GENERAL INTEREST PAPER

Control of *Salmonella* in Low-Moisture Foods I: Minimizing Entry of *Salmonella* into a Processing Facility

Part one of a three-part series

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ABSTRACT

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 past 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, products containing peanut-derived ingredients, and children's snacks made of puffed rice and corn with a vegetable seasoning. These outbreaks underscore the difficulty of eradicating *Salmonella* from the environment of dry product manufacturing facilities and highlight the need to reinforce industry preventive control measures through guidance based on the best available information. To address the need for industry-wide guidance, the Grocery Manufacturers Association formed a *Salmonella* Control Task Force to develop, through a review and synthesis of industry programs and information from the literature, this guidance document, which includes seven elements for the control of *Salmonella* in the manufacture of low-moisture foods. Two of the control elements, preventing ingress or spread in a facility and controlling raw materials, are described in this paper, along with background information on outbreaks and an overview of current industry practices. This is the first in a three-part series of articles.

INTRODUCTION

Low-moisture products such as peanut butter, infant formula, toasted cereals, and dry aniseed are characteristically low water activity (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 because of poor sanitation practices, poor equipment design, improper maintenance or poor ingredient control. As a result of an outbreak of *Salmonella enterica* serotype Tennessee infections associated with the consumption of peanut butter in 2006–2007 *(12)*, 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.

To address the need for industry-wide guidance, the Grocery Manufacturers Association (GMA) formed a *Salmonella* Control Task Force to develop a 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. The information in the guidance document is being published here in three general interest papers in order to ensure wide dissemination of the information.

OUTBREAKS AND RECALLS DUE TO *SALMONELLA* IN LOW-MOISTURE PRODUCTS

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 5,981 cases) of salmonellosis reported for FDA-regulated foods (exclud-

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

Year	Product implicated	Etiologic agent	Country	Reference
1970	Chocolate	*S.* Durham	Sweden	*(38)*
1972	Fishmeal[a]	*S.* Agona	US	*(21)*
1973	Milk powder	*S.* Derby	Trinidad	*(27)*
1982–83	Chocolate	*S.* Napoli	UK	*(43)*
1985–86	Chocolate	*S.* Nima	Canada, US	*(47)*
1987	Chocolate	*S.* Typhimurium	Norway, Finland	*(54)*
1993	Paprika-seasoned potato chips	*S.* Saintpaul, *S.* Javiana, *S.* Rubislaw	Germany	*(57)*
1993	Powdered infant formula	*S.* Tennessee	Canada, US	*(9)*
1995	Infant cereals	*S.* Senftenberg	UK	*(67)*
1996	Peanut butter	*S.* Mbandaka	Australia	*(64)*
1996	Peanut-flavored maize snack	*S.* Agona	Multiple countries[b]	*(55, 71)*
1998	Toasted oats cereals	*S.* Agona	US	*(10)*
2000–01	Raw almonds	*S.* Enteritidis	US, Canada	*(11)*
2001	Peanuts	*S.* Stanley, *S.* Newport	Multiple countries[c]	*(59)*
2001	Chocolate	*S.* Oranienburg	Multiple countries[d]	*(31, 36, 39, 79)*
2002	Tahini and Halva	*S.* Montevideo	Australia	*(75)*
2003–04	Raw almonds	*S.* Enteritidis	US, Canada	*(11)*
2006	Chocolate	*S.* Montevideo	UK	*(37)*
2006–07	Peanut butter	*S.*Tennessee	US	*(12)*
2007	Children's snack	*S.* Wandsworth, *S.*Typhimurium	US	*(13)*
2008	Puffed cereals	*S.* Agona	US[e]	*(14)*
2008	Powdered infant formula	*S.* Give	France	*(53)*
2008–09	Peanut butter, peanut butter-containing products	*S.* Typhimurium	US, Canada[f]	*(17)*

[a]*Salmonella* in a poultry product associated with human illnesses was traced back to fishmeal

[b]Including UK, US, and Israel

[c]Including Australia, Canada, and UK

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

[e]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

[f]One case was reported in Canada

ing eggs), only 2 were from low-moisture processed food products *(81)*. In addition, one outbreak resulted from cake batter ice cream in which the source of *Salmonella* Typhimurium was the cake batter mix *(33)*, 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 *(10)* and 628 cases attributed to peanut butter in 47 states between August 2006 and May 2007 *(12)*. These two outbreaks eventually accounted for 1,037 clinically confirmed cases of illness *(81)*. Moreover, a second major *Salmonella* outbreak in the US attributed to peanut butter and products containing peanut-derived ingredients *(17, 34)* 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. Because of the large number of unreported cases of salmonellosis for all types of products *(60)*, the actual number of cases was likely much higher.

