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Research Paper

Prevalence of *Cronobacter* spp. and *Salmonella* in Milk Powder Manufacturing Facilities in the United States

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ABSTRACT

The U.S. Food and Drug Administration (FDA) conducted a sampling assignment in 2014 to ascertain the prevalence of *Cronobacter* spp. and *Salmonella* in the processing environment of facilities manufacturing milk powder. *Cronobacter* was detected in the environment of 38 (69%) of 55 facilities. The average prevalence of *Cronobacter* in 5,671 subsamples (i.e., swabs and sponges from different facility locations) was 4.4%. In the 38 facilities where *Cronobacter* was detected, the average prevalence of positive environmental subsamples was 6.25%. In 20 facilities where zone information of the sampling location was complete, *Cronobacter* was most frequently detected in zone 4, followed by zone 3, then zone 2, with zone 1 yielding the lowest percentage of positive samples. The prevalence of *Cronobacter* across the zones was statistically different ($P < 0.05$). There was no significant association between product type (i.e., lactose, whey products, buttermilk powder, and nonfat dried milk) and prevalence of *Cronobacter* in the facility. *Salmonella* was detected in the environment of three (5.5%) of the 55 facilities; all three facilities produced dried whey product. The overall prevalence of *Salmonella* in 5,714 subsamples was 0.16%. In facilities in which *Salmonella* was detected, the average prevalence was 2.5%. *Salmonella* was most frequently detected in zone 4, followed by zone 3. *Salmonella* was not detected in zone 1 or zone 2. The disparity between *Salmonella* and *Cronobacter* prevalence indicates that additional measures may be required to reduce or eliminate *Cronobacter* from the processing environment.

HIGHLIGHTS

- *Cronobacter* was found in manufacturing areas of 69% of 55 U.S. milk powder facilities.
- *Salmonella* was found in 5.5% of 55 facilities.
- Both organisms were most frequently isolated from zone 4 locations.
- No significant association was found between product type and *Cronobacter* prevalence.
- Additional measures may be required to reduce or eliminate *Cronobacter* from the processing environment.

Key words: *Cronobacter*; Environmental sampling; Food manufacturing environment; Milk powder; Prevalence; *Salmonella*

The genus *Cronobacter* is currently composed of seven species: *C. sakazakii, C. malonaticus, C. turicensis, C. universalis, C. muytjensii, C. dublinensis,* and *C. condimenti (24, 27)*. *Cronobacter* spp. are gram-negative rods and facultative anaerobes, and they have a growth range of 5.5 to 45°C. *Cronobacter* spp. have been isolated from a wide variety of plant- and animal-based foods, including milk powder, powdered infant formula (PIF), spices, fruit and vegetables, wheat, dehydrated noodles, tea, instant soup, candy, and various raw meats *(25, 28, 32, 40, 42, 48)*.

All *Cronobacter* species, except for *C. condimenti,* are pathogenic to humans *(19, 25)*. However, Eshwar et al. *(12)* showed that *C. condimenti* was as pathogenic as other species in the zebrafish model. *Cronobacter* gained notoriety due to infections in infants; however, *Cronobacter* spp. can also cause illness in older children and adults. *Cronobacter* infections in adults can result in septicemia, as well as respiratory, wound, and urinary tract infections *(1, 22, 36)*. Infection of infants with *Cronobacter* can result in septicemia, necrotizing enterocolitis, and meningitis, and there is a high case-fatality rate (10 to 80%) *(43)*. *Cronobacter* infections in infants have been associated with consumption of PIF *(43)*; neonates (infants younger than 4 weeks of age) and infants younger than 2 months of age are at greatest risk of infection *(19)*. Recently Bowen et al. *(4)* and McMullan et al. *(30)* reported infantile *Cronobacter* septicemia-meningitis infections in which the infants consumed only expressed maternal breast milk.

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Contaminated personal breast pumps were found to be the source of the contamination.

Salmonella enterica is a leading cause of foodborne illness in many countries, including the United States *(15, 41)*. The symptoms of *Salmonella* infection usually include diarrhea, fever, and abdominal cramps. Children younger than 5 years of age have higher risk for *Salmonella* infection than other age groups *(5)*. Salmonellosis has been associated with a variety of food commodities, and outbreaks of foodborne illness have been reported in foods of both plant and animal origin *(35)*. Its ability to contaminate low-moisture foods has been recognized for some time, and outbreaks due to the consumption of milk powder, infant formula, cereals, nuts, peanut and nut butter, chocolate, and spices have been documented *(37)*.

