laboratory with sufficient accuracy, a surrogate organism or a non-microbial substance may be used for validation. When a surrogate organism or substance is used, a relationship between the target *Salmonella* strain and the surrogate needs to be established, and the surrogate should behave in a way that a correlation can be made in a conservative manner (Larkin, 2008). In practice, a surrogate that has heat resistance comparable to or greater than the target *Salmonella* strain (to build in a margin of safety) is usually selected. For example, studies in several laboratories were conducted to select a surrogate organism for *S.* Enteritidis PT 30, the pertinent pathogen for almonds (Wang, 2008). Correlation between *S.* Enteritidis PT 30 and a surrogate organism, *Enteroccocus faecium* NRRL B-2354 (also known as *Pediococcus* spp. NRRL B-2354), has been established for dry heat in the 250 – 310 °F (121.1 – 154.4 °C) range for almonds. *E. faecium* NRRL B-2354 was found to have inactivation characteristics comparable to *S.* Enteritidis PT 30 under dry heat conditions (Ceylan et al., 2008; Wang, 2008). In fact, the D-values for the surrogate were slightly higher than those for the pathogen in the 250 – 310 °F (121.1 – 154.4 °C) range for almonds subjected to dry heating.

Alternatively, particles containing enzymes can be passed through a plant processing step and tested for residual enzyme activity, thus providing an indication of process lethality. The use of enzymes for process validation has been described for different thermal processes (Tucker et al., 2002; CCFRA, 2008). Testing for phosphatase has been used to verify that the pasteurization of milk has occurred.

Common Industry Practices:

- Determine the target level of *Salmonella* reduction in the product and process under consideration.
    - The determination can be based on the rationale outlined by NACMCF (2006). The target level of *Salmonella* reduction should be such that the treated product presents a reasonable certainty of no harm to the consumer.
    - A targeted 2- to 5-log reduction is commonly selected based on a hazard analysis that includes historical association of ingredients with *Salmonella*, prevalence and extent of contamination (i.e., the incoming load of *Salmonella*), and the intended use of the final product. The selected log reduction should include a margin of safety, e.g., an additional 2-log reduction beyond the extent or levels of contamination expected to occur in the ingredients (NACMCF 1997a and 1997b; FSIS, 2006; FDA 2009c).
    - Where regulatory or industry standards for log reduction have been established, these should be applied. For example, based on a comprehensive risk assessment a 4-log reduction of *Salmonella* in raw almonds has been established in the US to ensure safety of the finished product.

- Determine the adequacy of the selected control measure and associated critical limits for processing.
    - Critical limits should be developed based on thermal parameters (e.g., D- and z-values, thermal death times) or non-thermal parameters of the most resistant and pertinent *Salmonella* serotype, based on occurrence in the product ingredients, processing environment, and/or association with an outbreak involving the product or similar products.
    - In many cases, processing conditions are initially driven by quality attributes and it is essential to determine whether these conditions can deliver the target log reduction (several quick trials in the lab can be done for a feasibility assessment; literature data can also be used). Working with process engineers to optimize the process to deliver the target log reduction while still maintaining product quality is a common approach used in the industry.
    - In practice, several approaches can be used for validating the adequacy of process parameters. As noted previously, if the process can be mimicked reasonably well in a laboratory (e.g., for oil roasting), then *Salmonella* can be used in process validation in a laboratory setting to confirm that the critical limits, when achieved, consistently result in the target *Salmonella* log reduction. If the process is too complex to mimic in a lab setting (e.g., heat extrusion), other approaches for validation may be used, such as determining lethality based on the processing conditions (e.g., integrated lethality based on time and temperature profiles) or using a suitable surrogate for validation on the processing line. In addition to process parameters, other critical factors such as the initial temperature and initial moisture level of the ingredient(s) should also be considered in lethality validation studies.
    - A non-pathogenic microbial surrogate or a non-microbial surrogate such as an enzyme can be used after appropriate validation. For example, *E. faecium* NRRL B-2354 has been determined to be an appropriate surrogate for *Salmonella* in the validation of processing methods for almonds (ABC, 2007).
- Use published data to guide the determination of whether a challenge study is needed for control measure validation.
    - The utility of literature data depends on the food or model matrix and the design used in the study to generate the data. According to the rationale outlined by NACMCF (2006), the value of a particular set of literature data will be enhanced if the matrix and conditions used to generate the data are similar to the product and process to which the data are being applied.
    - Available heat resistance data may be used to estimate log reduction by thermal processing in a low-moisture product. The ideal approach is to use available heat resistance data collected in the same food matrix, such as using D- and z-values obtained in wheat flour to calculate log reduction in wheat flour during heat processing. Care should be taken when using D- and z-values, as inactivation may not be linear. In some cases a non-linear heat resistance model may have been developed for a product (e.g., peanut butter, almonds) and this can also be used. When D- and z-values are not available in the food at the water activity under consideration, data in a product with similar composition may be used, e.g., data obtained in wheat flour or corn flour for cereal products. When data for a

food matrix are not available, data obtained in a model system (e.g., sucrose solution) with similar a_w may be used to estimate lethality. When using this approach, it is important to keep in mind uncertainties inherent in applying available data and assumptions made.

- In most cases, literature data are used to guide efforts in identifying parameters specific to a product of interest, whether a challenge study is needed, and how a challenge study may be designed. Whether published data are sufficient to support the adequacy of the lethality of a chosen control measure and associated critical limits depends on several factors. According to rationale developed from industry experience (Scott et al., 2005), if an evaluation based on literature data shows survival of *Salmonella* is not likely to occur, with a reasonable margin of safety, challenge studies would not be needed. For example, analysis of the time and temperature profiles for a heat extrusion process may indicate that, based on the a_w of the ingredients and the product, the process is expected to deliver *Salmonella* inactivation that would greatly exceed 5-log. On the other hand, if there is less confidence in using published data, then limited challenge studies may be needed to verify estimated log reduction based on literature data. If the evaluation shows that there is limited lethality for the product/process based on available heat resistance data, then additional studies or process re-design would be warranted.
- Use available scientific guidance, such as the NACMCF guidance on parameters for performing an inoculated pack/challenge study (soon to be published), for validation of control measures through microbiological challenge testing.
- Microbiological expertise is necessary to determine the relevance and validity of applying published data to a specific product and process. An experienced microbiologist or process authority should assist in the use and interpretation of published data.

- Consider both thermal and non-thermal control measures, with validation, to eliminate *Salmonella*.

  - Thermal processing can be used under dry or moist conditions. Moist heat treatment is followed by a drying step in the manufacturing of many low-moisture products. Where appropriate (e.g., for some spices and seeds) a combination of steam treatment (pressurized or non-pressurized) and drying may be used to inactivate *Salmonella*. In such cases, validation should focus on determining the lethality of the steam process alone as a conservative scenario or, if heating after the steam process is included in lethality calculations, the combined effects of the multiple processing steps should be validated.
  - Focus validation on the CCP used to deliver the target log reduction, when one of multiple steps effecting lethality is chosen as the CCP. Cumulative effect from multiple inactivation steps may be used to achieve the target log reduction, even though individual steps alone are not sufficient to achieve the target lethality, as long as the individual processing steps and the combined lethality are validated. Be aware that not all heating steps in a process will provide *Salmonella* inactivation. For example, spray drying is an evaporative cooling process that usually does not result in an appreciable inactivation. Another example of minimal to no *Salmonella* inactivation may be a finishing dryer following the heat extrusion process.

- For a low-moisture product (e.g., spray-dried milk) that starts with high-moisture ingredients (e.g., milk), the heat treatment process prior to drying should be readily verifiable and efforts should be concentrated on preventing post-lethality contamination during drying and the subsequent steps through finished product packaging.
- Examples of non-thermal control measures are treatment with an approved chemical for fumigation such as propylene oxide or ethylene oxide and treatment with irradiation.

- Once the lethality of the process is validated by scientific data, ensure the operation can deliver the critical limits and that the parameters are consistently met through in-plant validation, which is an integral part of the validation process. Subsequently, verification of process control may include activities such as records review, calibration of instruments, and periodic finished product testing or other type of independent checks.
- Also make sure raw material/ingredient suppliers validate their process and the control measures.

