



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

**Joint FAO/WHO expert meeting on microbiological risk assessment on powdered formula
for infants and young children**

FAO HQ, Rome, Italy, 15-19 June 2026

SUMMARY AND CONCLUSIONS

Issued in July 2026

A Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) on powdered formula for infants and young children was convened in Rome, Italy, from 15–19 June 2026 in response to the request by the fifty-fifth session of the Codex Committee on Food Hygiene (CCFH55). Outbreaks and recalls associated with powdered formula continue to occur across the globe caused by microorganisms such as botulinum neurotoxin (BoNT)-producing clostridia, *Cronobacter* spp., *Salmonella*, and by cereulide toxin produced by *Bacillus cereus*. The Expert Group reviewed recent scientific developments, data and evidence associated with these microorganisms and their toxins to provide recommendations for updating the guidance of the *Code of hygienic practice for powdered formulae for infants and young children* (CXC 66-2008).

This document summarizes the conclusions of the meeting. A full report will be published by FAO and WHO.

The meeting participants are listed in Annex 1 of this summary report. Emma Hartnett served as Chairperson.

More information on this work is available at:

<http://www.fao.org/food-safety/en/>

and

<https://www.who.int/foodsafety/en/>

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Background

In response to the request for scientific advice from the Codex Committee on Food Hygiene, JEMRA has provided scientific advice related to the safety of powdered formula for infants and young children since 2004. Past work has included the meetings and reports on *Enterobacter sakazakii* and other microorganisms in powdered infant formula (2004), *Enterobacter sakazakii* and *Salmonella* in powdered infant formula (2006), *Enterobacter sakazakii* (*Cronobacter sakazakii*) in powdered follow-up formula (2008) and also the risk assessment tool for *Cronobacter sakazakii* in powdered infant formula. These activities contributed to the development of the *Code of hygienic practice for powdered formulae for infants and young children* (CXC 66 - 2008).

Outbreaks and recalls associated with powdered formula continue to occur across the globe caused by microorganisms such as *Cronobacter sakazakii* and *Salmonella* spp., and recently *Clostridium botulinum*, and by cereulide toxin produced by *Bacillus cereus*. To address the issues and support a potential revision of CXC 66-2008, the fifty-fifth session of the Codex Committee on Food Hygiene (CCFH55) requested JEMRA to;

1. Conduct a risk assessment on spore-forming pathogens, including *Clostridium botulinum* and *Bacillus cereus*, in powdered formula;
2. Update the existing risk assessment and scientific advice on environmental pathogens (e.g. *Cronobacter* and *Salmonella*); and
3. Provide other relevant scientific advice that would inform recommendations on strengthened control measures across the production environment, covering all stages from primary production and packaging through to the reconstitution of the product, and including environmental monitoring programmes.

The meeting was convened to review the developments since the publication of previous JEMRA and Codex Alimentarius Commission documents on the subject; identify the information and data currently available and the knowledge gaps that need to be filled; and establish a pathway for addressing the food safety issues associated with powdered formula for infants and young children.

Powdered formula (PF) is subject to contamination with microbial pathogens and/or their toxins from multiple sources, including the component ingredients from which it is made and from environmental sources throughout the processing chain, up to and including the point at which it is reconstituted by the caregiver and fed to infants and young children. Prior works by JEMRA, the Codex Alimentarius Commission, and multiple public health authorities have identified a number of microbial pathogens and their toxins associated with illnesses and powdered formula.

A review of an expanded list of hazards previously identified by JEMRA was conducted with a focus to identify a priority group of microbial pathogens and/or their toxins that have been demonstrated to cause illness in infants and young children, linked to powdered formula. This priority group includes *Salmonella*, *Cronobacter* spp. and, based on this review, it was updated to include BoNT-producing Clostridia and *Bacillus cereus* sensu lato (s.l.) (cereulide).

The microbiological hazards identified by the previous JEMRA report still need to be watched. The Expert Group recommended that additional microorganisms (*Enterococcus*, *Pseudomonas*, and *Candida* spp.) should also be watched for increases in their risk potential in PF.

BoNT-producing clostridia

- The ingestion of BoNT-producing clostridial spores (not the ingestion of BoNT) results in infant botulism. In most infant botulism cases, the source of spores remains unknown.

- Low concentrations of BoNT-producing clostridial spores found in contaminated PF (<1 per 100g) present challenges in detection and enumeration requiring costly resources, laboratory authorizations and specialized skills.
- Indicators of BoNT-producing clostridial spores in PF should be evaluated for their feasibility and accuracy.
- BoNT-producing clostridial spores have previously been detected in PF but not definitively linked to infant botulism cases prior to 2025.
- Dairy ingredients have been demonstrated as a vehicle for BoNT-producing clostridial spores resulting in contamination of PF. Other potential sources of contamination require further investigation.
- Control of BoNT-producing clostridial spores starts with on-farm practices. Good agricultural practices and good on-farm hygiene practices that reduce spore counts may be applicable.
- The PF production processes are not designed to eliminate BoNT-producing clostridial spores. Mitigation strategies can potentially reduce spores prior to drying, and the effectiveness of these practices in reducing the risk of infant botulism should be explored.