Salmonella can survive desiccation and survive for long periods of time (months or years) in low-moisture foods such as dried milk products, nuts, pasta, and chocolate *(3, 11)*. There have been several multiyear salmonellosis outbreaks associated with low-moisture foods, for example, *Salmonella* Agona in infant formula produced in France (2005 to 2017), *Salmonella* Poona in infant formula produced in Spain (2010 to 2019), and *Salmonella* Agona in breakfast cereal in the United States (1998 to 2008) *(13, 14, 26, 45)*. In each outbreak, *Salmonella* was shown to be genetically related over the time span, indicating that the same strain of *Salmonella* persisted within the manufacturing facility for many years.

Studies have also shown that *Cronobacter* can persist in the environment of facilities that manufacture milk powder and PIF *(3, 6, 9, 17, 21, 34, 49, 50)*. The predominant *Cronobacter* species cultured from four Irish PIF production environments during an 18-month surveillance study was *C. sakazakii (50),* and the predominant sequence types (STs) found were *C. sakazakii* ST1 isolates. In another study, Chase et al. *(6)* found that an ST83 *C. sakazakii* strain had persisted in a Swiss PIF manufacturing facility for at least 4 years. Phylogenetic analysis using microarray and whole genome sequencing data showed that four of five ST83 strains from product and the environment were highly phylogenetically related, and microarray showed that between 5 and 38 genes differed from one another in these strains *(6)*. *Cronobacter* can also survive in PIF for lengthy periods of time during normal product storage *(10, 20)*. Furthermore, Yan et al. *(50)* posit that the adaptation of this pathogen to the PIF manufacturing environment could lead to the survival of these organisms in finished product and increase the risk of causing infections once the contaminated food is consumed.

Even though researchers have examined the presence of *Cronobacter* spp. and *Salmonella* in the processing environment in food manufacturing facilities, the studies normally targeted a single facility or a small number of facilities in a region. Large-scale or nationwide surveillance of *Cronobacter* in milk powder manufacturing facilities has never been reported in the United States, and there are no recently published studies of *Salmonella* prevalence in milk powder facilities. The U.S. Food and Drug Administration (FDA) conducts sampling assignments to update knowledge on known hazards, as well as to collect data on emerging hazards. A sampling assignment was conducted in 2014 to ascertain the prevalence of *Cronobacter* spp. and *Salmonella* in the processing environment of facilities manufacturing milk powder in the United States. In this article, we report the findings of this survey.

MATERIALS AND METHODS

Facilities. Milk powder manufacturing establishments under FDA jurisdiction were identified across the contiguous United States for a sampling assignment. The inspections were conducted in fiscal year 2014 (1 October 2013 to 30 September 2014), with 58 facilities inspected and sampled during the assignment.

Sample collection and transfer. Environmental samples for *Cronobacter* and *Salmonella* were collected from each facility (the target was a minimum of 100 subsamples for each organism from each facility). FDA uses the term "environmental sample" or "sample" to denote all of the swabs and sponges collected from a food manufacturing facility during 1 day of sampling. The individual swabs and sponges from separate sampling locations in the facility are termed "subsamples" or "subs" of the sample from that facility. Subsample collection was focused primarily on zones 1 to 3 (Table 1), and environmental swabs were collected as outlined in chapter 4 of the FDA's *Investigations Operation Manual (47)*. The swabs for *Cronobacter* and *Salmonella* were collected in tandem. Sampling was focused on potential niche areas for these organisms, such as equipment with hollow bodies due to poor hygienic design, areas that would be wet and redried, and areas that were cracked or had rough surfaces. The areas sampled included the floors, drains, and equipment frames (including near the floor); instantizing operations, including fluidizer beds and rewetting chambers, as well as vitamin addition equipment; flap or rotary valves after dryers, baghouses and sifters, dryer explosion chambers, powder hoppers in packaging areas, and powder silos interiors. In most cases, the subsamples were collected from areas of the facility where postdrying activities were conducted, but in some facilities subsamples were also collected from predrying operations.

Each FDA district had a specific servicing laboratory identified to analyze the samples. On the day of collection, the samples were placed into insulated shipping containers containing frozen gel packs and shipped via UPS next day air early morning delivery. If the samples could not be analyzed on receipt at the laboratory, they were stored at 4 $\pm$ 2°C. Sample analysis was initiated no later than 48 $\pm$ 2 h after sample collection.

