Challenges in the Control of Foodborne Pathogens in Low-Water Activity Foods and Spices

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Abstract Vegetative cells of some foodborne pathogens, as well as bacterial spores, are capable of surviving within dry processing environments and low-water activity foods for lengthy periods of time. Between 2007 and 2012, there were 7,315 cases of bacterial infection and 63 deaths due to contaminated low-water activity foods worldwide. *Salmonella* is the pathogen of greatest concern, responsible for 94 % of US low-water activity food recalls and 53 % of outbreaks worldwide from 2007 to 2012. This chapter provides an overview of the challenges of controlling foodborne microorganisms in low-water activity foods, including a description of practices for preventing pre- and post-process contamination. Potential sources of bacterial contamination in the food supply chain include incoming raw materials, the external environment (e.g., pests, water, and air), inadequate hygienic facility and equipment design, inadequate sanitation practices, and lack of process control. Primary control points include the sourcing of raw commodities and ingredients, controlling cross-contamination from harvest to post-process, controlling the entry of water into dry processing areas, employing effective dry cleaning and sanitation processes, and implementing validated lethal processes.

Keywords Low-water activity foods • Spices • Dry food processing

Introduction

Low-water activity foods are those with a water activity (a_w) level less than 0.70 (Blessington et al. 2013), and they do not support the growth of either vegetative or spore-forming bacteria. However, in the United States, 5,141 low-water activity food products were recalled from 2007 to 2012 because of bacterial pathogen

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contamination (FDA 2012). In 2009, three major recalls in the USA, involving pistachio nuts (662 products), dry milk (286 products), and peanut butter (3,918 products), were examples of serious health and economic burdens due to pathogen contamination of low-water activity foods. In 2012, peanut butter contaminated with *Salmonella* Bredeney resulted in 42 cases of infection and a large number of recalled products (CDC 2012a; FDA 2012). From 2007 to 2012, a total of 41 outbreaks (worldwide reports) involving low-water activity foods resulted in 7,315 cases leading to 536 hospitalizations and 63 deaths (CDC 2012a; EFSA 2009, 2010, 2011; Harris et al. 2012; Rodriguez-Urrego et al. 2008; SFI 2012).

The presence, survival, and heat resistance of bacterial pathogens in low-water activity foods provide a continuing challenge to the food industry (Podolak et al. 2010). Low-water activity foods include products which may or may not be subjected to a pathogen inactivation step. These foods may also contain ingredients that are added after the inactivation step (Scott et al. 2009). Reduction of risk for human illness can be achieved by controlling points of potential contamination in the field, during harvesting, processing, and distribution, as well as in retail markets, foodservice facilities, or the home. The effective application of such controls requires a coordinated effort between production, processing, and distribution. This chapter presents an overview of the challenges in controlling bacterial foodborne pathogens in low-water activity foods, with particular emphasis on available practices to prevent pre- and post-process contamination. Mycotoxigenic molds and their toxins will not be addressed.

Pathogens of Concern in Low-Water Activity Foods and Spices

Vegetative cells and endospores of many foodborne pathogens can survive in dry processing environments and low-water activity foods for lengthy periods of time (Beuchat et al. 2013). Disease outbreaks reported by various countries that were associated with low-water activity foods from 2007 to 2012 are presented in Table 1. Recalls of low-water activity foods in the USA from 2007 to 2012 are listed in Tables 2 and 3. Table 2 includes recalls of food products at the preprocessing stage (pre- and postharvest). Table 3 lists recalls of processed foods, some of which may not have undergone a lethal processing step. Bacterial pathogens which have been associated with outbreaks and/or recalls involving low-water activity foods during 2007 to 2012 include *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens*, enterohemorrhagic *Escherichia coli*, *Listeria monocytogenes*, *Salmonella enterica*, and *Staphylococcus aureus* (Tables 1, 2, and 3). *Cronobacter* spp. (formerly, *Enterobacter sakazakii*) has rarely been the cause of reported outbreaks (Beuchat et al. 2013). However, *Cronobacter* may be present and survive for long periods of time in powdered infant formula; hence, it is a pathogen of concern in these foods.

Table 1 Foodborne disease outbreaks associated with low-water activity foods between 2007 and 2012, worldwide

