Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Bacterial Pathogens in Powdered Infant Formula - April 1, 2015 to March 31, 2018

Food microbiology - Targeted surveys - Final report

Canada

Summary

Powdered infant formula is commonly consumed by newborns and infants in Canada. Unfortunately, the consumption of reconstituted powdered infant formula has been associated with recalls and outbreaks of foodborne illnesses in Canada and worldwide, with the main pathogens of concern being *Cronobacter* species (spp.) and *Salmonella* spp. While rare, infections with these pathogens in babies can be fatal. Contamination can occur at any point in the food production chain and have been previously traced back during food safety investigations to the production facility and equipment used to prepare the infant formula. Newborns and infants are considered a vulnerable population as their immune systems are still developing and therefore at an increased risk for foodborne illnesses.

Considering the factors mentioned above and their relevance to Canadians, a variety of powdered infant formulas were selected for targeted surveys. The purpose of the surveys was to generate baseline information on the occurrence of pathogenic bacteria in this commodity. Over the course of this three year study (April 1, 2015 to March 31, 2018), a total of 3962 samples were collected from retail locations in 11 cities across Canada. All 3962 samples were tested for Enterobacteriaceae. 2965 samples were tested for generic *Escherichia coli* (*E.coli*) and *Salmonella* spp. 997 samples were tested for *Cronobacter* spp. Enterobacteriaceae and generic *E.coli* are indicator organisms as their levels found in foods are used to assess the overall sanitation conditions throughout the food production chain.

Salmonella spp., *Cronobacter* spp., and generic *E.coli* (> 1.8 Most Probable Number / gram (g)) were not found in any samples. Enterobacteriaceae were detected in 2/3962 (0.05%) of the samples.

The Canadian Food Inspection Agency (CFIA) conducted additional sampling/testing in response to the Enterobacteriaceae positive samples. No product recalls were issued. No reported illnesses were associated with any of the contaminated products.

Overall, our survey results suggest that Canadian retail powdered infant formula is safe for consumption. However 2 samples in our survey were found to be contaminated with Enterobacteriaceae which may indicate a loss of sanitation controls, inadequate processing or post-processing contamination. Consequently, as with all foods, safe handling practices are recommended for producers, retailers and consumers.

What are targeted surveys?

Targeted surveys are used by the CFIA to focus its surveillance activities on areas of highest health risk. The information gained from these surveys provides support for the allocation and prioritization of the Agency's activities to areas of greater concern. Originally started as a project under the Food Safety Action Plan (FSAP), targeted surveys have been embedded in the CFIA's regular surveillance activities since 2013. Targeted surveys are a valuable tool for generating information on certain hazards in foods, identifying and characterizing new and emerging hazards, informing trend analysis, prompting and refining health risk assessments, highlighting potential contamination issues, as well as assessing and promoting compliance with Canadian regulations.

Food safety is a shared responsibility. The CFIA works with federal, provincial, territorial and municipal governments and provides regulatory oversight of the food industry to promote safe handling of foods throughout the food production chain. The food industry and retail sectors in Canada are responsible for the food they produce and sell, while individual consumers are responsible for the safe handling of the food they have in their possession.

Why did we conduct this survey?

Powdered infant formula is commonly consumed by newborns and infants in Canada[1]. Unfortunately, the consumption of reconstituted powdered infant formula has been associated with recalls and outbreaks[2-4] of foodborne illnesses in Canada and worldwide, with the main pathogens of concern being *Cronobacter* spp. and *Salmonella* spp. While rare, infections with these pathogens in babies can be fatal. Contamination can occur at any point in the food production chain and have been previously traced back during food safety investigations to the production facility and equipment used to prepare the infant formula. Newborns and infants are considered a vulnerable population as their immune systems are still developing and therefore at an increased risk for foodborne illnesses.