Analysis of environmental samples. *Cronobacter* spp. analysis was conducted as outlined in chapter 29 of the *Bacteriological Analytical Manual* (BAM) *(44)*. Isolate identifications were conducted using bioMerieux Rapid 32 E identification strips or the VITEK 2 (bioMerieux, Hazelwood, MO).

Salmonella analysis was conducted using VIDAS *Salmonella* (SLM) Easy *Salmonella* (bioMerieux), using AOAC method 2011.03 *(2)*. Confirmation was conducted as outlined in BAM, chapter 5 *(46)*.

Statistical analysis. Frequency tables were created to examine the association between *Cronobacter* and zone, product, and environmental monitoring program, respectively, as well as for *Salmonella* and zone. A chi-square or Fisher's exact test, where appropriate, was used to test for independence. R software (https://www.R-project.org/) *(38)* was used for all statistical analyses.

TABLE 1. *Definition of zones for environmental monitoring*[a]

Zone	Description
Zone 1	All direct food contact surfaces, such as mixers, conveyors, utensils, racks, work tables, etc.
Zone 2	Areas directly adjacent to food contact surfaces (zone 1).
Zone 3	The area immediately surrounding zone 2. If the zone 3 area is contaminated with a pathogen, that could lead to contamination of zone 2 via actions of humans or movement of machinery. Zone 3 areas include, e.g., corridors and doorways leading into food production areas or areas in a large production room that are further away from food handling equipment than typical zone 2 areas. Walls, phones, forklifts, and "mules," even if physically located in zone 2, should be considered zone 3 due to a decreased likelihood of cross-contamination.
Zone 4	Generally considered a remote area, outside of food production areas. If the zone 4 area is contaminated with a pathogen, that could lead to contamination of zone 3 via the actions of humans or machinery. Zone 4 areas include, e.g., an employee locker room if not immediately adjacent to food production rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

[a] Adapted from FDA *(47)*.

RESULTS

Data from 3 of 58 inspected facilities were excluded from analysis because microbiological analysis was not conducted on the samples from one facility and two of the facilities were not producing milk powder at the time of sampling. Therefore, data were available from 55 facilities.

In these 55 facilities, 5,671 environmental subsamples were collected and analyzed for *Cronobacter,* an average of 103 subsamples per facility. The minimum subsample number collected from one facility was 55, the maximum was 176. *Cronobacter* was detected in the environment of 38 (69%) facilities. In the 38 facilities where *Cronobacter* was detected, 4,005 subsamples were collected, of which 250 were positive for *Cronobacter,* yielding a prevalence of positive environmental subsamples of 6.25%. The overall prevalence of *Cronobacter* in the 5,671 subsamples from 55 facilities was 4.4%. The number of subsamples that tested positive for *Cronobacter* within a single facility ranged from 0 to 41 (0 to 41%).

For *Salmonella,* 5,714 subsamples were collected and analyzed, an average of 104 per facility. The minimum subsample number collected from one facility was 55, the maximum was 176. *Salmonella* was detected in the environment of 3 (5.5%) of the facilities (359 subsamples were collected, of which 7 were positive). In the three facilities in which *Salmonella* was detected, the average prevalence was 2.5%. The overall prevalence for *Salmonella* in the 5,714 subsamples collected from 55 facilities was 0.16%.

TABLE 2. *Prevalence of* Cronobacter *spp. by zone within the processing environment*[a]

	No. of subsamples collected	No. (%) positive
Zone 1	89	1 (1.1)
Zone 2	870	39 (4.5)
Zone 3	993	86 (8.7)
Zone 4	35	5 (14.3)
Not assigned	2	0

[a] Refer to Table 1 for definitions. Environmental samples were collected from 20 milk powder production facilities in the United States from various locations within each facility.

For statistical analysis regarding the presence of *Cronobacter* in milk powder facilities, a subset of data from 20 facilities (1,989 subsamples) was used. This subset of facilities was selected because it had the most complete information on zones sampled and product types during sampling and because *Cronobacter* was detected in at least one environmental subsample in all 20 facilities. In these 20 facilities, most of the subsamples that were collected and tested for *Cronobacter* were from zones 2 and 3 (Table 2). *Cronobacter* was most frequently detected in zone 4 (14.3% of subsamples positive), followed by zone 3 (8.7%), zone 2 (4.5%), and zone 1 (1.1%). The prevalence of *Cronobacter* across the zones was not the same ($P < 0.05$), although the sampling was biased toward the collection of samples from zones 2 and 3.