Stage[a]	Year	Microorganism	Product	Cases	Location	Reference
NA[b]	2008	*Salmonella* spp.	Rice, seeds, nuts, and almonds	2	EU	(EFSA 2010)
	2007	*B. cereus*	Rice, seeds, nuts, and almonds	62		(EFSA 2009)
	2007	*E. coli* STEC		45		
		Salmonella spp.		34		
		S. aureus		26		
		Staphylococcus spp.		120		
		B. cereus	Herbs and spices	149		
		C. perfringens		19		
		Salmonella spp.		3		
Preprocessing (pre- and postharvest)	2011	*E. coli* O104:H4	Fenugreek seeds	4321	Germany	(EFSA 2011)
	2009	*E. coli* O157:H7	Raw cookie dough	77	USA (30 states)	(CDC 2012a)
	2007	*S.* Weltevreden	Alfalfa seeds	25	EU (Scandinavia)	(SFI 2012)
No lethality	2011	*E. coli* O157:H7	Raw shelled walnuts	11	Canada	(CDC 2012a)
		E. coli O157:H7	In-shell hazelnuts	8	USA (3 states)	
	2008	*S.* Rissen	White ground pepper	87	USA (Multistate)	
Ingredient in processed food	2011	*S.* Enteritidis	Turkish pine nuts	43	USA (5 states)	(CDC 2012a)
	2010	*S.* Montevideo	Black pepper in salami	272	USA (44 states)	
Processed food	2012	*S.* Bredeney	Peanut butter	42	USA (20 states)	(CDC 2012a)
		S. Infantis	Dry dog food	49	USA (20 states)	
		S. Oranienburg	Dry milk	16	Russia	(SFI 2012)
	2010	*B. cereus*	Rice	103	USA (Florida)	(CDC 2012a)
				6	USA (Pennsylvania)	
				22	USA (Tennessee)	
		C. botulinum	Dried tofu	NA	Taiwan	(SFI 2012)

(continued)

Table 1 (continued)

Stage[a]	Year	Microorganism	Product	Cases	Location	Reference
	2009	*B. cereus*	Rice	13	USA (Alabama)	(CDC 2012a)
				15	USA (Washington)	
		S. Montevideo	Pistachios roasted	NA	USA	
		S. Enteritidis	Fried rice	11	USA (Virginia)	
	2008	*B. cereus*	Rice	10	USA (Georgia)	(CDC 2012a)
		C. perfringens	Spanish rice	2	USA (Colorado)	
		S. Kedougou	Infant formula	42	Spain	(Rodriguez-Urrego et al. 2008)
		S. Agona	Rice cereals	28	USA (15 states)	(CDC 2012a)
		S. Enteritidis	Rice	82	USA (Washington)	
		Salmonella spp.	Sweets and chocolate	4	EU	(EFSA 2010)
		Salmonella spp.	Infant formula	8	France	(SFI 2012)
		S. Typhimurium	Peanut butter	714	USA (46 states)	(CDC 2012a)
		C. botulinum	Peanut butter	5	Canada	(Harris et al. 2012)
	2007	*B. cereus*	Fried rice	8	USA (Washington)	(CDC 2012a)
		S. Schwarzengrund	Dry pet food	62	USA (18 states)	
		Salmonella spp.	Sweets and chocolate	242	EU	(EFSA 2009)
		Salmonella spp.	Imperial rice	27	USA (Florida)	(CDC 2012a)
		S. Tennessee	Peanut butter	425	USA (44 states)	
		S. Wandsworth	Rice and corn snack	75	USA (20 states)	

[a]Stage of the food chain where contamination took place
[b]Information was not specified regarding the source

Table 2 Recalls associated with low-water activity foods not receiving a lethality treatment or at a preprocessing (pre- and postharvest) stage in the USA between 2007 and 2012 (FDA 2012)

Stage[a]	Year	Microorganism	Product implicated
Preprocessing	2010	*Salmonella* spp.	Black pepper
			Garlic powder
	2009		Hazelnut
No lethality treatment	2012	*E. coli* O157:H7	Organic cacao nibs
	2011	*E. coli* O157:H7	Hazelnut and mixed nut products
		Salmonella spp.	Bulk Turkish pine nuts
			Organic celery seed
			Pine nuts
			Peppermint organic tea
			Soybean flour and soy meal
	2010	*Salmonella* spp.	Black pepper
			Black peppercorns
			Nutmeg
			Nuts
			Seasonings
			Sesame seeds
			Shelled walnuts
			Spice packages
			Pistachio kernel products
			Seasoning salt
			Gravy mix
			Onion dip mix
			Seasoning mixes
			Dip mix
			Soup mix
			Sauce mix
			Soy grits and flour
	2009	*Salmonella* spp.	Hazelnut
			Hazelnut kernels
			Raw shelled hazelnut kernels
			Red pepper
			Shelled hazelnuts and shelled organic hazelnuts
			White and black pepper
			Curry spice
	2007	*Salmonella* spp.	Parsley powder dehydrated bulk
			Four-cheese risotto mix
Preprocessing/no lethality treatment[b]	2010	*Salmonella* spp.	Spices, spice blends, rub, seasoning
			Walnuts
			Whole raw pistachios and kernels
	2009		Shelled hazelnuts
			Raw hazelnut kernels

[a]Stage of the food chain where contamination occurred
[b]Recall included products which received no lethality treatment and products that were contaminated at preprocessing (pre- and postharvest)

Table 3 Recalls associated with processed low-water activity foods in the USA between 2007 and 2012 (FDA 2012)