Table 6-1. Heat resistance of *Salmonella* in food matrices as influenced by a_w

Study	*Salmonella* serotype	Heating medium	Water activity (a_w)	Temperature (°C)	D-value (min)	z-value (°C)
Barrile and Cone, 1970	Anatum	Milk chocolate	Not reported	90	11	24.2
Harris, 2008	Enteritidis PT 30	Almonds (oil-roasted)	Not reported	121	0.85	27
		Almonds (blanched)	Not reported	70	1.0	29
Goepfert and Biggie, 1968	Typhimurium	Milk chocolate	Not reported[a]	70	816	19.0
				80	222	
				90	75	
	Senftenberg 775W	Milk chocolate	Not reported[a]	70	440	18.0
				80	116	
				90	36	
Archer et al., 1998	Weltevreden	Wheat flour	0.50-0.60[b]	69-71	80	30.3
				72-74	45	
				75-77	40-45	
			0.46-0.50[b]	69-71	55	53.9
				72-74	55	
				75-77	40-45	
			0.41-0.45[b]	69-71	55	19.6
			0.36-0.40[b]	72-74	75	15.2
				75-77	80	
			0.31-0.35[b]	69-71	345	29.2
				75-77	85	
			0.25-0.30[b]	69-71	165	34.7
				72-74	240	
				75-77	150	
VanCauwenberge et al., 1981	Newington	Corn flour (15% moisture)	Not reported	49	18	Not reported
	Typhimurium				48	
	Kentucky				66	
	Anatum				48	
	Senftenberg				300	
	Cubana				150	
	Thompson				264	
	Tennessee				594	
	Senftenberg	Corn flour (10% moisture)	Not reported	49	366	Not reported
	Anatum				156	

Liu et al., 1969	Senftenberg 775W	Animal feed[c] (15 % moisture)	Not reported	71.1	10.0	10.4
		Animal feed[c] (10 % moisture)	Not reported	71.1	115.2	11.0
Sumner et al., 1991	Typhimurium	Chocolate syrup	0.75	65.6	2.7	8.3
			0.83 (product A)	65.6	1.2	6.2
			0.83 (product B)	65.6	3.2	7.7
			0.84	65.6	2.7	8.3

[a] Moisture level probably less than 2.5%.
[b] Value of a_w measured after drying the inoculated wheat flour.
[c] Simulated-naturally contaminated meat and bone meal stabilized at the indicated moisture level was used in the study.

Table 6-2. Heat resistance of *Salmonella* in model systems as influenced by a_w

Study	*Salmonella* serotype	Heating menstruum	Water activity (a_w)	Temperature (°C)	D-value (min)	z-value (°C)
Akinleye, 1994	Typhimurium	Salt solution	0.42	90	32.3	30.3
				100	12.5	
				110	18.2	
				120	8.9	
			0.31	90	20	40
				100	12.7	
				110	16.7	
				120	10.6	
Sumner et al., 1991	Typhimurium	Sucrose solution	0.83	65.5	40.2	7.6
			0.85	65.5	19.2	6.5
			0.89	65.5	4.8	6.9
			0.94	65.5	1.4	7.7
			0.98	65.5	0.29	7.6

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

The adequacy of the *Salmonella* control program should be verified on an ongoing basis to assure effectiveness and drive continuous improvement. Verification should focus on implementing a robust environmental monitoring program that has been designed to identify transient and/or resident *Salmonella* in the processing areas. Appropriate corrective action procedures must be developed to address positive *Salmonella* findings with the intent of containing the contamination, identifying the potential source, and eliminating the problem. This section focuses on environmental monitoring and corrective actions to be taken when *Salmonella* is found in the environment, since this is one of the most important verification activities in low-moisture product manufacturing. Other verification activities, such as those for critical control points in a HACCP system, are well covered elsewhere (NACMCF, 1998; CAC, 2003; ISO, 2005; Scott and Stevenson, 2006).

Environmental monitoring is an essential component for *Salmonella* control, as it provides a microbiological assessment of a plant's environment and an assessment of the effectiveness of sanitation and the overall *Salmonella* control program (Zink, 2007a; McNamara, 2007; Hall, 2007). Environmental monitoring is not, in itself, a control measure. Rather, it is a tool to verify the effectiveness of the overall *Salmonella* control program. Monitoring results provide critical information to improve *Salmonella* control in the plant environment. This information should be used to correct problem areas before they pose a risk to finished product. With this understanding, it is critical that the program be designed and implemented in a way to maximize detection of *Salmonella.* A robust environmental monitoring program is one of many prerequisite programs that together provide a firm foundation for effective food safety management.

The target organism for environmental monitoring for low-moisture foods should be *Salmonella*. Scientific literature suggests the pathogen is more persistent in the environment than other organisms such as coliforms and Enterobacteriaceae. A suitable indicator for *Salmonella* has not been identified (EFSA, 2007). Testing with enumeration of Enterobacteriaceae, however, may help assess moisture control in areas in the processing environment intended to remain dry (ICMSF, 2002b). Enterobacteriaceae is a useful indicator of process hygiene and it may be monitored in parallel as a hygiene indicator for verification of general sanitation effectiveness. However, it cannot be a substitute for the direct monitoring of *Salmonella* because, while high levels of Enterobacteriaceae suggest an increased risk for the presence of *Salmonella*, low levels of Enterobacteriaceae do not guarantee the absence of the pathogen (EFSA, 2007; Cordier, 2008).

Environmental monitoring for *Salmonella* is generally conducted on non-product contact surfaces (non-PCSs). Non-PCSs in the Primary *Salmonella* Control Area (PSCA) should be the main focus of routine monitoring for *Salmonella*. However, environmental monitoring for *Salmonella* should also be conducted in other areas of the facility (e.g., wet processing or handling of raw materials). Monitoring in these areas can provide insight into the potential for *Salmonella* to be present and potentially spread into the PSCA. Within the PSCA, non-PCS areas adjacent to PCSs should be monitored with relatively high frequency. If these areas are not maintained in sanitary condition, they may pose a risk of product contamination. Non-PCSs within the PSCA that are more distant from PCSs should be sampled with medium to high frequency, and non-PCSs outside the PSCA, should be sampled with low to medium frequency (Table 7-1). Each facility should determine the frequency adequate for its product

and process. In general, high, medium and low frequency would correspond to daily/weekly, monthly, and quarterly testing, respectively.

Testing of a PCS and finished product may be done under some circumstances as part of the overall verification of *Salmonella* control. PCS testing may play an important role in hygienic qualification for equipment prior to use or for investigation of positive *Salmonella* findings. Periodic product testing can be useful in verifying that the food safety system for *Salmonella* control is working. Sampling plans used by the industry for product testing include those described in the FDA BAM (FDA 2003 and 2007) and those described by ICMSF (ICMSF, 2002a). However, because it has well-known limitations in finding low levels of contamination, product testing alone is not a reliable means for assuring the absence of *Salmonella* (ICMSF, 2002a).

An adequate number of samples should be taken at appropriate frequencies for the environmental monitoring program to be effective. The number of samples and the frequency of sampling depend on the operation and facility. The sampling frequency can, in part, be based on current industry practices.

The first step in developing the frequency of testing and the test sites in an environmental monitoring program is to establish a solid baseline. Weekly monitoring may be considered as a starting point and the frequency revised based on the results over time. For example, in a facility that has historical testing data that show consistent *Salmonella* negatives in the environment based on a rigorous sampling program, the monitoring frequency can be reduced. On the other hand, a facility should be prepared to increase monitoring when changes in the operation warrant more monitoring, e.g., ingredient changes, leaky roof, drain back up, construction events, equipment installation, or finding *Salmonella* during routine environmental monitoring.

An official or validated method, such as the FDA BAM *Salmonella* method (FDA, 2007) or ISO 6579 (2002), should be used for testing. For some products methodology may need to be modified and validated, as some food components (e.g., high fat levels) can complicate the sample preparation and pre-enrichment step and other aspects of the analysis. Both methods include a section on the testing of environmental samples. An alternative method may be used after it is validated as equivalent in sensitivity and specificity to a standard reference method for environmental samples or for the product being tested. Choosing a validated method is important because a method validated for one purpose may not be suitable for another purpose; similarly, a method validated for individual sample units may not be suitable for testing sample composites (McNamara, 2007).

Common Industry Practices:

- ❒ Develop a written program for routine environmental monitoring.
    - The program should include elements such as identification of sampling sites, frequency of sampling, number of samples, sampling procedure, and test method. Examples of these elements are described in Table 7-1. Corrective actions to be taken when a positive is found should also be outlined (see examples in Table 7-2).