The prevalence of *Cronobacter* as a function of the product manufactured at the time of sampling was also analyzed (Table 3). The products were lactose, whey products, buttermilk powder, and nonfat dried milk (NFDM). In some facilities, samples were collected across different product categories (i.e., the facility was manufacturing more than one product during the inspection); therefore, the "number of facilities" in Table 3 adds to greater than 20. There was no significant association between product type and prevalence of *Cronobacter* spp. in the facility ($P = 0.167$).

Information about the environmental monitoring program in a facility was collected during some of the inspections (Table 4, these are the same 20 facilities used

TABLE 3. *Prevalence of* Cronobacter *spp. by type of product manufactured at the time of environmental sampling*[a]

Product	No. of facilities	No. of subsamples	No. (%) positive
Lactose	6	459	24 (5.2)
Whey products	10	901	62 (6.9)
Buttermilk powder	1	100	12 (12)
NFDM[b]	3	307	20 (6.5)
Not reported	4	222	13 (5.9)

[a] Environmental samples were collected from 20 milk powder production facilities in the United States, from various locations within each facility.

[b] NFDM, nonfat dried milk.

TABLE 4. *Organisms targeted in the environmental monitoring program in 21 U.S. milk powder production facilities*[a]

Organisms targeted[b]	No. of facilities
Salmonella	1
Salmonella and *Listeria*	3
Salmonella, Listeria, and *Enterobacteriaceae*	1
Salmonella, Listeria, and coliforms	2
Salmonella, Listeria, and *Cronobacter*	2
No program	1
No data	11

[a] Data were reported by the facility.
[b] Organisms targeted in the environmental monitoring program.

for the statistical analysis of *Cronobacter,* plus one additional facility that tested positive for *Salmonella*). The information was collected during an interview with facility personnel; the details were not verified by reviewing the facilities' programs. Of the 10 facilities with data available, all except one had a program that included testing for *Salmonella*. Two of the facilities reported that their plan included testing for *Cronobacter,* and one other facility reported testing for *Enterobacteriaceae* (Table 4). Statistical analysis was not included due to the small size of the data set.

Salmonella was detected in the environment of three facilities (Table 5). All three facilities where *Salmonella* was detected were producing a dried whey product at the time of sampling. In these three facilities, 89.7% of the subsamples that were collected and tested for *Salmonella* were from zones 2 and 3. *Salmonella* was most frequently detected in zone 4 (21.7% of subsamples positive), followed by zone 3 (2.6%). *Salmonella* was not detected on surfaces in zone 1 or zone 2 in any of the facilities. As with *Cronobacter,* a majority of the *Salmonella* subsamples were collected from zones 2 and 3.

The prevalence of *Salmonella* and *Cronobacter* in the environment of three milk powder production facilities that yielded *Salmonella*-positive samples is compared in Table 6. Due to the low number (three) of facilities with *Salmonella* detected in the environment, statistical comparisons were not made between *Cronobacter* and *Salmonella* data in the facilities. No clear pattern between the presence of *Salmonella* and *Cronobacter* was noted. For example, *Cronobacter* was not detected in the environment of facility A, which had greatest number of *Salmonella* positives (Table 6).

TABLE 5. *Prevalence of* Salmonella *by zone within the processing environment*[a]

	No. of subsamples	No. (%) positive
Zone 1	9	0
Zone 2	125	0
Zone 3	154	4 (2.6)
Zone 4	23	5 (21.7)

[a] Refer to Table 1 for definitions. Environmental samples were collected from three milk powder production facilities in the United States, from various locations within each facility.

TABLE 6. *Prevalence of* Salmonella *and* Cronobacter *in the environment of facilities that yielded* Salmonella*-positive samples*[a]

Facility	No. of subsamples collected/facility[b]	No. of subsamples positive for *Salmonella*	No. of subsamples positive for *Cronobacter*
A	100	7	0
B	109	1	7
C	102	1	6

[a] Environmental samples were collected from three milk powder production facilities in the United States, from various locations within each facility.
[b] The number of subsamples collected and tested per organism, e.g., 100 samples for *Salmonella* and 100 samples for *Cronobacter*.

DISCUSSION

This sampling assignment was conducted in 2014, prior to the FDA's publication in 2015 of the regulation "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods" (21 CFR Part 117). This regulation applies to milk powder manufacturers and defines the term "environmental pathogen." It requires that manufacturers producing ready-to-eat food consider the risk of contamination by environmental pathogens during their hazard analysis and, if these hazards require a preventive control, that they implement appropriate controls and verification of these controls. In 2014, an environmental monitoring program to verify control of environmental pathogens was not a regulatory requirement.