Microorganism	Year	Product implicated
C. botulinum	2008	Chai concentrate
L. monocytogenes	2012	Popcorn with select flavors
	2010	Peanut butter, dips, spreads, cheese, salsa
	2007	Italian sausage hoagie
Salmonella spp.	2012	Crush roasted Thai red pepper
		Crackers
		Prebiotic powder formula
		Dog food
		Flake fish food
	2011	Dry cat food
		Natural peanut butter chunky
		Peanut butter
		Powdered protein products
		Snack products with chili
	2010	Cat food
		Corn chips
		Pet food
		Egg noodle
		Pancake, cake, and cookie mix
		Potato chips
		Potato crisps
		Pretzels
		Spreads
		Batter mix
		Cheese ball mix
		Mixes containing pretzels
		Snack mix
		Snack mix and cashews
		Barbecue potato chips
	2009	Dry roasted hazelnut kernels
		Chocolate-covered peanuts
		Instant oatmeal variety pack
		Maple and brown sugar instant oatmeal
		Variety pack instant oatmeal
		Dry roasted hazelnut kernels
		Instant nonfat dried milk, whey protein (286 products)
		Peanut butter and paste (3,918 products)
	2008	Pancake and waffle mix
		Pet food
		Puffed rice wheat cereals
		Dry pet food
	2007	Peanut butter
		Roasted sesame tahini
		Topping, chocolate and peanut butter flavor
		Corn sticks
		Sweet dairy whey powder
		White chocolate baking squares

Bacillus cereus is widespread in nature (Granum 2007) and has been involved in four outbreaks between 2007 and 2012 that were associated with consumption of cooked rice served in restaurants, banquets, prison, or the home (Table 1). *B. cereus* was also responsible for two outbreaks in the EU involving cereals, as well as herbs and spices (Table 1). The presence of *B. cereus* has not been the cause of low-water activity product recalls between the years 2007 and 2012 in the USA (Tables 2 and 3). *B. cereus* is frequently found in raw materials such as vegetables, starch, and spices, due to its presence in soil and on growing plants, in food ingredients such as flours, and in dry foods such as milk powders and cereals. However, *B. cereus* must grow in a food to large numbers (>10^5 CFU/g) to cause an outbreak. Spores of *B. cereus* can survive in dry foods and dry processing environments for long periods of time. These spores can then germinate and grow in reconstituted products that are not properly processed and/or stored (Beuchat et al. 2013). The temperature and moisture conditions in which processed food is stored are critical factors to preventing spore germination and outgrowth.

Similarly, *C. botulinum* spores are commonly present in soil and the intestinal tract of animals (Johnson 2007). Botulism can result from the ingestion of botulinum neurotoxin preformed in foods. *C. botulinum* spores can also grow and produce the toxin in the gastrointestinal (GI) tract under certain conditions. Outbreaks of botulinum intoxication in the last five years were associated with the consumption of peanut butter (Canada, 2008) and dried tofu (Taiwan, 2010) (Table 1). In 2003, the presence of *C. botulinum* spores in honey resulted in a severe case of infant botulism in the USA (Barash et al. 2005). Isolates from the honey reflected those found in local soil (Beuchat et al. 2013).

Like *C. botulinum*, *C. perfringens* is also present throughout the natural environment, including soil, foods, dust, and the intestinal tract of animals (McClane 2007). Spores of *C. perfringens* survive well in dust and on surfaces and are resistant to routine cooking temperatures (McClane 2007). *C. perfringens* produces toxins and exhibits rapid growth in many foods (McClane 2007). *C. perfringens* was responsible for an outbreak involving cooked rice in the USA (2008) and one involving herbs and spices in the EU (2007) (Table 1). Spores of *C. perfringens* have also been detected in powdered infant formula (Beuchat et al. 2013), where the bacterium would be of concern if rehydrated formula was subject to temperature abuse for growth of clostridia to occur.

Enteric pathogens, such as enterohemorrhagic *E. coli* and *Salmonella*, can contaminate raw agricultural commodities through vehicles such as raw or improperly composted manure, irrigation water containing untreated sewage, or contaminated wash water (Beuchat and Ryu 1997). Contact with animals and unpasteurized products of animal origin are additional routes of contamination (Beuchat and Ryu 1997). Contact surfaces, including human hands, are potential points of contamination (Beuchat and Ryu 1997). *Cronobacter* species such as *C. sakazakii* are also members of the *Enterobacteriaceae* family and have been isolated from dry milk. However, the natural habitat of this pathogen remains unknown (Pagotto et al. 2007). Growth of enteric pathogens in food is not necessary for them to cause illness.