Over the past 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 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 *(5)*. A review of recall records at FDA by Vij and colleagues *(77)* showed that from 1970 to 2003, there were 21 recalls involving spices and herbs contaminated with *Salmonella*. Sixteen of these recalls

TABLE 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	*(23, 24)*
1982	*S.* Napoli	2–23	Chocolate bars from Italy	Contaminated water (postulated)	272	England, Wales	*(40)*
1985–1986	*S.* Nima	0.04–0.24	Chocolate coins from Belgium	Unknown	_	Canada	*(47)*
1987	*S.* Typhimurium	≤1	Chocolate products from Norway (postulated)	Avian contamination	349	Norway, Finland	*(54)*
2001–2002	*S.* Oranienburg	1.1–2.8	Two chocolate brands from Germany	Unknown	439	Germany, other European countries	*(79)*

[a]Adapted from Werber et al.

[b]In each outbreak, the identified vehicles were traced to a single manufacturer.

occurred during 2001–2004, and 12 of them involved spices imported from around the world (India, Spain, Turkey, Egypt, Jamaica, Mexico, and Taiwan). The products in these recalls included ground black pepper, ground cumin, ground oregano, paprika, red pepper powder, ground sage, sesame seeds as well as ground thyme, and the herb basil leaves *(77)*.

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 2). In an outbreak attributed to paprika and paprika-powdered potato chips *(57)*, *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 *(83)*. Chocolate contaminated with low levels of *Salmonella* Montevideo was associated with a number of cases in the UK in 2006 *(2, 37)*. A chocolate-related outbreak provided the first strong evidence that large numbers of salmonellae were not necessarily a prerequisite for human infection *(25, 26, 27)* 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 *(78)*.

Salmonella infections associated with the consumption of contaminated confectionery products such as chocolate, candy and cocoa powder, although rare, have been known since the late 1960s *(25, 50)*. For example, cocoa powder contaminated with *Salmonella* Durham was used in confectionery products that caused an outbreak affecting 110 people in Sweden *(38)*. 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 *(23, 24, 38, 40, 54)*. 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 to 2.8 cells per gram *(79)*. *Salmonella* Nima was found at levels as low as 0.04 cells/g in Belgium-made chocolate coins implicated in an outbreak in Canada *(47)*.

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 *(50, 61)*. However, outbreaks from low-moisture products have continued to occur periodically (Table 1). Notably, an outbreak associated with puffed wheat and rice cereal *(14)* 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 that 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 *(15)*. The dog food manufacturer has since closed the implicated production facility because of a second recall linked to the same organism *(16)*. These outbreaks underscore the difficulty of 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.

PERSISTENCE OF *SALMONELLA*

Salmonella can persist for long 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 months of storage at room temperature *(74)*, in peanut butter products after 6 months of storage at room temperature and after storage for more than 6 months at refrigeration temperature *(6)*. *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 *(76)*. 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*

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). *Salmonella* Typhimurium was reported to have a D-value of 816 min at 66°C in molten chocolate *(41)* and 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 *(70)*. 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 *(46)*. 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 *(29)*, and more than 260 min was needed to reduce *Salmonella* by 7 log CFU/g at 70°C in peanut butter *(70)*. 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 *(1)*, in comparison to 4.25 min at 121°C needed for 5-log reduction based on the D-value *(46)*. Increasing solids level in dried milk increased the heat resistance of *Salmonella* Alachua *(28)*. At 57°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°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 setting them on the basis of the nonlinear Weibull model. Because of variations in these parameters, it is important, when published heat resistance data are applied to certain food processes, that the conditions under which the values were obtained not be significantly different from the product or process conditions used by the processor.

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 a_w below 0.85, including products such as cereal, chocolate, spray-dried milk, infant formula, and peanut butter. A total of 17 companies/plants 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 *Salmonella* on non-product contact surfaces, 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%) implemented the following practices: testing of "*Salmonella*-sensitive" ingredients (either in house or by the supplier); inclusion of equipment sanitary design review in the *Salmonella* control program; and vali-dation of 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 particularly 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 being asked about industry practices, respondents were asked about situations that could introduce water into the facility, and 56% of them reported 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 *(56)* on industry practices of environmental monitoring for non-meat products. Among 20 respondents with programs to monitor the process environment for pathogens, 15 monitored for *Salmonella* weekly or monthly. 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 fewer than 10 or 21–50 samples. More than half of the respondents (12 out of 20) divided the process environment into zones, with samples being 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), and still others did both (3 out of 20). The vast majority of the sampling was done by plant personnel (18 out of 20) but occasionally it was done 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 *(32)*. A detailed description on the management of *Salmonella* and *E. sakazakii* (*Cronobacter* spp.) in powdered infant formula was also published recently *(22)*. 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 as follows:

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 = 25 g), 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) in which the organism is recognized as a significant hazard. Strategies considered effective for controlling *Salmonella* in confectionery products *(80)* include an understanding of 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 the following seven principles *(63)*:

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 *Salmonella* 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 *Salmonella* contamination in low-moisture products.