The milk powder manufacturing process uses pasteurized milk, which is then concentrated and dried through evaporation and spray drying, respectively. *Cronobacter* and *Salmonella* are inactivated during pasteurization of milk; therefore, presence of these organisms in the final milk powder product indicates contamination from the postpasteurization environment or from the addition of contaminated ingredients after pasteurization. Depending on the application, milk powder can be considered a ready-to-eat product, which can be prepared and consumed without a kill-step (e.g., in the home of the consumer). It is also used as an ingredient in the manufacturing of numerous food and beverage products, including products for infants (such as PIF), the elderly, and the immunocompromised. Depending on the application, the milk powder may or may not undergo an additional lethality treatment. Therefore, if milk powder is to be used as an ingredient in ready-to-eat products for infants, the immunocompromised, or the elderly, it is important to source this material from manufacturers that apply strict hygienic control measures and production strategies to prevent recontamination by environmental pathogens such as *Salmonella* and *Cronobacter*.

In the current study, environmental samples were collected from 55 milk powder production facilities and tested for *Cronobacter* and *Salmonella*. In other published literature investigating *Cronobacter* in milk powder processing facilities, samples were taken from a smaller number of facilities, typically in the range of three to five

(e.g., references *9, 16, 21*). In the present study, *Cronobacter* was isolated from the environment of 38 (69%) of 55 milk powder production facilities. In previous studies, *Cronobacter* was detected in the manufacturing environment of all milk powder facilities that were tested, e.g., five of five facilities in Australia *(9)*; three of three facilities in China *(16),* four of four facilities in Europe *(29)*.

Although *Cronobacter* was detected in at least one environmental subsample in 69% of the facilities, the prevalence within the facilities was generally low, with an average of 6.25% of the subsamples positive in the 38 facilities where *Cronobacter* was detected. When considering the overall prevalence in the samples collected from the 55 facilities, 4.4% of the subsamples tested positive for *Cronobacter*. These numbers are lower than what has been reported in some other studies. For example, Craven et al. *(9)* reported that 32% of their 298 samples were positive; Kandhai et al. *(29)* collected 68 samples and reported a range of 9 to 35%. (Note: In the literature on this topic, the term "sample" is used to denote a location within a manufacturing facility where a single sponge or swab is taken and tested; it is equivalent to the FDA term "subsample.") The prevalence observed in the current study is more in line with the findings of Fang et al. *(16),* who reported that 10.6% of the samples collected from goat milk powder facilities were positive for *Cronobacter*. Other studies have focused on sampling in one facility, in some instances with multiple visits over an extended period (e.g., months). In these studies, the prevalence of *Cronobacter* on environmental surfaces has varied; for example, Reich et al. *(39)* reported 0%, in contrast with Hein et al. *(21),* who reported 39.4%. These studies have been conducted with different sampling and testing methodologies and have been conducted in different countries, which may contribute to the variation in results. Another possible reason for a higher prevalence in studies conducted more than 10 years ago is that industry awareness regarding *Cronobacter* has increased, which may have led to improved control measures in recent years.

In contrast to *Cronobacter, Salmonella* was found in only 3 of the 55 milk powder production facilities in the United States. These results are consistent with earlier studies targeting *Salmonella* in milk powder plants. In 1985, a study was undertaken by the National Research Council of the U.S. Department of Agriculture *Salmonella* surveillance program for nonfat dried milks. The study found that numerous milk powder plants were still not designed to ensure the containment of microbiological contamination, in particular *Salmonella (31)*. The level of *Salmonella* contamination in skim milk powder in the United States was found to drop from 0.44% in 1980 to 0.06% in 1988 *(31)*. Environmental samples collected as part of the *Salmonella* surveillance program from dry skim milk facilities from 1966 to 1985 ranged from a high of 8.2% in 1967 to a low of 2.3% in 1985 *(31)*. The reduction during this period was attributed to the gradual introduction of preventive measures in the form of codes of practice by organizations such as Codex Alimentarius *(7)*. These control measures focused on (i) prevention of ingress by *Salmonella* into the plant; (ii) avoidance of growth and spread in case of entry; (iii) application of hygienic controls, equipment and facility hygienic design, and hygienic zoning principles; and (iv) establishment of a raw material control program and use of *Salmonella*-free ingredients *(18)*. Today, the incidence of *Salmonella* in dry milk powders can be considered to be rare. The few events that are reported are typically attributed to errors in the application of the preventive hygiene measures or a breakdown of hygienic controls.