Shiga toxin-producing *E. coli* has been associated with several foodborne illness outbreaks involving low-water activity foods (Table 1). A major outbreak occurred in Germany in 2011, due to fenugreek sprouts from *E. coli* O104:H4-contaminated seeds imported from Egypt. Also, in 2011, raw shelled walnuts and hazelnuts (which do not undergo a lethal processing treatment) were the vehicle of two *E. coli* O157:H7 outbreaks in North America. *E. coli* O157:H7-contaminated raw cookie dough, not intended to be consumed raw, caused a major outbreak in the USA in 2009. The specific ingredient in the cookie dough that was contaminated was not definitively identified (Beuchat et al. 2013); however, wheat flour (a low-a_w ingredient) was suspected, influencing the manufacturer to now use heat-treated flour in its cookie dough product. Enterohemorrhagic *E. coli* is widely present in and able to colonize farm environments, but it does not survive well in low-water activity environments (Beuchat et al. 2013). This is likely why its involvement in outbreaks and recalls of low-water activity foods is more limited than that of *Salmonella*.

Salmonella is responsible for the vast majority of foodborne illness outbreaks (Table 1) and US recalls (Tables 2 and 3) associated with low-water activity foods in the past 6 years (2007–2012). *Salmonella* is widespread in nature and survives in dry foods for weeks, months, or even years (Chang et al. 2013; Beuchat and Mann 2010a; Komitopoulou and Peñaloza 2009; Beuchat and Scouten 2002; Burnett et al. 2000; Archer et al. 1998). Food composition, water activity, and temperature collectively influence its survival in foods (He et al. 2011; Mattick et al. 2001; Corry 1974; Dega et al. 1972; Moats et al. 1971). The pathogen exhibits increasing resistance at decreasing water activity during heat treatment (Beuchat and Scouten 2002; Doyle and Mazzotta 2000; Archer et al. 1998). The presence of fat in the food offers additional protection against inactivation by heat (Ma et al. 2009; Shachar and Yaron 2006; van Asselt and Zwietering 2006; Juneja and Eblen 2000). In an extensive review, conducted by Podolak et al. (2010) on the sources and risk factors of *Salmonella* in low-water activity foods, its presence was linked to cross-contamination through poor sanitation practices, substandard facility and equipment design, improper maintenance, poor operational and manufacturing practices (GMPs), as well as inadequate ingredient control and pest control. Carrasco et al. (2012) provided an in-depth review of the role that cross-contamination plays in the contamination of low-water activity foods with *Salmonella*.

Similar to *Salmonella*, *Cronobacter* species including *C. sakazakii* is able to survive in low-water activity foods for long periods of time (Caubilla Barron and Forsythe 2007; Gurtler and Beuchat 2007; Lin and Beuchat 2007). Neither *Salmonella* nor *Cronobacter* will survive typical pasteurization treatments in foods having high water activity. Hence, as with *Salmonella*, contamination of processed, low-water activity foods with *Cronobacter* usually occurs as a result of poor process control or by post-process contamination (Breeuwer et al. 2003).

Although not involved in as many low-water activity food outbreaks and recalls as *Salmonella*, *Staphylococcus aureus* is also well adapted to survival in low-water activity environments. Humans and animals are the main reservoirs of this toxin producer, which is able to survive for months after contaminating a dry food (Beuchat et al. 2013; Scott 1958). Contamination of food can occur by direct human contact, indirectly by skin fragments, or through respiratory tract droplet nuclei (Seok Seo and Bohach 2007). Sanitation and hygienic manufacturing practices and appropriately designed facilities and equipment play a crucial role in preventing food contamination.

L. monocytogenes has not been involved in low-water activity food-associated outbreaks reported between 2007 and 2012 but has been the causative agent of several US product recalls of these foods (Table 3). *L. monocytogenes* is a well-documented contaminant of soil, water, and avian and mammalian feces (Swaminathan et al. 2007) and, because of its widespread distribution, can contaminate foods by many routes.

Origin of Pathogen Contamination in Low-Water Activity Foods

The origin of pathogen contamination in low-water activity foods depends on the history and use of the food. A number of raw materials and ingredients of primary agricultural origin are consumed without processing or are included as an added ingredient in a previously processed food (e.g., nuts, herbs, and spices). Other low-water activity raw agricultural products are used in the manufacture of processed low-water activity foods (e.g., peanuts in peanut butter), and others are intended to be cooked or heat processed before consumption (e.g., wheat flour, oats). A discussion of potential sources of contamination in the supply chain during preharvest, postharvest, processing, and post-processing follows.