- Sampling devices noted in the program should be appropriate for the types of samples collected and validated as necessary. For example, if sponges are used, they must not contain preservatives and validation of *Salmonella* recovery is recommended.
- Sampling sites should be delineated into zones to facilitate program development, provide focus to critical sampling areas, and help direct appropriate corrective actions. For example, four zones may be established:
    - Zone 1 for PCSs in the Primary *Salmonella* Control Area;
    - Zone 2 for non-PCSs adjacent to or within close proximity to PCSs in the Primary *Salmonella* Control Area;
    - Zone 3 for non-PCSs more distant from PCSs in the Primary *Salmonella* Control Area and process areas outside the Primary *Salmonella* Control Area; and
    - Zone 4 for areas outside the process area (e.g., employee entrance, locker room, warehouse, loading dock).
- Routine environmental monitoring should target testing non-PCSs under normal operating conditions. Samples taken post-sanitation provide sanitation verification only and would not meet the true intent of environmental sampling. A "seek and destroy" philosophy should be adopted in environmental monitoring. This means the monitoring program is designed to aggressively search for *Salmonella*, particularly in environmental sites where *Salmonella* might be expected to be present, might concentrate, or might grow and spread. Table 7-3 provides examples of potential *Salmonella*-positive sites based on food industry experience. The listing in Table 7-3 is by no means inclusive of all potential sites.
- Using only preset sample sites is not recommended since it significantly limits the scope of sampling and will likely miss emerging areas of concern. However, some sites may be sampled on a continuing basis to assess trends. Sampling data should be reviewed on a routine basis. The sampling program should be dynamic and responsive to the data generated.
- A rotation schedule should be developed to allow all areas of the plant to be sampled on a periodic basis, e.g., weekly monitoring with rotation of sites between different areas of the plant, with all sites sampled within a specified time period (e.g., monthly or quarterly). However, this should not be set-up in a manner that excludes the sampling of an area of concern identified in a "non-scheduled" area. The sampling plan should be flexible and allow for additional samples to be collected where appropriate.

❒ Increase environmental monitoring (frequency and/or number of samples), as well as other control measures, in response to plant events such as during and after construction, and after equipment installation and major repairs are completed. An example of intensified control and monitoring is shown in Table 7-4.

❒ Develop a policy on whether and when to test PCSs and/or finished product and a program for this testing.

- Testing of PCS, if included in the program, should be done only after a policy has been established with regard to the impact of a PCS-positive on finished product

and the actions to be taken. Routine testing of PCSs is not particularly meaningful in verification because, given an effective *Salmonella* control program, contamination, if any, is likely to be sporadic and sampling is unlikely to find positives on PCS.

- PCS testing may be done as part of corrective actions for an environmental positive, e.g., in sampling for investigational purposes following positive *Salmonella* findings in areas that may pose a risk for PCS contamination on the line (see Table 7-2). PCS testing may also be valuable under other circumstances such as hygienic qualification of a piece of equipment prior to use in production, e.g., for new equipment or newly-acquired equipment that has been used in another facility.

- Manufacturers should decide whether or not to conduct finished product testing based on an evaluation of risk. Customer requirements (i.e., Certificates of Analysis) may also dictate the need for finished product testing.

  - Whenever finished product testing is performed, the tested lot should be isolated, placed on hold, and only released into commerce if the product tests negative for *Salmonella*.

  - **If a product sample tests positive for *Salmonella*, the tested lot is considered adulterated and should not be released into commerce. As noted previously, retesting should not be conducted for the purpose of negating the initial test results (Rainosek, 1997; ICMSF 2002c). Resampling almost always increases the chance of accepting a contaminated lot. The lower the prevalence level of *Salmonella* in the product, the more difficult it will be to confirm, and it is virtually impossible to confirm very low prevalence by resampling (ICMSF, 2002c)**

  - Retesting for investigational purposes only (i.e. to try to determine level or incidence of contamination in the sample) may be appropriate.

  - The lot associated with a positive sample may be reworked using a validated inactivation step. In addition to product disposition, other corrective actions may be taken as appropriate (see below)

- An official or validated method should be used to test samples taken from the environment or finished product.

  - The FDA BAM method (2007) and the ISO 6579 method (2002) apply to various products described in the methods, as well as to environmental samples. The FDA BAM method and the ISO 6579 method are considered the official method in the US and EU, respectively. A method that has been validated to be equivalent in specificity and sensitivity to one of these official methods may also be used. According to the FDA (2007), a validated rapid method is generally used for screening, with negative results accepted as such, but positive results require cultural confirmation by the appropriate official method. Isolate subtyping with a method such as serotyping or genetic fingerprinting may be used for tracking and troubleshooting purposes.

  - Compositing environmental samples (combining multiple sponges or swabs into one pre-enrichment) or pooling (combining 2-5 post-enrichment samples into one test sample to be run on a rapid method) is generally not recommended. A

positive finding on a composited sample cannot identify the specific location of the positive and results in broader, less focused corrective actions. However, there may be some situations where compositing may be appropriate, e.g., samples taken from multiple drains in the same processing area, where it is less important to pinpoint the site. If a "pooled" sample comes up positive, the individual enrichments that made up the pooled sample can be immediately retested separately to pinpoint the positive sample(s). However, this process adds delay in determining the location of a positive compared to testing samples individually. The ability to composite or pool samples is method dependent and must be validated. Implications of compositing or pooling should be carefully considered.

- Corrective actions must be taken when *Salmonella* is detected in an environmental monitoring or finished product sample. In most cases, corrective actions are triggered by presumptive *Salmonella* test results since waiting for the final confirmation could take up to a week.
  - If a positive is found in any of the four sampling zones, the site should be examined and potential causes investigated. It may be advantageous to have a pre-assigned team to assist in the investigation and to help direct corrective actions.
  - Corrective actions to be taken should be based on an assessment of the potential for finished product contamination given the location of the positive site in the environment. (A positive in Zone 2, 3, or 4 (non-PCS) does not automatically implicate finished product.)
  - Corrective actions should include appropriate procedures, such as those described in Table 7-2, and be accompanied by re-sampling of the initial positive and adjacent areas.
  - All corrective actions taken, including re-sampling results, should be documented.

Table 7-1. Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of Sample Sites *	Test for	Frequency	Number of Samples**
Zone 1	Product contact surfaces (PCS) in the Primary *Salmonella* Control Area	Conveyors, filler hoppers, scrapers/utensils, packaging equipment, etc.	Indicator Organisms (e.g. Aerobic Plate Count; Enterobacteriaceae); *Salmonella* only when special circumstances dictate	Post-Sanitation or as needed for investigational, validation, or verification purposes	Line Dependent
Zone 2	Non-PCS within close proximity to PCS in Zone 1. - areas that, if contaminated, could reasonably lead to PCS contamination (i.e., under normal operational practices)	Exterior of equipment, legs/frameworks, motor housings, catwalks, control panels, scrap carts, floor drains, HVAC vents, vacuum cleaners if used near PCSs, air filters, weight scales, floor mats at packaging, etc.	*Salmonella*	Weekly, Biweekly, or Monthly	5-10
Zone 3	Non-PCS within process area but more removed from PCS. - areas that, if contaminated, could <u>not</u> reasonably lead to PCS contamination without mechanical or human intervention (i.e., employee using compressed air to clean floors or a piece of equipment being moved)	Cleaning tools (brooms, squeegees), floor scrubbers, forklifts, floor drains, traffic pathways into process area, ceiling drain pipes, wall/floor junctures, wash stations, ingredient storage areas, etc.	*Salmonella*	Weekly or Monthly	3-6
Zone 4	Non-PCS outside processing areas. - areas that, if contaminated, could spread to the processing area via foot or equipment traffic (i.e. waste carts picking up contamination in compactor room)	Compactor areas, employee entrances, locker rooms, storage rooms, labs	*Salmonella*	Monthly or Quarterly	2-4

* It is recommended that a facility assessment be done to identify sampling sites, in order to include potentially problematic areas. Weekly monitoring may be considered as a starting point to establish a solid baseline and the frequency may be revised based on results over time.

** In general, a greater number of samples are taken in Zone 2 than Zone 3 and in Zone 3 than Zone 4 – a ratio of 5:3:2, 6:3:1, 7:2:1, 8:1:1 have been used depending on the product and process, although other approaches may be effective. A larger facility with multiple process lines may take a greater number of samples than those indicated for the zones.