Considering the factors mentioned above and their relevance to Canadians, a variety of powdered infant formula samples were selected for targeted surveys. The purpose of the surveys was to generate baseline information on the occurrence of pathogenic bacteria in this commodity. Over the course of this 3 year study (April 1, 2015 to March 31, 2018), a total of 3962 samples were collected from retail locations in 11 cities across Canada. The samples were analysed in 2 groups based on the analyses conducted. Group I samples consisted of 2965 samples tested for generic *E.coli*, Enterobacteriaceae and Salmonella spp. Group II samples consisted of 997 samples tested for Enterobacteriaceae and *Cronobacter* spp. Generic *E.coli* and Enterobacteriaceae are both indicator organisms as their levels found in foods are used to assess the overall sanitation conditions throughout the food production chain.

What did we sample?

For this survey, a sample consisted of a single or multiple unit(s) (individual consumer-size package(s)) from a single lot with a total weight of at least 250g. All samples were collected from national retail chains and local/regional grocery stores located in 11 major cities across Canada. These cities encompassed four geographical areas:

- Atlantic (Halifax and Saint John)
- Quebec (Quebec City, Montreal)
- Ontario (Toronto, Ottawa)
- West (Vancouver, Kelowna, Calgary, Saskatoon and Winnipeg).

The number of samples collected from these cities was in proportion to the relative population of the respective areas. Samples were collected between April 1, 2016 and March 31, 2018.

A variety of domestic, imported, conventional and organic products were sampled. Sample collection was evenly distributed throughout the year.

What analytical methods were used and how were samples assessed?

Samples were analyzed using methods published in Health Canada's *Compendium of Analytical Methods for the Microbiological Analysis of Foods*[5] and methods published by the International Organization for Standardization[6] (table 1). The assessment criteria used in this survey (table 1) are based on the principles of *Health Canada's Interim Microbiological Criteria for Powdered Infant Formula*[7] and Health Canada's *Health Products and Food Branch Standards and Guidelines for Microbiological Safety of Foods*[8].

Table 1 - Analytical methods and assessment criteria for powdered infant formula

Bacterial analysis	Method identification number[a]	Satisfactory	Investigative	Unsatisfactory
Salmonella spp.	MFHPB-20	Absent in 25g	Not Applicable (N/A)	Present in 25g
Cronobacter spp.	MFLP-27M[b] ISO 22964	Absent in 125g	N/A	Present in 125g
Enterobacteriaceae	ISO 21528	Absent in 10g	Present in 10g	N/A
Generic *E. coli*	MFHPB-19	≤ 1.8 MPN/g	1.8 < x ≤ 10 MPN/g	> 10 MPN/g

[a] The methods used were the published versions at the time of analysis.

[b] A modified primary enrichment procedure was used whereby samples were diluted 1:10 in pre-warmed (37°C) Buffered Peptone Water and incubated at 37°C for 22-26 hours. All subsequent steps were performed as described in MFLP-27.

As *Salmonella* spp. is considered pathogenic to humans its presence would have been considered a violation of the *Food and Drugs Act* (FDA) Section 4(1)a[9] and would therefore have been assessed as unsatisfactory. *Cronobacter* spp. is capable of infecting all humans, however infection in immunocompromised individuals can be serious and in infants can be life threatening. Consequently, its presence in powdered infant formula would have been considered a violation of the *Food and Drugs Act* (FDA) Section 4(1)a[9] and would therefore have been assessed as unsatisfactory.

Unlike harmful bacterial pathogens (such as *Salmonella* spp., *Cronobacter* spp.), generic *E.coli* and Enterobacteriaceae are commonly found in the intestines of humans and most strains are harmless. They are considered to be indicator organisms and their levels present in a food product are used to assess the overall sanitation conditions throughout the food chain from production to the point of sale. Their presence at some levels is tolerated. An investigative assessment which may result in further follow-up actions is associated with the detection of Enterobacteriaceae and elevated levels of generic *E.coli* (1.8 <x ≤ 10 MPN/g). As the results are based on the analysis of one unit (n=1), further sampling may be required to verify their levels in the lot. An unsatisfactory assessment is associated with the presence of high levels of generic *E.coli* (>10 MPN/g) as it may indicate a breakdown in good manufacturing practices (sanitation practices), and therefore possibly warranting the initiation of follow-up activities to determine the source of the contamination and improve sanitation conditions along the food chain.