Pre- and Postharvest Contamination (Preprocessing)

The likelihood of bacterial pathogens being present in a raw food at the preprocessing stage (pre- and postharvest) of the food chain is associated with the pathogens being present in the production environment. The type and population of microorganisms on nuts, seeds, cereal grains, herbs, and spices are mainly determined by the soil and plant microflora. Nuts come in contact with the soil during harvest (e.g., hazelnuts, almonds, pecans, walnuts) or growth (e.g., peanuts). Seeds (e.g., cacao beans), herbs, and spices (ICMSF 2005) may also be in contact with the soil during harvest and/or growth. A variety of bacteria can grow on cereal crops (e.g., bacilli, enteric bacteria), and cereal grains are subject to microbiological contamination while growing in the field (Gilbert et al. 2010). For example, a *Salmonella* Agona outbreak in 2002 involving herbal tea in Germany was traced back to contaminated aniseeds imported from Turkey. The source of contamination was attributed to the use of manure as a natural fertilizer (Koch et al. 2005). In 2011, in Germany, an *E. coli* O104:H4 outbreak involving 4,321 cases (Table 1) was traced back to contaminated seeds imported from Egypt. The imported fenugreek seeds were processed by a single German producer into sprouts (EFSA 2011). The European Food Safety Authority (EFSA) found no evidence of environmental contamination at the sprout producer or signs of employee cross-contamination. Hence, the contamination was attributed to the importer, and the source of the contamination speculated to be the use of natural fertilizer or contaminated irrigation water during seed production (EFSA 2011).

Although soils are partially removed from nuts, plants, cereals, and seeds during harvest, significant amounts can still remain and thus be brought into storage and processing facilities (Danyluk et al. 2007). Kokal and Thorpe (1969) observed *E. coli* contamination on almonds obtained from both the trees and from the ground where they were left to dry. In another study by Marcus and Amling (1973), the proportion of pecan samples contaminated with *E. coli* collected from cattle-grazed orchards was sixfold higher than that of samples from non-cattle-grazed orchards. Sources of soil contamination in the field include bacteria in the farm environment, animal waste, contaminated manure/compost, biological solids from human waste water, and contaminated irrigation water (Jacobsen and Bech 2012; Critzer and Doyle 2010; Beuchat and Mann 2010b; Isaacs et al. 2005).

Water is, in general, a major source of microbial contamination in food commodities that are eventually marketed as low-water activity foods. Possible preharvest sources are runoff from nearby animal pastures and irrigation from a contaminated source (FDA 1998). The type of irrigation is also a contributing factor. There is a lower likelihood of transmitting pathogens from contaminated water through drip irrigation than an overhead sprinkler system (Berger et al. 2010; FDA 1998). The use of water in postharvest processing is also a risk factor. The addition of water to dust or dried raw materials can result in rapid outgrowth of the bacteria present (Danyluk et al. 2007). Control of water in storage and processing environments is one of the most critical factors in reducing the risk of pathogen contamination of dry foods. Water can also present suitable conditions for production of heat-stable microbial toxins by, for example, *B. cereus* (Beuchat et al. 2013).

Dust also increases the risk of cross-contamination by accumulating microorganisms that can be spread by airflow (Podolak et al. 2010; Doan and Davidson 2000). For example, when hulls and shells of almonds and macadamia nuts are mechanically removed from the kernel under dry conditions, large volumes of fine particulate matter are generated. This dust, comprised of soil, hulls, and shells, is difficult to eliminate from the processing environment and can contribute significantly to cross-contamination of the kernels (Danyluk et al. 2007). The first US reported outbreak of salmonellosis traced to chocolate occurred in 1973, where 119 cases of infection with *S.* Eastbourne were linked to contaminated raw cocoa beans (Craven et al. 1975). *Salmonella* was also detected in accumulated dust at the bean-processing areas (Craven et al. 1975). Pathogen-contaminated dust is often associated with product contamination, and the unexpected addition of water to this dust creates exceptionally high-risk conditions due to the logarithmic increase in pathogen numbers that may occur.

In addition to natural microflora, soil, water, and dust, birds, rodents, and insects all influence the risk of pathogen contamination of nuts, seeds, herbs, cereals, and spices (Danyluk et al. 2007; Doan and Davidson 2000). Worker hygiene and sanitation can also be important (FDA 1998; Podolak et al. 2010).

Sources of microbial contamination on raw potatoes and on low-water activity products derived from them include their natural microflora, soil, dust, water, and contaminants from human handling and animals (Doan and Davidson 2000). Contamination of raw milk and dairy products also results from direct contact with contaminated sources in the farm environment (e.g., soil, water, and equipment) and excretion from the udder of an infected ruminant (Oliver et al. 2005). Potatoes, however, are rarely consumed raw, and milk sold in interstate commerce is required, by law, to undergo a pasteurization process prior to commercial distribution (CFR 21 1240.61 2013). Hence, the presence of pathogenic microorganisms in low-water activity dairy as well as potato products is usually associated with either the lack of process control or post-process contamination.

Processing and Post-process Contamination

Contamination of low-water activity foods with pathogenic bacteria during processing and post-process is mainly due to cross-contamination (Carrasco et al. 2012; Podolak et al. 2010). Processed low-water activity foods receiving a pathogen inactivation treatment were responsible for 54 % of US recalls and 63 % of outbreaks (reported worldwide) between 2007 and 2012 (Tables 1 and 3). Minimally processed foods (which do not receive a lethal step) have been responsible for fewer US recalls (35 %) and outbreaks globally (12 %). Of the pathogens involved, *Salmonella* was responsible for 94 % of all low-water activity food product recalls and 53 % of total outbreaks between 2007 and 2012. Therefore, *Salmonella* is the pathogen of greatest concern in processed and minimally processed low-water activity food.