Table 7-2. Examples of corrective action procedures following positive *Salmonella* findings in the plant environment

Zone 2, 3, or 4: Response to a Single Positive

Corrective actions must be taken when a *Salmonella* positive is found in any zone. Corrective actions should be initiated based on presumptive positive test results. The actions should aim to eliminate potential sources of the contamination.

Corrective actions common to Zone 2, 3, and 4 may include the following:

- Initiate pre-assigned response team to conduct a preliminary investigation to determine potential cause or source for the contamination (e.g., water leaks, maintenance activity, construction, etc.). The suspect site and surrounding areas should be examined as part of the investigation.
- Take immediate actions to correct any GMP deficiencies based on findings. These may include:
  - Quarantine the suspect area and limit access to the area.
  - Reinforce hygienic practices with appropriate employees (retrain if necessary).
  - Re-examine cleaning frequencies and revise as appropriate.
  - Eliminate water and water collection points, if present.
  - Repair damaged floors/walls and other structural damage as appropriate.
  - Re-examine traffic patterns. Where necessary and feasible, limit traffic flows (both employees and mobile equipment) through the area, restrict fork truck movement, redirect high risk traffic patterns from adjacent areas, etc.
- If desired, conduct investigational sampling of the suspect and surrounding areas prior to cleaning. Precaution should be taken to avoid spreading potential contamination from the suspect area to other areas in the plant.
- Thoroughly clean/sanitize and dry the positive site and the surrounding area. Use dry, controlled wet, and/or wet cleaning as appropriate according to guidelines described in Element 4.
- Re-sample the implicated area and other sites within the surrounding and traffic pattern areas. If the positive is found in Zone 3, Zone 2 sites in the implicated area should be sampled and tested to verify that contamination has not spread to areas closer to PCSs; if the positive is in Zone 4, all Zone 3 sites close to the implicated area should be sampled and tested to verify that contamination has not spread into the process area.
- Increase sampling frequency, e.g., from weekly to once every two days in Zone 3, from weekly to daily for Zone 2. After 3 consecutive

negatives, the routine sampling frequency and rotation plan for the *Salmonella* monitoring may be resumed.

Zone 4 areas are remote from production and generally present low risk to product. However, results from Zone 4 do provide information about the non-production environment and traffic flow. Although it is expected that *Salmonella* may be found occasionally in Zone 4, a positive finding should prompt additional actions beyond routine sanitation.

A Zone 3 positive, in the absence of a Zone 2 positive, is an early indicator of a sanitation program that is not robust enough. The implicated process may or may not be suspended based on the positive location and its proximity to product contact surfaces.

Zone 2: Additional Actions for a Single Positive

- Stopping production for sanitation may be appropriate under certain circumstances where finished product or PCSs may be at risk.
- Whether or not to disassemble the line depends on the equipment associated with the positive site and how close the site is to finished product. Breaking down the line may not always be warranted if cleaning and re-sampling can be conducted without affecting PCSs. For example, the outside of a cooling tunnel and support frames may fall into a Zone 2 sampling category and these sites should not affect product contact surfaces or cause the line to be broken down. However, if deemed necessary, break down the line from the positive site on, and disassemble equipment as necessary to ensure all PCSs are accessible for cleaning and sanitation. Thoroughly clean, sanitize, and dry the line and the surrounding areas starting from the positive site through the end of the line.
- Conduct pre-operational inspections on the line equipment and in the area as applicable. Include Zones 2 & 3, and possibly Zone 1, as necessary in the sampling plan to re-qualify the line. Pre-operational test results should be obtained and confirmed negative prior to start-up if Zone 1 samples are included.
- Product testing may or may not be necessary depending on where the positive site was located. If finished product testing is already conducted as part of the overall food safety program (e.g., products with a *Salmonella* specification), intensified product testing may be initiated following any Zone 2 *Salmonella* positive finding. For example, the stringency of the sampling plan may increase from a plan with 3 samples of 25 g each to a case 11 (n=10), case 14 (n=30), or case 15 (n=60) depending on the situation, with c=0 in all cases; or from testing a 375 g composite to testing 2x 375 g (750 g) or 4x 375 g (1500 g). Whenever a product lot is subjected to testing, the lot should be held and only released if the test result is negative for *Salmonella*.

Special Circumstances: Consecutive Positives (all Zones)

When a sound control program for *Salmonella* is in place, finding multiple and/or consecutive positives may indicate that the primary source is a harborage site, where the organism may have become established and is multiplying. This can lead to an increased risk for spreading the organism and ultimately process line contamination. Corrective actions outlined below may be followed for problem resolution.

- Map the contamination sites on a layout of the facility to aid in locating the source of contamination, or at least suggest additional sites to sample. It is critical that a harborage site, if one exists, be found and eliminated. This usually means taking more samples than those taken during routine monitoring in the affected and traffic flow areas.
- Reinforce GMP training and hygienic practices and provide additional attention to sanitation procedures.
- Visually inspect areas for potential niches. Intensify cleaning activities around these areas.
- Visually inspect handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices.
- Review equipment cleaning and preventative maintenance protocols and revise if necessary.
- Examine processing equipment and consider equipment redesign if necessary.
- PCS or product testing may be necessary or need to be intensified for Zone 2 consecutive positives. In some operations, testing may involve testing of worst-case samples on the line, e.g., sifter tailings on a spray dryer system. Line samples may be taken at various times and/or from various locations to help pinpoint potential contamination sites. Investigational samples should be analyzed individually, not as composites.
- Depending on the location of the positive, consideration should be given to testing Zone 1 sites. For example, consideration should be given to testing Zone 1 sites (i.e., PCSs) as a response to multiple positives in Zone 2. Consideration may also be given to Zone 1 testing under other circumstances such as qualification for new equipment or relocated equipment, product tests positive, or products are implicated by epidemiologic investigations in an outbreak.

Table 7-3. Examples of locations and situations in facilities that can serve as potential sources for spread of *Salmonella*

Process area

- Aspirator line
- Dust collection system
- Filter sock
- Air conveyance system, e.g., rotary air lock, cyclone, air locks, duct work, pneumatic conveyance system
- Inside a pump that was disassembled
- Inside an air duct
- Exposed insulation
- Eroded flooring
- Space between walls
- Poorly sealed wall/floor junction
- Leaky roof
- Leaky drain pipe
- Conveyor
- Bucket elevator
- Fork lift
- Employees
- Fans
- Cat walks
- Central and/or portable vacuums
- Maintenance tools
- Floor scrubber
- Floor squeegee
- Mop head
- Drain
- Insects, rodents, and other pests

Outside of process area

- Fire exit, for example, used by construction crew to enter and exit the facility
- Entrance to employee locker room
- Pathway to trash compactor
- Receiving dock
- Insect light traps
- Areas where employees may congregate, such as a designated smoking area

* This list is by no means all-inclusive.

Table 7-4. An example of intensified environmental monitoring and control in response to special plant events

Plant events include construction, new equipment installation in the processing areas, or other events that may affect the Primary *Salmonella* Control Area. Plant traffic controls, room air pressure, sanitation activities, etc. should be assessed during construction activities. Intensified environmental control procedures and action steps may be required, including:

- Reinforce GMP practices and traffic patterns with outside contractors.
- Set-up temporary control barriers within the plant as applicable.
- Increase cleaning frequency of adjacent areas during construction, after equipment installation, and after major repairs are completed.
- Sampling and testing for *Salmonella* should be performed in the construction and adjacent areas during construction.
- Increase environmental monitoring (frequency and/or number of samples) after construction, equipment installation, or major repairs are completed. The sampling sites and frequency should be determined based on a team evaluation of the following: plant location of construction activities; type of construction (e.g., installation, demolition, material removal); duration of construction activities; types of environmental controls implemented, etc.

SUMMARY AND CONCLUSIONS

Several significant outbreaks of foodborne salmonellosis have been linked to products produced in low-moisture food manufacturing environments. The control of *Salmonella* in these environments is challenging and highly specialized. This guidance has been developed based on a synthesis of industry practices and programs, as well as information from the literature. Application of the guidance, in terms of control elements and stringency of control, will depend on the product and process, including the intended use of the product.