SCOPE OF THE GUIDANCE

This guidance describes practices for the control of *Salmonella* when manufacturing low-moisture foods with 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 contamination occurs after the inactivation step. *Salmonella* outbreaks associated with low-moisture products may occur because of the inclusion of contaminated raw ingredients, insufficient processing, or post-processing contamination *(8)*.

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 three publications, of which this is the first. Manufacturers of low-moisture products may consider modifying their programs where necessary, based upon this guidance. 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 *(18)* and the Codex general principles of food hygiene *(7)*, as are HACCP principles and application guidelines *(7, 52, 63, 69)*. 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.

This paper highlights Elements 1 and 5, both of which address measures to minimize the entry of *Salmonella* into a processing facility. Other elements are covered in subsequent papers *(19, 20)*.

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) *(45, 62, 83)*. 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* ranged from 0.14% to 1.32% in wheat flour *(73)*, from 1.5% to 8.2% in untreated spice samples *(65)*, and was 1.5% in production samples and 1.1% in retail samples of dried spices and herbs in the UK *(68)*. 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 *Salmonella* into, and spread it in, a manufacturing facility), improper air flow (e.g., air flow from non-ready-to-eat area to ready-to-eat area), 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 *(42, 72)*. 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

TABLE 3. Example check list related to potential *Salmonella* ingress and spread in a facility

Subject/Questions	Comments
PHYSICAL FACILITY & PLANT DESIGN	
1. Ceiling (drop ceilings) and 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?	
• See page 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 contact surfaces (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.)?	

finished product or relationship to the terminal *Salmonella* inactivation step.

Common Industry Practices

- ❏ Conduct a hazard analysis to determine potential sources of *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 *(7)*.
  - – Inspect intake vents to ensure that they are of sanitary design, cleanable, and 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 and 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 that 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 3.
  - 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 that the problems have been corrected by conducting enhanced environmental monitoring for the affected area according to procedures outlined in Element 7 *(20)*.
  - 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, as 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) or post-lethality area vs. raw or pre-lethality area. See Element 2 for more discussion *(19)*.
  - Outline traffic patterns properly and ensure employee compliance through education and training.
  - Inspect pallets and trailers regularly, keep them in good repair, and do not store them 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 *(51)* and is not a source of *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 *(19)*.
- ❏ 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. Because *Salmonella* can 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 *(8)*.
  - 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 4. 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 5: ESTABLISH A RAW MATERIALS/INGREDIENTS CONTROL PROGRAM

Low-moisture products may be manufactured in such 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 also 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 *(13)* 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 *(58, 82)*. The manufacturer sourced ingredients from both domestic and international suppliers. An outbreak associated with potato chips in Germany *(57)* 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 *(17, 34)*, 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 *(17, 34)*. 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 in the *Salmonella* Typhimurium outbreak found a number of deficiencies *(35)*, including deficiencies in process control, e.g., lack of validation of the roasting step, and in GMPs, e.g., deficiencies in facility integrity and maintenance, plant construction and design, protection of equipment/containers/product against contamination, separation of raw and finished products, pest control, and 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 *(35)*. FDA inspectors found that, in approximately a dozen instances, the plant released a product that had initially tested positive for *Salmonella* after retesting yielded negative results. Environmental samples collected by FDA inspectors at the facility tested positive for *Salmonella* Senftenberg and Mbandaka *(35)*. 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 *(30, 32)*. 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 4 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 because appropriate process controls have been implemented. 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 *(44)* 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
  - – Grant supplier approval that is specific to an individual facility or processing line.
  - – Conduct supplier requalification 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 its food safety program and its compliance to the program.
  - – Provide the supplier with ingredient specifications and ensure that 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 *(3, 4, 48)* 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 the lethality step. This is particularly important for situations involving new or unknown suppliers or where confidence in the supplier's *Salmonella* control program is lacking. 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.
  - – Use the FDA BAM or an ICMSF sampling plan (e.g., cases 10–15), 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 (*49, 66*; 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 <u>only</u> after acceptable test results are received.

SUMMARY AND CONCLUSIONS

Although *Salmonella* outbreaks from low-moisture products are relatively rare, they often impact large numbers of people. Human illnesses have been attributed to the handling of contaminated dry pet foods, as well as the consumption of a wide variety of contaminated low-moisture products. Control of *Salmonella* in low-moisture foods presents numerous challenges to manufacturers. The heat resistance of the organism can be much greater at reduced a_w than in high-moisture foods, *Salmonella* can persist for extended periods of time in dry environments, prevention of recontamination requires stringent adherence to GMPs, and the presence of water in the environment can lead to growth niches that can be a source of contamination. To address the need for industry-wide guidance, the GMA *Salmonella* Control Task Force has developed guidance through a review and synthesis of industry programs and information from the literature. This paper described the *Salmonella* problem, the need for and the scope of the guidance and common industry practices to minimize the potential for *Salmonella* to enter the facility, including through stringent adherence to GMPs and control of raw materials/incoming ingredients. The two papers to follow outline additional practices that industry should follow to prevent product contamination.

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