Therefore, the questions that should be asked and answered are, is it possible to achieve the same level of control for *Cronobacter* as that achieved for *Salmonella*? Are there differences between the control measures for *Cronobacter* and *Salmonella*? Cordier *(8)* suggests that the preventive control measures described above for *Salmonella* form the basis of the management and control for *Cronobacter* and are also a prerequisite to control this environmental pathogen in dry powder processing operations. Cordier *(8)* goes on to recommend that control measures more stringent than the existing strategy will be necessary to control *Cronobacter*. The application of existing hygienic practices targeted toward control of *Salmonella* will only minimize, and not completely suppress, the presence of *Cronobacter*. The most successful additional strategy to impact the control of this pathogen is the very strict management of moisture in the processing environment, with the target being complete elimination of any water. This is a difficult task; the cleaning and sanitation practices currently observed for some dairy powder operations serve to introduce moisture into the manufacturing environment and equipment interiors, for a variety of reasons: e.g., formulation changeover, allergen control, equipment design. This results in a risk for both *Salmonella* and *Cronobacter* proliferation within manufacturing environments and equipment. Consequently, manufacturers may wish to consider utilizing additional hygienic measures and implementing additional environmental monitoring for drying systems, especially with equipment postdrying chambers. In respect to *Cronobacter* and *Enterobacteriaceae* in general, even the slightest traces of water can lead to rapid increase in the population and a higher probability of process contamination *(8)*. Therefore, it is imperative that strict management of water be constantly applied for the processing environment, near the process line and wherever the product may be exposed to the environment (such as filling), and for packaging areas, in areas where condensation might occur with cooling within equipment after shutdown (e.g., baghouses), and in equipment where moisture is intentionally introduced (e.g., instantizers). These areas of the process are more commonly managed at a higher hygienic control than warehouses or nonproduction areas of a dry powder plant. Where *Cronobacter* has been identified as a hazard of concern, facilities should consider the hygienic design of their processing equipment and modify sanitation procedures specifically to address this pathogen. For example, they could employ dedicated lines where strict hygienic control measures are applied to prevent line recontamination from the environment.

In the current study, both *Cronobacter* and *Salmonella* were detected more frequently in zones 4 and 3. Zone 4

areas are those outside the food production areas, including employee locker rooms, dry goods storage warehouses, finished product warehouses, cafeterias, hallways, and loading dock areas. Although the percentage of zone 4 subsamples collected in the present study was low compared with zone 2 and 3 subsamples, the results of this study are consistent with other studies. Craven el al. *(9)* also reported that the occurrence of *Cronobacter* was higher in "nonprocessing areas" (49% positive rate). Zone 4 areas are not likely to be cleaned with the same regularity or thoroughness as food processing areas; zone 4 areas may also accumulate dust and can be subject to higher moisture conditions due to roof leaks, faulty sprinklers, leaking water or steam valves, or a drain backup. Dust has been reported to be a source of *Cronobacter (32)*. In the current study, the data collection format was not conducive to making conclusions about the specific sites where *Cronobacter* was isolated. Other studies that were designed to explore this question have reported areas that frequently tested positive for *Cronobacter*: spray drying rooms *(9, 16),* entrances to spray drying rooms *(9),* and packaging rooms *(16),* as well as air filters *(33),* floors, and vacuums *(23)*.

This study presented data on the prevalence of *Cronobacter* and *Salmonella* in milk powder production facilities in the United States. Understanding the prevalence of *Cronobacter* and *Salmonella* can help manufacturers design programs to control these pathogens in these facilities. It would appear that many U.S. milk powder production facilities are doing a good job of controlling *Salmonella* in the environment. However, *Cronobacter* was found in many of the facilities. The disparity between *Salmonella* and *Cronobacter* prevalence indicates that controls for *Salmonella* may not eliminate *Cronobacter* from the environment. Where *Cronobacter* is a hazard of concern, facilities should strictly manage moisture in the dry processing operations close to product flow and should design sanitation procedures to specifically address this pathogen. Manufacturers should also identify and address possible routes of contamination for *Cronobacter* into the finished product intended for infants and sensitive consumers, including the potential of contamination from zone 4 areas into processing areas.

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