There are knowledge gaps to be filled. The lack of adequate *Salmonella* inactivation data in specific products at various water activity levels has hindered industry's ability to evaluate the adequacy of certain processes (such as baking of peanut butter cookies) in the event that an ingredient was found contaminated with *Salmonella*. For example, in response to the 2008-2009 *Salmonella* Typhimurium outbreak linked in part to peanut butter, many peanut butter-containing products were recalled because there was little basis for the companies involved to evaluate the adequacy of the lethality of the specific processes. Although heat resistance data for *Salmonella* in peanut butter were available, data on inactivation of *Salmonella* in peanut butter-containing cookie dough were not published. The application of the data based on peanut butter was not appropriate to determine whether the baking process was adequate to eliminate the level of *Salmonella* expected in the contaminated ingredient (i.e., peanut butter).

Development and validation of additional dry cleaning methods is needed to help minimize the risk of post processing contamination. Further work is needed to develop practical molecular subtyping tools with high discriminatory power to facilitate more effective environmental monitoring and *Salmonella* control. Molecular subtyping tools will help establish links between isolates (e.g., from ingredients and processing environment), and differentiate transient versus resident strains in the environment (ICMSF, 2002b). Conducting surveys to determine the prevalence and concentration of *Salmonella* in widely used raw ingredients, in combination with using such data to conduct risk assessments for various products or product/process combinations, will generate further scientific support for the appropriate log reduction, and facilitate the determination and evaluation of effective control measures and risk mitigation strategies. To this end, more research on dose-response is needed to improve risk assessments because available *Salmonella* dose-response models, such as the one derived from human studies (FAO/WHO, 2002; FSIS, 2005) where a cocktail of serotypes in buffer was fed to healthy adults, may not be representative of the susceptibility of the general population or the risk from low-moisture products. As indicated previously, in some instances, illnesses occurred upon consumption of low-moisture products contaminated at levels <1 cfu/g depending on the host, the product, and the *Salmonella* strain.

Continuing research to enhance knowledge in areas such as molecular subtyping tools, more efficient environmental sampling, rapid detection, effective thermal and non-thermal *Salmonella* inactivation processes, and the determination of the appropriate level of *Salmonella* reduction in various low-moisture products, coupled with sharing common industry practices, will enable industry to more efficiently and effectively reduce the risk of *Salmonella* contamination in low-moisture products.

REFERENCES

ABC (Almond Board of California). 2007. Processing authority kit. http://www.almondboard.com/About/content.cfm?ItemNumber=25135&token=58482&userID. Accessed October 28, 2008.

Abd, S. J., K. L. McCarthy, and L. J. Harris. 2008. Use of the Weibull model to evaluate the impact of storage time and temperature on thermal inactivation of *Salmonella* Enteritidis PT 30 on oil-roasted almonds. P1-33, IAFP 2008 Abstract Book. IAFP annual meeting, August 3-6, Columbus, Ohio.

ACMSF (Advisory Committee on the Microbiological Safety of Food). 2006. Cadbury recall update 1 August 2006: Conclusion from ACMSF meeting 30 June. http://www.food.gov.uk/news/newsarchive/2006/aug/cadbury. Accessed October 28, 2008.

Akinleye, I. O. 1994. The effect of water activity on the heat resistance of *Salmonella* Typhimurium. A thesis submitted to the University of reading. Reading, UK.

AMI (American Meat Institute). 2002. Ten sanitary principles for equipment design. AMI, Washington, DC.

AMS (USDA Agricultural Marketing Service). 2007. Almonds grown in California; outgoing quality control requirements. Final Rule. Federal Register Vol. 72, No. 61, March 30, 2007, pp. 15021-15036. http://edocket.access.gpo.gov/2007/pdf/07-1557.pdf. Accessed October 28, 2008.

Archer J., E. T. Jervis, J. Bird, and J. E. Gaze. 1998. Heat resistance of *Salmonella weltevreden* in low-moisture environments. J. Food Prot. 61: 969-973.

Barrile, J. C., and J. F. Cone. 1970. Effect of added moisture on the heat resistance of *Salmonella anatum* in milk chocolate. Appl. Microbiol. 19:177-178.

Betts, R. 2007. "Water, water, everywhere nor any drop to drink" – The problem of *Salmonella* in low-moisture foods. IAFP Special Interest Session on *Salmonella* growth, persistence and survival in low-moisture foods and their environment – strategies for control. IAFP annual meeting, July 8-11, Buena Vista, Florida.

Burnett, S. L., E. R. Gehm, W. R. Weissinger, and L. R. Beuchat. 2000. Survival of *Salmonella* in peanut butter and peanut butter spread. J. Appl. Microbiol. 89:472-477.

CAC (Codex Alimentarius Commission). 2003. *Recommended International Code of Practice General Principles of Food Hygiene.* CAC/RCP 1-1969, Revision 4 (2003). World Health Organization-Food and Agriculture Organization of the United Nations, Rome, Italy. http://www.codexalimentarius.net/web/standard_list.do?lang=en. Accessed October 28, 2008.

CAC (Codex Alimentarius Commission). 2008. Code of hygiene practice for powdered formulae for infants and young children. CAC/RCP 66. World Health Organization-Food and Agriculture Organization of the United Nations, Rome, Italy. http://www.codexalimentarius.net/web/standard_list.do?lang=en. Accessed January 22, 2008

CCFRA (Camden & Chorleywood Food Research Association). 2008. Heat processing of packaged foods: guidelines for establishing the thermal process. CCFRA Guidelines No. 56 (2008). Gloucestershire, UK.

CDC (Centers for Disease Control and Prevention). 1993. *Salmonella* serotype Tennessee in powdered milk products and infant formula – Canada and United States, 1993. Morb. Mortal. Wkly. Rep. 42: 516-517.

CDC (Centers for Disease Control and Prevention). 1998. Multistate outbreak of *Salmonella* serotype Agona infections linked to toasted oats cereal – United States, April-May, 1998. Morb. Mortal. Wkly. Rep. 47: 462-464.

CDC (Centers for Disease Control and Prevention). 2004. Outbreak of *Salmonella* serotype Enteritidis infections associated with raw almonds – United States and Canada, 2003-2004. Morb. Mortal. Wkly. Rep. 53:484-487.

CDC (Centers for Disease Control and Prevention). 2007a. Multistate outbreak of *Salmonella* serotype Tennessee infections associated with peanut butter – United States, 2006-2007. Morb. Mortal. Wkly. Rep. 56: 521-524.

CDC (Centers for Disease Control and Prevention). 2007b. *Salmonella* Wandsworth outbreak investigation, June - July 2007. Information updated as of July 18, 2007. http://198.246.98.21/salmonella/wandsworth.htm. Accessed October 28, 2008.

CDC (Centers for Disease Control and Prevention). 2008a. Investigation of outbreak of infections caused by *Salmonella* Agona. http://198.246.98.21/salmonella/agona/. Accessed September 2, 2008.

CDC (Centers for Disease Control and Prevention). 2008b. Multistate outbreak of human *Salmonella* infections caused by contaminated dry dog food – United States, 2006-2007. Morb. Mortal. Wkly. Rep. 57: 521-524.

CDC (Centers for Disease Control and Prevention). 2008c. Update: Recall of dry dog and cat food products associated with human *Salmonella* Schwarzengrund infections --- United States, 2008. Morb. Mortal. Wkly. Rep. 57: 1200-1202.

CDC (Centers for Disease Control and Prevention). 2009. Multistate outbreak of *Salmonella* infections associated with peanut butter and peanut butter-containing products – United States, 2008-2009. Morb. Mortal. Wkly. Rep. 58:1-6. http://www.cdc.gov/mmwr/pdf/wk/mm58e0129.pdf. Accessed January 30, 2009.

Ceylan, E., G. Huang, and M. Carter. 2008. Comparison of moist heat inactivation rates of *Salmonella* Enteritidis PT 30 and *Pediococcus* spp. NRRL B-2354 on whole almonds under commercial plant conditions. P1-30, IAFP 2008 Abstract Book. IAFP annual meeting, August 3-6, Columbus, Ohio.

CFR (Code of Federal Regulations). 2008a. 9 CFR 590.575: Heat treatment of dried [egg] whites. http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr590.575.pdf. Accessed January 31, 2009.

CFR (Code of Federal Regulations). 2008b. 21 CFR 110: Current good manufacturing practice in manufacturing, packing, or holding human food. http://www.access.gpo.gov/nara/cfr/waisidx_08/21cfr110_08.html Accessed January 31, 2009.

CFR (Code of Federal Regulations). 2008c. 21 CFR 179.26: Irradiation in the production, processing and handling of food. http://edocket.access.gpo.gov/cfr_2008/aprqtr/pdf/21cfr179.26.pdf. Accessed January 31, 2009.