Various sources and manufacturing practices contribute to cross-contamination in the processing facility. Raw materials (Scott et al. 2009) are a major source of pathogens. Lack of effective prerequisite programs at the supplier can result in pathogens being introduced into the facility through raw materials. In some cases, the presence of pathogens in raw materials cannot be prevented by currently acceptable growing, harvesting, and preprocessing practices. In addition to directly contaminating the end product, pathogen-containing raw materials can contaminate equipment, employees, and other product lines. Raw materials which are not further processed can also contaminate finished products if they are as an ingredient subsequent to the final lethality treatment in a process. For example, in 2007, an outbreak in the USA involving *S.* Wandsworth, *S.* Typhimurium, *S.* Mbandaka, and *S.* Haifa resulted in 75 cases of infection associated with consumption of a contaminated corn and puffed rice snack (Table 1). The seasoning mix, which was used as an added ingredient after a lethal process was applied to the heat-treated cereals, was the source of the contamination. The seasonings were obtained from domestic as well as international suppliers (Sotir et al. 2009). A 2010 outbreak of 272 *S.* Montevideo infections in the USA was associated with consumption of contaminated salami (Table 1). The source of contamination was red and black pepper applied to the surface of salamis after the lethal process. The pepper was produced in Asia, distributed by a US spice company, and finally delivered to the salami processing facility (CDC 2012b). *S.* Montevideo was isolated from samples of the crushed red and black pepper. These results underline the risk of cross-contamination from raw materials, highlighting the need for strict supplier control when raw materials are used as an added ingredient to processed food.

A second major source of pathogen cross-contamination in dry foods is the environment, which includes personnel, equipment, pests, dust, water, and air (Beuchat et al. 2013). Employees carrying pathogens via shoes or clothing worn outside the plant can lead to cross-contamination if the plant and its personnel are not adhering to good manufacturing practices (GMPs) as described in 21 CFR110 (Podolak et al. 2010; Scott et al. 2009). Pests (e.g., birds, insects, rodents) may also carry pathogens through openings in buildings that require repair (including the roofs, floors, and doors). For example, birds' nests can shed pathogens into the facility through a roof leak, unfiltered air intakes, etc. (Scott et al. 2009). Contaminated equipment entering the facility can also introduce pathogens (Scott et al. 2009). Ventilation units connected to outside air without proper filtration, as well as unsanitary vents, are an additional source of contamination from the external environment (Scott et al. 2009). A 2008–2009 salmonellosis illness outbreak associated with processed peanuts (Tables 1 and 3) resulted in one of the largest food product recalls in US history (Wittenberger and Dohlman 2010). A joint FDA and Georgia Department of Agriculture investigation of the production facility revealed multiple possibilities for sources of *Salmonella* contamination, including evidence of rain and other water leakage into areas used to store roasted peanuts, as well as practices that allowed for cross-contamination between raw and roasted peanuts (Cavallaro et al. 2011). The FDA investigation of the 2012 peanut butter outbreak (*S.* Bredeney) found raw in-shell peanuts outside the plant in uncovered trailers and exposed to rain (FDA 2013a). Birds were also observed landing on these trailers (FDA 2013a). Inside the warehouse, facility doors were open to the outside, allowing pests to enter the premises (FDA 2013a). The combination of pathogens in the processing environment and lack of water control has often led to product contamination because of the high populations of pathogens that can result if growth occurs.

A third major source of cross-contamination is the lack of proper facility and equipment design, including deficiencies in GMPs (Beuchat et al. 2013; Carrasco et al. 2012; Podolak et al. 2010). An inspection of the US dry dog food production facility associated with a 2012 outbreak of *S.* Infantis infection revealed that the processing facility did not have hygienic equipment and facility design (CDC 2012c). There were no hand washing and sanitizing facilities where needed. Equipment had gouges and cuts, with attempted repairs using duct tape and cardboard (CDC 2012c). Equipment had accumulated food residue and dust in areas with poor access to cleaning (CDC 2012c). Similarly, the investigation of the peanut butter processing facility associated with a 2012 outbreak of salmonellosis revealed that there were no hand-washing sinks in the peanut production or packaging areas (FDA 2013a). There were also no documented cleaning records (FDA 2013a). There was a leaking sink in a washroom, which resulted in water accumulation on the floor (FDA 2013a). In addition, employees had bare-hand contact with ready-to-package peanuts and were found to improperly handle equipment and tools (FDA 2013a).