Bacillus cereus

- *Bacillus cereus* sensu lato (s.l.), previously known as *Bacillus cereus* group, includes several species with high genetic similarities, but diversity of pathogenic traits that create challenges for conclusive species identification in routine diagnostics, outbreak investigations and surveillance.
- *Bacillus cereus* s.l., including emetic strains that can produce cereulide, have been detected in PF, but often the origin of contamination is unknown.
- Cereulide production during the manufacture of arachidonic acid (ARA) oil, an optional ingredient in infant formula, has been linked to infant illness. Cases of illness from the consumption of PF have not been directly attributed to *Bacillus cereus* s.l. bacteria in PF.
- *Bacillus cereus* s.l. is ubiquitous and its entrance into the PF production and processing environment cannot be entirely avoided. Contamination of PF with *B. cereus* s.l. can occur at multiple steps in the production and processing chain.
- Controlling the growth and toxin production of *B. cereus* s.l., particularly for emetic *B. cereus* capable of producing cereulide, is critical throughout all stages of production, processing, preparation and storage.
- Cereulide toxin is highly stable and is neither inactivated nor removed by hygienic or control measures in PF manufacturing/production.
- As the presence of cereulide in the absence of *B. cereus* s.l. has been demonstrated in ingredients where *B. cereus* s.l. was removed in the production process relying on *B. cereus* s.l. enumeration as the sole indicator of the likelihood of cereulide presence is insufficient.

Cronobacter spp. and *Salmonella*

- Illnesses caused by *Cronobacter* spp. and *Salmonella* acquired from contaminated PF continue to occur, highlighting the continued need for risk mitigation strategies.

General Considerations

- Recent illnesses attributed to the consumption of contaminated PF highlight the need to address BoNT-producing clostridia and cereulide toxin produced by *Bacillus cereus* s.l. as relevant hazards in PF and PF ingredients.
- Over the past 20 years, ingredient diversity, including optional ingredients, different ingredient formulations, production methods, and the complexity of the supply chain have increased.
- The production of PF includes a number of processing steps. Each step includes risk mitigation considerations and their effectiveness varies by pathogen at each step in the production process.
- Powdered formula manufacturers should implement supplier risk management programs addressing BoNT-producing clostridia and cereulide toxin produced by *Bacillus cereus* s.l. in ingredients.
- Good Hygienic Practices (GHP) in PF manufacturing could be enhanced especially regarding processing area segregation, limiting line breaches, relative humidity control, along with strengthened pathogen environmental monitoring.
- The Expert Group reaffirms the importance of controlling moisture and limiting the use of wet sanitation in PF manufacturing as described in GHP.
- Hygiene indicators such as Enterobacteriaceae monitoring do not replace or reduce the need for pathogen-specific testing during environmental monitoring.

Conclusions

- Root cause analysis should be enhanced by industries and governmental agencies following process control failures, including contamination events.
- There is a lack of collecting, reporting and sharing of surveillance data on the burden of diseases attributed to PF. Such data would inform risk assessment.
- Current consumer preparation recommendations designed to reduce the risk posed by *Salmonella* and *Cronobacter* spp. may not be effective for the control of BoNT-producing clostridial spores and growth and toxin production by *Bacillus cereus* s.l.. Further analysis is required.
- Consumers often rely on social media for information about infant feeding, including time-saving practices and feeding products. Risk messaging on PF preparation, handling and storage by caregivers to ensure the safety of PF needs to adapt to these changing consumer behaviours.
- Preparation methods continue to change and these should be considered in future risk assessments to ensure current practices are reflected in risk reduction recommendations.
- Conducting risk assessments for some toxin-producing microorganisms poses challenges in terms of differences in risk assessment methodologies between microorganisms and chemical toxins. Consideration should be given to these differences.
- The Expert Group compiled relevant data and information to identify knowledge gaps and to support future risk assessments on BoNT-producing clostridia and *Bacillus cereus* s.l. (cereulide).

Annex 1: List of participants

EXPERTS

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Annex 2: Recommendations on the modification of Codex Alimentarius documents

Disclaimer: The following recommendations may be updated following availability of risk assessment results.

Throughout the document:

- Update *Enterobacter sakazakii* to *Cronobacter* spp.
- Update to include BoNT-producing clostridia.
- Update to include cereulide toxin as a result of its involvement in cases of illness in 2026, and *B. cereus* sensu lato (the organism producing cereulide) for the potential as an indicator of process control.

Introduction

- Expand to cover PF ingredients and not just PF.
- Update to include latest information on the number of cases of illness.

2.1.2 Roles of Governments, industry, and Consumers

- Expand to include additional on-farm practices to reduce spore loads on dairy ingredients destined for PF production.

Section III – Primary Production

- Consider the inclusion of a section for steps during primary production that may reduce spore load.

4.2.1 Design and layout

- Include the need for sloped equipment to promote residue removal.
- Expand to include additional methods to prevent *Cronobacter* spp. ingress and transfer during PF manufacturing that exceed what is minimally described in the GHP.

4.2.2 Internal structures and fittings

- Include additional considerations when extreme weather events or natural disasters occur, for example considerations for maintaining designated dry areas during extreme rainfall events.

4.3.1 General

- Include the need to reduce line breaches (i.e., compromising the integrity of the line).

5.2.4 Microbiological cross-contamination

- Include that Enterobacteriaceae testing in an environmental monitoring program does not replace or reduce the need for *Cronobacter* spp. testing.

9.4 Education

- Expand education and communication with caregivers to specify that honey is a high-risk food for infants due to BoNT-producing clostridia.
- Expand education on consumer safety during PF preparation, handling and storage.