Clark, M., A. F. Kaufmann, and E. J. Gangarosa. 1973. Epidemiology of an international outbreak of *Salmonella agona*. Lancet 2:490-493.

Cordier, J.-L. 2008. Production of powdered infant formula and microbiological control measures, pp. 145-185. *In* J. M. Farber, and S. Forsythe (eds.). *Enterobacter sakazakii*. ASM Press. Washington, DC.

Craven, P.C., W. B. Baine, D. C. Mackel, W. H. Barker, E. J. Gangarosa, M. Goldfield, H. Rosenfeld, R. Altman, G. Lachapelle, J. W. Davies, and R. C. Swanson. 1975. International outbreak of *Salmonella eastbourne* infection traced to contaminated chocolate. Lancet 1:788-793.

Danyluk, M. D., A. R. Uesugi, and L. J. Harris. 2005. Survival of *Salmonella* Enteritidis PT 30 on inoculated almonds after commercial fumigation with propylene oxide. J. Food Prot. 68: 1613-1622.

Danyluk, M.D., L. J. Harris, and D. W. Schaffner. 2006. Monte Carlo simulations assessing the risk of salmonellosis from consumption of almonds. J. Food Prot. 69:1594-1599.

D'Aoust, J.-Y., B. J. Aris, P. Thisdele, A. Durante, N. Brisson, D. Dragon, G. Lachapelle, M. Johnston, and R. Laidley. 1975. *Salmonella eastbourne* outbreak associated with chocolate. Can. Inst. Food. Sci. Technol. J. 8:181-184.

D'Aoust, J.-Y. 1977. *Salmonella* and the chocolate industry: a review. J. Food Prot. 40:718-727.

D'Aoust, J.-Y. 1989. *Salmonella*, pp. 327-445. *In*: M. P. Doyle (ed.). Foodborne Bacterial Pathogens. Marcel Dekker, New York.

D'Aoust, J.-Y., and J. Maurer. 2007. *Salmonella* species, pp. 187-236. *In*: M. P. Doyle and L. R. Beuchat (eds.). Food Microbiology: Fundamentals and Frontiers. 3rd ed. ASM Press. Washington, DC.

Dega, C. A., J. M. Goepfert, and C. H. Amundson. 1972. Heat resistance of salmonellae in concentrated milk. Appl. Microbiol. 23:415–420.

Doyle, M. P. and L. Ma. 2009. Recent findings from studies on the heat inactivation of *Salmonella* Tennessee and other isolates in peanut butter. February 4. Personal communication.

EFSA (European Food Safety Authority). 2007. Opinion of the Scientific Panel on Biological Hazards (BIOHAZ) on the request for review of the opinion on microbiological risks in infant formulae and follow-on formulae with regard to Enterobacteriaceae as indicators. Adopted on January 24, 2007. The EFSA J. 444:1-14. http://www.efsa.europa.eu/en/science/biohaz/biohaz_opinions/ej444_infant_formulae.html. Accessed January 28, 2009.

EFSA (European Food Safety Authority). 2008. Microbiological risk assessment in feeding stuffs for food-producing animals - Scientific Opinion of the Panel on Biological Hazards. Adopted on June 5, 2008. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902004131.htm. Accessed October 28, 2008.

EHEDG (European Hygienic Engineering & Design Group). 2001. General hygienic design criteria for the safe processing of dry particulate materials. EHEDG guidelines 22. http://www.ehedg.org/guidelines.htm. Accessed October 28, 2008.

EHEDG (European Hygienic Engineering & Design Group). 2003. Hygienic engineering of plants for the processing of dry particulate materials. EHEDG guidelines 26. http://www.ehedg.org/guidelines.htm. Accessed Oct. 2008.

EHEDG (European Hygienic Engineering & Design Group). 2008. Guidelines 31: Hygienic engineering of fluid bed and spray dryer plants; Guidelines 33: Hygienic engineering of discharging systems for dry particulate materials; Guidelines 36: Hygienic design of transfer systems for dry particulate materials. http://www.ehedg.org/guidelines.htm. Accessed October 28, 2008.

Ethelberg, S. 2002. International outbreak of *Salmonella* Oranienburg, October-December 2001, Part 2: Denmark. Euro Surveill. 6(3):pii=2006. http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=2006. Accessed October 28, 2008.

FAO/WHO (Food and Agriculture Organization/World Health Organization). 2002. Risk assessment of *Salmonella* in eggs and broiler chickens. Microbiological Risk Assessment Series 1 and 2. http://www.who.int/foodsafety/publications/micro/salmonella/en/index.html. Accessed December 15, 2007.

FAO/WHO (Food and Agriculture Organization/World Health Organization). 2006. *Enterobacter sakazakii* and *Salmonella* in powdered infant formula. Microbiological Risk Assessment Series 10. http://www.who.int/foodsafety/publications/micro/mra10/en/index.html. Accessed August 15, 2007.

FDA (Food and Drug Administration). 2003. Bacteriological Analytical Manual (BAM) Online Chapter 1: Food sampling and preparation of sample homogenate. April 2003 Revision. http://www.cfsan.fda.gov/~ebam/bam-1.html. Accessed October 28, 2008.

FDA (Food and Drug Administration). 2005. FDA issues nationwide alert on possible health risk associated with cold stone creamery "cake batter" ice cream. Press release on July 1, 2005. http://www.fda.gov/bbs/topics/NEWS/2005/NEW01200.html. Accessed October 28, 2008.

FDA (Food and Drug Administration). 2007. Bacteriological Analytical Manual (BAM) Online Chapter 5: *Salmonella*. December 2007 Revision. http://www.cfsan.fda.gov/~ebam/bam-5.html#Prep. Accessed October 28, 2008.

FDA (Food and Drug Administration). 2009a. Recall of products containing peanut butter: *Salmonella* Typhimurium. Updated: January 28, 2009. http://www.fda.gov/oc/opacom/hottopics/salmonellatyph.html. Accessed January 28, 2009.

FDA (Food and Drug Administration). 2009b. Peanut Corporation of America (PCA), Blakely, GA: FDA form 483 (inspectional observations) Jan 9 - 27, 2008 [2009]. http://www.fda.gov/ora/frequent/default.htm. Accessed January 28, 2009.

FDA (Food and Drug Administration). 2009c. Guidance for industry: measures to address the risk for contamination by *Salmonella* species in food containing a peanut-derived product as an ingredient. http://www.cfsan.fda.gov/~dms/pnutguid.html. Accessed March 14, 2009.

Fisher, I. S., B. de Jong, W. van Pelt, J. Aramini, C. Berghold, F. Matthys, J. Powling, and A. Siitonen. 2002. International outbreak of *Salmonella* Oranienburg, October-December 2001, Part 3: other countries. Euro Surveill. 6(3):pii=2007. http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=2007. Accessed October 28, 2008.

Froning, G. W., D. Peters, P. Muriana, K. Eskridge, D. Travnicek, and S. Sumner. 2002. International egg pasteurization manual. Prepared in cooperation with the United Egg Association and American Egg Board.

FSA (Food Standards Agency). 2006. Cadbury Schweppes plc recalls a range of its own brand chocolate products due to possible contamination with *Salmonella*. UK Food Standards Agency, Food Alerts June 23, 2006. http://www.food.gov.uk/enforcement/alerts/2006/jun/cadburychoc. Accessed October 28, 2008.

FSIS (Food Safety and Inspection Service). 1999. Appendix A: Compliance guidelines for meeting lethality performance standards for certain meat and poultry products. http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix_A.htm. Accessed July 15, 2008.

FSIS (Food Safety and Inspection Service). 2005. Risk Assessment for the impact of lethality standards on salmonellosis from ready-to-eat meat and poultry products. http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp**.** Accesses December 15, 2007.

FSIS. 2006. Time-temperature tables for cooking ready-to-eat poultry products. http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/RTE_Poultry_Tables.pdf . Accessed December 15, 2006.

Gastrin, B., A. Kampe, K. Nystrom, B. Oden-Johanson, G. Wessel, and B. Zetterberg. 1972. An epidemic of *Salmonella durham* caused by contaminated cocoa. Lakartidningen 69:5335-5338.

Gill, N., B. Reilly, and H. Smith. 2008. International surveillance network for the enteric infections *Salmonella* and VTEC O157 – Enter Net. http://www.hpa.org.uk/hpa/inter/enter-net_outbreaks.htm. Accessed February 15, 2008.

