



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Bacterial pathogens and indicators in powdered infant formula - April 1, 2018, to March 31, 2024

Food microbiology - Targeted surveys - Final report



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Summary

A 6-year (April 1, 2018, to March 31, 2024) targeted survey¹ analysed 898 samples of powdered infant formula for the presence of the pathogen *Cronobacter* spp. Of the 898 samples, 479 were also tested for the pathogen *Salmonella* spp. All 898 samples were also tested for Enterobacteriaceae, which is used as an indicator of the hygienic and sanitary conditions of the food supply chain from production to the point of sale.

99.7% of the samples tested were found to be satisfactory. *Salmonella* spp. was not detected in any (0 of 479) of the samples. *Cronobacter* spp. was detected in 1 of 898 (0.1%) samples. Enterobacteriaceae was detected in 2 of 898 (0.2%) samples. The Canadian Food Inspection Agency (CFIA) conducted appropriate follow-up activities and food recalls were issued by industry. There were no reported illnesses related to these products.

Overall, our survey results indicate that powdered infant formula sold in Canada is generally safe for consumption. However, as with all food, and especially those that are intended for infants, good hygienic practices are recommended for producers, retailers, and consumers.

Why the survey was conducted

This survey, which started in 2015, was conducted to provide enhanced oversight of the quality and safety of powdered infant formula sold at retail in Canada. This report includes survey results from April 1, 2018, to March 31, 2024. Survey results from previous years (April 1, 2015, to March 31, 2018) are available².

Powdered infant formula is commonly consumed by newborns and infants in Canada³. Unfortunately, the consumption of reconstituted powdered infant formula has been associated with recalls^{4,5} and outbreaks^{6,7,8,9} 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. Unlike liquid infant formula (i.e. ready-to-feed and liquid concentrates), powdered infant formula is not sterile and therefore steps must be taken to prepare it properly¹⁰. Contamination can occur at any point in the food production chain such as during production, packaging, and/or during preparation for consumption. Previous food safety investigations have traced back contamination events 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. Consequently, if pathogens are present in the foods they consume, there is a potential for foodborne illness to occur.



When the survey was conducted

The survey is ongoing, however the results reported herein are for samples collected over a 6-year period from April 1, 2018, to March 31, 2024.

Where the samples were collected from

Samples were collected from national retail chains and local/regional grocery stores located in the following 11 major cities across Canada:

- Halifax
- Moncton
- Quebec City
- Montreal
- Ottawa
- Toronto
- Winnipeg
- Saskatoon
- Calgary
- Vancouver
- Victoria

The planned number of samples to be collected from each city was based on the population of the province in which the city was located relative to the total population of Canada.

Total number and description of samples collected

A total of 898 powdered infant formula samples were collected. Samples were limited to those labelled for newborns and infants aged 0 to 6 months and 0 to 12 months. A sample consisted of a single or multiple consumer sized packages of the same lot weighing at least 250 g.

What the samples were tested for

All samples were tested for *Cronobacter* spp. and Enterobacteriaceae. From April 1, 2021, to March 31, 2024, samples were also tested for *Salmonella* spp. *Cronobacter* spp. and *Salmonella* spp. are pathogenic bacteria while Enterobacteriaceae is an indicator of the overall hygienic and sanitary conditions under which the samples have been processed, stored, and transported.

Methods used to test the samples

Samples were analyzed using analytical methods published in Health Canada's *Compendium of Analytical Methods*¹¹ and the International Organization for Standardization¹² that were suitable for the testing of powdered infant formula.

How the samples were assessed

The samples were assessed using criteria based on the principles of Health Canada's *Good manufacturing practices for infant formula*¹³.

Table 1 - Assessment criteria

Bacteria	Satisfactory	Investigative	Unsatisfactory
<i>Cronobacter</i> spp.	Not detected in 125 g	Not applicable	Detected in 125 g
<i>Salmonella</i> spp.	Not detected in 125 g	Not applicable	Detected in 125 g
Enterobacteriaceae	Not detected in 10 g	Detected in 10 g	Not applicable

Survey results

99.7% of the samples tested were found to be satisfactory. *Salmonella* spp. was not detected in any (0 of 479) of the samples. *Cronobacter* spp. was detected in 1 of 898 (0.1%) samples. Enterobacteriaceae was detected in 2 of 898 (0.2%) samples.

Table 2 - Analysis assessment results

Bacteria	Number of samples tested	Satisfactory	Investigative	Unsatisfactory
<i>Cronobacter</i> spp.	898	897	Not applicable	1
<i>Salmonella</i> spp.	479	479	Not applicable	0
Enterobacteriaceae	898	896	2	Not applicable

Survey results are also presented by country of origin (table 3), production practice (table 4), and product type (table 5).

Table 3 - Assessment results by country of origin

Country of origin	Number of samples tested (%)	Satisfactory	Investigative	Unsatisfactory
England	2 (0.2)	2	0	0
France	8 (0.9)	8	0	0
Ireland	86 (9.6)	86	0	0
Netherland	14 (1.6)	14	0	0
United States	588 (65.5)	585	2	1
Unknown ^a foreign country	200 (22.3)	200	0	0
Total	898 (100)	895	2	1

Table 4 - Assessment results by production practice

Production practice	Number of samples tested (%)	Satisfactory	Investigative	Unsatisfactory
Conventional	804 (89.5)	802	1	1
Organic	94 (10.5)	93	1	0
Total	898 (100)	895	2	1

Table 5 - Assessment results by product type

Product type	Number of samples tested (%)	Satisfactory	Investigative	Unsatisfactory
Hypoallergenic	58 (6.5)	58	0	0
Milk-based	783 (87.2)	780	2	1
Soy-based	57 (6.3)	57	0	0
Total	898 (100)	895	2	1

What the survey results mean

A previous Canadian² study on the microbiological quality and safety of powdered infant formula showed similar prevalence rates of *Salmonella* spp. and lower prevalence rates of *Cronobacter* spp. and Enterobacteriaceae compared to the current study. Differing prevalence rates between studies may be attributable to differences in product types tested, product origin, study design, etc.

Overall, our survey results indicate that powdered infant formula sold in Canada is generally safe for consumption. However, as with all food, and especially those that are intended for infants, hygienic practices are recommended for producers, retailers, and consumers.

^a The product origin could not be assigned from the product label, or available sample information, however the product was imported into Canada.

What is done with the survey results

All results are used to:

- inform risk management decisions.
- support program design and re-design.

While no illnesses were related to the investigative and unsatisfactory samples, these results triggered appropriate follow-up actions including:

- food safety investigations
- follow-up with the retailer, importer, and manufacturer
- review of manufacturer production practices
- additional sampling and testing
- food recalls

Where to access the survey data

The data will be accessible on the [Open Government Portal](#).

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