What were the survey results?

A total of 3962 samples were collected and analysed in 2 groups based on the analyses conducted. Group I samples consisted of 2965 samples tested for *Salmonella* spp., Enterobacteriaceae and generic *E.coli*. Group II samples consisted of 997 samples tested for *Cronobacter* spp and Enterobacteriaceae.

Salmonella spp, *Cronobacter* spp., and generic E.coli (> 1.8 MPNg) were not found in any samples. Enterobacteriaceae were detected in 2/3962 (0.05%) of the samples.

Sample assessment results can be found in table 2.

Table 2 - Assessment results of powdered infant formula

Group	Bacterial analysis	Number of samples tested	Satisfactory	Investigative	Unsatisfactory
I	Enterobacteriaceae	2965	2964	1	N/A
	Salmonella spp.			N/A	0
	Generic *E.coli*			0	0
II	Enterobacteriaceae	997	996	1	N/A
	Cronobacter spp.			N/A	0
Total		**3962**	**3960**	**2**	**0**

All of the samples tested were imported from various countries. The majority of the samples were imported from the United States (81%, 3228/3962) (table 3).

Table 3 – Assessment results of powdered infant formula by product origin

Product origin	Number of samples tested	Satisfactory	Investigative
Import	3962	3960	2
Ireland	176	176	0
Netherlands	39	39	0
United Kingdom	11	11	0
United States	3228	3226	2
Unknown	508	508	0
Total	**3962**	**3960**	**2**

Of the 3962 samples tested, 3473 (88%) were conventional while 489 (12%) were organic (table 4).

Table 4 – Assessment results of powdered infant formula by production practice

Production practice	Number of samples tested (% of total samples)	Satisfactory	Investigative
Conventional	3473 (88%)	3471	2
Organic	489 (12%)	489	0
Total	**3962**	**3960**	**2**

A variety of powdered infant formula product types were analysed, with the majority of the samples being milk-based (81%, 3209/3962) (table 5).

Table 5 – Assessment results by powdered infant formula product types

Product type	Number of samples tested (% of total samples)	Satisfactory	Investigative
Hypoallergenic	366 (9%)	365	1
Milk-based	3209 (81%)	3208	1
Soy-based	387 (10%)	387	0
Total	**3962**	**3960**	**2**

What do the survey results mean?

In this survey, all (100%) of the samples were free of *Salmonella* spp, *Cronobacter* spp. and generic *E. coli* (> 1.8 MPN/g). Enterobacteriaceae were detected in 2/3962 (0.05%) of the samples.

Very few studies similar to ours have been published. One study[10] conducted in the United Kingdom (UK) and published in 2004 investigated the presence of *Salmonella*, Enterobacteriaceae, *Cronobacter spp.* (*Enterobacter sakazakii*) and general microbial flora (Aerobic Plate Count (APC)) in 82 powdered infant formula milk samples purchased from retailers in the UK and other European countries. *Salmonella* was not detected in any of the samples. The APC for the majority (78%) of the samples was found to be $\leq 10^2$. Enterobacteriaceae was isolated from one sample (1.2%, 1/82) and *Cronobacter* spp. (*Enterobacter sakazakii*) was isolated from 2 samples (2.4%, 2/82).

No trends were observed in our study when comparing country of origin (table 3), method of production (table 4) or product type (table 5).

The CFIA conducted additional sampling/testing in response to the Enterobacteriaceae positive samples. No product recalls were issued. No reported illnesses were associated with any of the contaminated products.

Overall, our survey results suggest that Canadian retail powdered infant formula is safe for consumption. However, 2 samples in our survey were found to be contaminated with Enterobacteriaceae which may indicate a loss of sanitation controls, inadequate processing or post-processing contamination. Consequently, as with all foods, safe handling practices are recommended for producers, retailers and consumers.

References

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