Gill, O. N., P. N. Sockett, C. L. Bartlett, M. S. B. Vaile, B. Rowe, R. J. Gilbert, C. Dulake, H. C. Murrell, and S. Salmaso. 1983. Outbreak of *Salmonella napoli* infection caused by contaminated chocolate bars. Lancet i: 574–577.

Goepfert, J. M., and R. A. Biggie. 1968. Heat resistance of *Salmonella typhimurium* and *Salmonella senftenberg* 775W in milk chocolate. Appl. Microbiol. 16:1939-1940.

Graham, D. J. 2005. Improving building design. pp. 123-147. *In*: H. L. M. Lelieveld, M. A. Mostert, and J. Holah (eds.). Handbook of hygiene control in the food industry. Woodhead Publishing Ltd., Cambridge, England.

Graham, D. J. 2007. Twenty-two common design errors that produce unsanitary conditions in a food plant. Graham Sanitary Design Consulting. Jackson, MI.

Greenwood, M. H. and W. L. Hooper. 1983. Chocolate bars contaminated with *Salmonella napoli*: an infectivity study. Brit. Med. J. 286:1394.

GMA (Grocery Manufacturers Association). 2008. Food Supply Chain Handbook. GMA, Washington, DC. http://www.gmabrands.com/publications/GMA_SupplyChain2.pdf. Accessed July 15, 2008

Hall, P. 2007. *Salmonella* in low-moisture foods: learning from the past… looking to the future. IAFP Special Interest Session on *Salmonella* growth, persistence and survival in low-moisture foods and their environment – strategies for control. July 10. Orlando, Florida.

Harris, L. J. 2008. *Salmonella* – factors affecting resistance to heat. IAFP Symposium S8 - Validating processes for reducing *Salmonella* in low water activity foods. IAFP annual meeting, August 3-6, Columbus, Ohio.

Hockin, J. C., J.-Y. D'Aoust, D. Bowering, J. H. Jessop, B. Khanna, H. Lior, M. E. Milling. 1989. An international outbreak of *Salmonella nima* from imported chocolate. J. Food Prot. 52:51-54.

Holah, J. 2005. Improving zoning within food processing plants. pp. 148-167. *In*: H. L. M. Lelieveld, M. A. Mostert, and J. Holah (eds.). Handbook of Hygiene Control in the Food Industry. Woodhead Publiching Ltd., Cambridge, England.

ICMSF (International Commission on Microbiological Specifications for Foods). 2002a. Sampling plans and selection of cases and attributes plans, pp. 123-172. *In* Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Kluwer Academic/Plenum Publishers, New York.

ICMSF (International Commission on Microbiological Specifications for Foods). 2002b. Sampling to assess control of the environment, pp. 199-224. *In* Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Kluwer Academic/Plenum Publishers, New York.

ICMSF (International Commission on Microbiological Specifications for Foods). 2002c. Experience in the use of two-class attributes plans for lot acceptance, pp. 183-197. *In* Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Kluwer Academic/Plenum Publishers, New York.

ICMSF (International Commission on Microbiological Specifications for Foods). 2005a. Cocoa, chocolate, and confectionery. Chapter 10. pp. 467–479. *In* Microorganisms in Foods 6: Microbial Ecology of Food Commodities. 2nd ed. Kluwer Academic/Plenum Publishers. New York.

ICMSF (International Commission on Microbiological Specifications for Foods). 2005b. Cereals and cereal products Section IV, Flour, starches, and meals, pp. 409-413; Nuts, oilseeds, and dried legumes Section VI, Legume products, pp. 460-461. *In* Microorganisms in Foods 6: Microbial Ecology of Food Commodities. 2nd ed. Kluwer Academic/Plenum Publishers. New York.

ICMSF (International Commission on Microbiological Specifications for Foods). 2005c. Water, pp. 574-596. *In* Microorganisms in Foods 6: Microbial Ecology of Food Commodities. 2nd ed. Kluwer Academic/Plenum Publishers. New York.

ISO (International Organization for Standardization). 2002. ISO 6579: Microbiology of food and animal feeding stuffs – horizontal method for the detection of *Salmonella* spp. International Organization for Standardization. http://www.iso.org/iso/home.htm. Geneva, Switzerland.

ISO (International Organization for Standardization). 2005. *Food Safety Management Systems – Requirements for Any Organization in the Food Chain,* ISO 22000:2005, 1st ed. http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=35466

Jeong, S., B. P. Marks, and E. T. Ryser. 2008. Inactivation of *Salmonella* Enteritidis PT 30 by low-energy X-ray irradiation on almonds at different water activities. P1-31, IAFP 2008 Abstract Book. IAFP annual meeting, August 3-6, Columbus, Ohio.

Jourdan, N., S. Le Hello, G. Delmas, J. Clouzeau, C. Manteau, B. Désaubliaux, V. Chagnon, F. Thierry-Bled, N. Demare, F. X. Weill, and H. de Valk. 2008. Nationwide outbreak of *Salmonella* enterica serotype Give infections in infants in France, linked to infant milk formula, September 2008. Euro Surveill. 13(39):pii=18994. http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=18994. Accessed October 15, 2008.

Kapperud, G., S. Gustavsen, I. Hellesnes, A. H. Hansen, J. Lassen, J. Hirn, M. Jahkola, M. A. Montenegro, and R. Helmuth. 1990. Outbreak of *Salmonella typhimurium* infection traced to contaminated chocolate and caused by a strain lacking the 60-megadalton virulence plasmid. J. Clin. Microbiol. 28: 2597-2601.

Killalea, D., L. R. Ward, D. Roberts, J. de Louvois, F. Sufi, J. M. Stuart, P. G. Wall, M. Susman, M. Schwieger, P. J. Sanderson, I. S. Fisher, P. S. Mead, O. N. Gill, C. L. Bartlett, B. Rowe. 1996. International epidemiological and microbiological study of outbreak of *Salmonella agona* infection from a ready to eat savory snack – I: England and Wales and the United States. Brit. Med. J. 313:1105-1107.

Kuehm, J. 2002. Industry survey on environmental monitoring for pathogens, *Salmonella* methodology, and in process microbial control (non-meat processes). Presented at the 2002 Food Industry Microbiology Round Table. September 17, 2002. Chicago, IL. Personal communication.

Larkin, J. W. 2008. *Salmonella* – factors affecting resistance to non-thermal processes. IAFP Symposium S8 - Validating processes for reducing *Salmonella* in low water activity foods. IAFP annual meeting, August 3-6, Columbus, Ohio.

Liang, A. 2008. Investigation and control of pathogens in dry foods and dry food processing environments. Presented at the Conference on Investigation and Control of Pathogens in Dry Foods and Dry Food Processing Environments. Bloomington, MN, October 6-7, 2008.

Liu, T. S., G. H. Snoeyenbos, and V. L. Carlson. 1969. Thermal resistance of *Salmonella* senftenberg 775W in dry animal feeds. Avian Dis. 13:611-631.

Lehmacher, A., J. Bockemuhl, and S. Aleksic. 1995. Nationwide outbreak of human salmonellosis in Germany due to contaminated paprika and paprika-powdered potato chips. Epidemiol. Infect. 115:501-511.

Little, C. 2001. *Salmonella* Stanley and *Salmonella* Newport in imported peanuts - update. Euro Surveill. 5(43):pii=2041. http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=2041. Accessed January 28, 2008

Ma, L., G. Zhang, P. Gerner-Smidt, and M. P. Doyle. 2008. Comparison of thermal tolerance between outbreak-associated and clinical isolates of *Salmonella* Tennessee in peanut butter. P1-02, IAFP 2008 Abstract Book. IAFP annual meeting, August 3-6, Columbus, Ohio.

Marks, B. P. 2008. Factors to consider in modelling thermal inactivation. IAFP Symposium S8 - Validating processes for reducing *Salmonella* in low water activity foods. IAFP annual meeting, August 3-6, Columbus, Ohio.

Mattick, K. L., F. Jorgensen, P. Wang, J. Pound, M. H. Vandeven, L. R. Ward, J. D. Legan, H. M. Lappin-Scott, and T. J. Humphrey. 2001. Effect of challenge temperature and solute type on heat tolerance of *Salmonella* serovars at low water activity. Appl. Environ. Mircobiol. 67: 4128-6136.

Mead, P. S., L. Slutsker, V. Dietz, L. F. McCaig, J. S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. Emerg. Infect. Dis. 5:607-625.