Separate hygiene zones are generally established by compartmentalization of a food processing facility. Zones should be established based on an evaluation of risk (Beuchat et al. 2013; Chen et al. 2009a). The lack of proper control measures in each zone, including the transition areas, could result in cross-contamination from the low-hygiene to high-hygiene zones (Chen et al. 2009a). This includes a lack of adequate physical separation, control of traffic and airflow, employee attire, as well as cleaning and the use of water (Beuchat et al. 2013; Chen et al. 2009a). Indeed, the use of water in the processing of low-water activity foods is one of the major risk factors for pathogen contamination (Beuchat et al. 2013; Chen et al. 2009a). Different areas of a processing facility have different water requirements. Hence, much of the microbiological control in a dry processing facility is focused on keeping areas dry to avoid resuscitation and growth of dormant microorganisms (Beuchat et al. 2013; Chen et al. 2009a). One of the most difficult challenges is to design and operate a processing facility that can be properly cleaned and sanitized, while maintaining separation of dry and wet areas of the facility. Lack of proper hygiene practices and controls can ultimately lead to pathogens finding a growth niche in the facility (Chen et al. 2009a). Bacteria attached to surfaces in the presence of water are less sensitive to disinfection, especially when present in a biofilm (Aviles et al. 2013; Møretrø et al. 2012). Hence, an environment that may appear marginally dustier after dry cleaning may be much lower risk than a wet-cleaned environment without visual dust. This is because wet cleaning introduces moisture into cracks and areas that are difficult to clean and may not fully dry before production start-up (Chen et al. 2009a). This can ultimately lead to the development of large concentrations of microorganisms in hidden growth niches.

Finally, for low-water activity foods that are subjected to a lethal process, a major source of pathogen contamination is a lack of adequate process control (Podolak et al. 2010; Chen et al. 2009b). This may be the result of using unvalidated or inadequately controlled processing operations. Generic lethality processing standards for high-moisture foods should not be used for low-water activity foods, as they may result in inadequate pathogen inactivation (Podolak et al. 2010). For example, in the *Salmonella* outbreak investigation of Georgia processed peanuts in 2008–2009, there was uncertainty as to whether the peanut roaster routinely reached a temperature sufficient to kill *Salmonella* (Cavallaro et al. 2011).

Current Challenges in the Control of Foodborne Pathogens in Low-Water Activity Foods

Controlling foodborne pathogens in low-water activity foods is an ongoing challenge. Raw materials may be produced under conditions in which the entry of pathogens into the food is not or cannot be controlled. Dry foods may be contaminated with pathogens during harvest and storage and through preprocessing environments.

Control of pests, dust, and water is essential for pathogen control in these foods, yet facility and equipment design may be inadequate to control these factors and conventional wet cleaning/sanitation practices may promote pathogen survival and growth by not controlling water. Many low-water activity food products are considered ready to eat and are not cooked before consumption as well as have a long shelf life; hence, the production process must comply with high standards of hygiene. Parameters for inactivation of pathogens in processing dry foods are often not well defined or validated. As such, many products have no history of being subject to validated pathogen-killing processes. The fact that pathogens survive during storage of these foods for long periods of time and that these foods often have a long shelf life substantially increases their risk to public health.

Processing Practices to Reduce Pathogen Contamination in Low-Water Activity Foods

Potential sources of pathogen contamination in low-water activity foods and ingredients are numerous and varied; hence, multiple processing practices specific for the product are usually necessary for reducing the risk of contamination. The Grocery Manufacturers Association (GMA) has developed guidelines to control *Salmonella* in processing facilities and enhance the microbial safety of low-water activity foods (GMA 2009). An industry handbook for safe processing of nuts was also developed (GMA 2010a) as well as equipment (GMA 2010b) and facility (GMA 2010c) design checklists to self-evaluate compliance with GMA sanitary design principles. Additionally, in light of the burden of foodborne illnesses in the USA, the FDA has issued the Food Safety Modernization Act (FSMA) rule, which was signed into law in January 2011. This law shifts the focus of regulators from responding to an event to preventing one from occurring, using a risk-based approach (FDA 2013b). Guidance for industry and rules related to the FDA FSMA include produce food safety standards, preventive controls for human food, a foreign supplier verification program, preventive controls for animal food, and accredited third-party certification (FDA 2013b). Guidance documents advise food processors to assess the risk that ingredients may contain pathogens. For this, a series of questions involving the nature of the product, the type of treatment used on the product, the use of the product, whether the process to kill pathogens was validated, and the cooking instructions for consumers must be addressed (Beuchat et al. 2013). Good agricultural, manufacturing, and hygienic practices need to be employed at every step in the processing/manufacturing chain. In the processing facility, segregated hygiene areas must be established based on the need for moisture control and exposure of product to the environment, and an environmental monitoring program must be established for the pathogen of greatest risk. Hygienic principles of equipment design and installation need to address the need for water control and dry and wet cleaning. An overview of available practices during preharvest, postharvest, processing, and post-processing follows.