Mettler, A. E. 1994. Present day requirements for effective pathogen control in spray dried milk powder production. J. Soc. Dairy Technol. 47:95-107.

McNamara, A.-M. 2007. *Salmonella*: the organism, its habitat, and testing. IAFP Special Interest Session on *Salmonella* growth, persistence and survival in low-moisture foods and their environment – strategies for control. IAFP annual meeting, July 8-11, Buena Vista, Florida.

NACMCF (National Advisory Committee on Microbiological Criteria for Foods). 1997a. Recommendations on fresh juice. http://www.cfsan.fda.gov/~mow/nacmcf.html. Accessed December 15, 2006.

NACMCF (National Advisory Committee on Microbiological Criteria for Foods). 1997b. Preliminary draft report of the Fresh produce Working Group of NACMCF. February 3, Memo from C. DeRoever to the NACMCF Fresh Produce Working Group.

NACMCF (National Advisory Committee on Microbiological Criteria for Foods). 1998. Hazard analysis and critical control point principles and applications guidelines. J. Food Prot. 61:762-775.

NACMCF (National Advisory Committee on Microbiological Criteria for Foods). 2006. Supplement: Requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization. J. Food Prot. 69:1190-1216.

Ng, H., H. G. Bayne, and J. A. Garibaldi. 1969. Heat resistance of *Salmonella*: the uniqueness of *Salmonella senftenberg* 775W. Appl Microbiol. 17: 78–82.

Ng, S., G. Rouch, R. Dedman, B. Harries, A, Boyden, L. McLennan, S. Beaton, A. Tan, S. Heaton, D. Lightfoot, M. Vulcanis, G. Hogg, W. Scheil, S. Cameron, M. Kirk, J. Feldheim, R. Holland, C. Murray, N. Rose, and P. Eckert. 1996. Human salmonellosis and peanut butter. Comm. Dis. Surveill. 20(14): 326.

Pafumi, J. 1986. Assessment of the microbiological quality of spices and herbs. J. Food Prot. 49:958-963.

Rainosek, A. P. 1997. Inherent risks in acceptance sampling, pp. 530-537. *In* R. E. Martin, R. L. Collette, and J. W. Slavin (eds.). Fish Inspection, Quality Control, and HACCP: A Global Focus Technomic Publishing Co., Inc. Lancaster, PA.

Rushdy, A. A., J. M. Stuart, L. R. Ward, J. Bruce, E. J. Threlfall, P. Punia, and J. R. Bailey. 1998. National outbreak of *Salmonella senftenberg* associated with infant food. Epidemiol. Infect. 120:125-128.

Sagoo, S.K., C. L. Little, M. Greenwood, V. Mithani, K. A. Grant, J. McLauchlin, E. de Pinna, and E. J. Threlfall. 2009. Assessment of the microbiological safety of dried spices and herbs from production and retail premises in the United Kingdom. Food Microbiol. 26:39-43.

Scott, V. N. 2005. How does industry validate elements of HACCP plans? Food Control. 16:497-503.

Scott, V. N. and K. E. Stevenson (ed.). 2006. HACCP: A Systematic Approach to Food Safety, 4th ed. Food Products Association, Washington, D.C.

Scott, V. N., K. E. Stevenson, and D. E. Gombas. 2006. Verification procedures. pp. 91-98. *In* V. N. Scott and K. E. Stevenson (ed.), HACCP: A Systematic Approach to Food Safety, 4th ed. Food Products Association, Washington, D.C.

Shachar, D. and S. Yaron. 2006. Heat tolerance of *Salmonella enterica* serovars Agona, Enteritidis, and Typhimurium in peanut butter. J. Food Prot. 69:2687-2691.

Shohat, T., M. S. Green, D. Merom, O. N. Gill, A. Reisfeld, A. Matas, D. Blau, N. Gal, P. E. Slater. 1996. International epidemiological and microbiological study of outbreak of *Salmonella agona* infection from a ready to eat savoury snack--II: Israel. Brit Med. J. 313:1107-1109.

Silliker Laboratories. 2002. Controlling *Salmonella*: Strategies that work. IAFP AV Library. http://www.foodprotection.org/memberinterest/AV_Library_Listing.pdf.

Sperber, W.H. and the North American Millers' Association Microbiology Working Group. 2007. Role of microbiological guidelines in the production and commercial use of milled cereal grains: A practical approach for the 21st century. J. Food Prot. 70: 1041-1053.

Sumner, S., T. M. Sandros, M. C. Harmon, V. N. Scott, and D. T. Bernard. 1991. Heat resistance of *Salmonella typhimurium* and *Listeria monocytogenes* in sucrose solutions of various water activities. J. Food Sci. 6:1741-1743.

Tamminga, S. K., R. R. Beumer, E. H. Kampelmacher, and F. M. van Leusden. 1976. Survival of *Salmonella eastbourne* and *Salmonella typhimurium* in chocolate. J. Hig. (London). 76:41-47.

Tauxe, R. V., S. J. O'Brian, and M. Kirk. 2008. Outbreaks of food-borne diseases related to the international food trade. pp. 69-112. *In*: M. P. Doyle, and M. C. Erickson (eds). Imported Food: Microbiological Issues and Challenges. ASM Press. Washington, DC.

Tucker, G. S., T. Lambourne, J. B. Adams, and A. Lach. 2002. Application of a biochemical time-temperature integrator to estimate pasteurisation values in continuous food processes. Innov. Food Sci. Emerg. Technol. 3:165-174.

Tuncan, E. 2008. Translating laboratory data to equipment validation. IAFP Symposium S8 - Validating processes for reducing *Salmonella* in low water activity foods. IAFP annual meeting, August 3-6, Columbus, Ohio.

Uesugi, A. R., M. D. Danyluk, R. E. Mandrell, and L. J. Harris. 2007. Isolation of *Salmonella* Enteritidis phage type 30 from a single almond orchard over a 5-year period. J. Food Prot. 70:1784–1789.

VanCauwenberge, J. E., R. J. Bothast, and W. F. Kwolek. 1981. Thermal inactivation of eight S*almonella* serotypes on dry corn flour. Appl. Environ. Microbiol. 42:688-691.

Vij, V., E. Ailes, C. Wolyniak, F. J. Angulo, and K. C. Klontz. 2006. Recalls of spices due to bacterial contamination monitored by the U.S. Food and Drug Administration: the predominance of salmonellae. J. Food Prot. 69: 233-237.

Wang, G. 2008. Surrogate selection strategy. IAFP Symposium S8 - Validating processes for reducing *Salmonella* in low water activity foods. IAFP annual meeting August 3-6, Columbus, Ohio.

Waterman, S. R. and P. L. C. Small. 1998. Acid-sensitive enteric pathogens are protected from killing under extremely acidic conditions of pH 2.5 when they are inoculated onto certain solid food sources. Appl. Environ. Microbiol. 64:3882-3886.

Werber, D., J. Dreesman, F. Feil, U. van Treeck, G. Fell, S. Ethelberg, A. M. Hauri, P. Roggentin, R. Prager, I. S. T. Fisher, S. C. Behnke, E. Bartelt, E. Weise, A. Ellis, A. Siitonen, Y. Andersson, H. Tschäpe, M. H.Kramer, and A. Ammon. 2005. International outbreak of *Salmonella* Oranienburg due to German chocolate. BMC Infect. Dis. 5:7doi:10.1186/1471-2334-5-7. http://www.biomedcentral.com/1471-2334/5/7. Accessed January 28, 2009.

Williams Jr., J., R. Clavero, J. H. Silliker, and R. S. Flowers. 2006. Microbial control for confectionery plants. The Manufacturing Confectioner, April 2006, pp. 75-78.

Zink, D. 2007a. The return of *Salmonella*. IAFP Special Interest Session on *Salmonella* growth, persistence and survival in low-moisture foods and their environment – strategies for control. IAFP annual meeting, July 8-11, Buena Vista, Florida.

Zink, D. 2007b. FDA concerns about food safety. Presented at the Regulatory Update session at the Grocery Manufacturers/Food Products Association 2007 Fall Conference. October 30 – November 1, 2007.

Zink, D. 2008. Environmental investigation and regulatory response: *Salmonella* Tennessee in peanut butter in the United States, 2007. IAFP Symposium S1- 2008 Foodborne disease update: *Salmonella* in processed foods. IAFP annual meeting, August 3-6. Columbus, Ohio.