Practices to Reduce Contamination at Pre- and Postharvest (Preprocessing)

Preharvest and harvest control of pathogen contamination is critical for low-water activity foods that do not undergo a lethal processing treatment. To mitigate the risk of pathogens in the soil, growers should adopt measures to ensure that animal waste from adjacent fields or waste storage facilities does not contaminate production sites (FDA 1998; Simonne and Treadwell 2008; Gilbert et al. 2010). This includes providing barriers to secure manure storage and treatment areas and implementing good agricultural practices to minimize leachate (FDA 1998; Simonne and Treadwell 2008). Wildlife, farm, and other domestic animals should be excluded from the fields (FDA 1998; Simonne and Treadwell 2008). Additionally, the sources, distribution, and quality of water should be identified, and the risk of pathogen contamination from such sources should be assessed (FDA 1998). Wells should be maintained in proper working condition, water should be tested for microbiological quality periodically, and good agricultural practices (GAPs) should be followed (FDA 1998; Gilbert et al. 2010). GAPs with regard to fertilization and irrigation should be in place (Simonne and Treadwell 2008; Gilbert et al. 2010). Best practices for each product should be individually assessed, and training programs in worker health and hygiene must be established (FDA 1998; Simonne and Treadwell 2008). Toilet facilities should be accessible, properly located, and clean (with hand-washing stations and proper sewage disposal) (FDA 1998; Simonne and Treadwell 2008). Storage facilities should be cleaned prior to use (FDA 1998; Gilbert et al. 2010). Harvesting and packaging equipment should be appropriately designed and used and kept clean (FDA 1998; Gilbert et al. 2010). As much dirt and mud as possible should be removed from the product before it leaves the field (FDA 1998). Ensuring the raw agricultural product is quickly and thoroughly dried is crucial (Beuchat et al. 2011).

Reducing Contamination During Processing and Post-process (Including Minimally Processed Low-Water Activity Food)

The first step in reducing contamination during processing is to control the quality of incoming raw materials and ingredients. Knowledge about ingredient suppliers and verifying the effectiveness of their control programs is important. For this, a supplier approval program should be in place (Scott et al. 2009). The supplier control program is of particular importance for raw or processed ingredients, which are added to the final product after the latter has gone through an inactivation step (e.g., spices and nuts). Following a sampling and testing plan such as that established by The International Commission on Microbiological Specifications for Foods (ICMSF) case 15 ($n=60$, $c=0$, $m=0$) wherein each of the 60 samples is 25 g is useful, realizing that sampling and testing alone does not ensure the absence of pathogens (Scott et al. 2009).

Ensuring that there is no post-process recontamination of the product is the next step to mitigating pathogen contamination (Beuchat et al. 2011). For this, compartmentalization of the facility into processing lines, wet and dry zones, and hygiene zones should be established by physical means (Beuchat et al. 2013). Wet processing lines should be constructed according to the same criteria as ultrahigh temperature (UHT) processing lines, with cleaning being conducted in a separate room from the main line (Beuchat et al. 2011). Within the dry zones, different hygiene zones must be established, where appropriate and traffic within different hygiene zones must be controlled (Beuchat et al. 2011). Dry zones should be kept dry and cleaned using a dry cleaning/sanitation process (Beuchat et al. 2011; Gilbert et al. 2010). Monitoring programs targeting the external environment, employee sanitation, operational and manufacturing practices, and presence of pests must also be established, as well as hygienic design of buildings and equipment (Chen et al. 2009a; Gilbert et al. 2010).

Another important aspect of pathogen control efforts is process control and validation (Beuchat et al. 2011; Chen et al. 2009b). Food processors should determine the process parameters that provide an appropriate level of protection (ALOP) for each product. Validation of the selected process parameters is critical (Beuchat et al. 2013; Chen et al. 2009b).

Finally, verification that the validated control measures are properly functioning, that standard operating procedures as well as hygienic practices are in place (verified by environmental monitoring), and that overall the final product adheres to predefined safety criteria (including finished product microbiological testing) assures the effectiveness of the food safety management system that is in place and drives continuous improvement (Chen et al. 2009b).

Conclusions

Major challenges for pathogen control in low-water activity foods include sourcing of low-risk raw commodities and ingredients, controlling cross-contamination from harvest to post-process, and implementing and monitoring validated lethal processes. The ability of pathogens to survive for long periods of time in dry foods, ingredients, and processing environments greatly increases the challenge of controlling pathogens in low-water activity foods. Food processors should assess the risk of pathogen contamination of the product and ingredients. Effective controls for incoming raw materials and ingredients should be in place as well as monitoring programs addressing the external environment, employee sanitation, operational and manufacturing practices, and presence of pests, as well as appropriate hygienic design of building and equipment. Process control, which includes validation and verification of control measures, is essential to increase the effectiveness of food safety management systems and effectively reduce risks to public health.

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