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Supporting document 4

Microbiological assessment

Proposal P1066 – Review of young child formula

Executive summary

Food Standards Australia New Zealand (FSANZ) undertook a microbiological assessment of powdered young child formula (for children aged 1–3 years) under Proposal P1066 to inform risk management decisions relating to microbiological criteria, preparation requirements and existing non-regulatory guidance. This work builds on earlier FSANZ assessments of powdered infant and follow-on formula (Proposals P1028 and P1039) and addresses the absence of Codex-specified microbiological safety criteria for most young child formula products.

A semi-quantitative microbiological risk assessment, consistent with international guidance has been completed. The assessment compared estimated risks under different microbiological criteria at end of formula manufacture and caregiver preparation scenarios. The assessment focused on the public health risk associated with *Cronobacter* and *Salmonella* in powdered young child formula consumed in Australia and New Zealand. The level of protection estimated for infants aged < 6 months under existing Australia and New Zealand Food Standards Code (the Code) requirements for infant-formula was used as the reference baseline. Different combinations of microbiological criteria and preparation scenarios were assessed to determine what would provide an estimated level of protection for young child formula comparable to the infant baseline. The scenarios included:

- Levels of hazards in the Australia and New Zealand formula supply were assessed under infant-formula-equivalent microbiological criteria.:
    - *Cronobacter*: not detected in 30 × 10 g
    - *Salmonella*: not detected in 60 × 25 g
- Estimated levels of hazards were also assessed under scenarios with no microbiological criteria.
- For *Salmonella*, additional sensitivity analyses were conducted using less stringent microbiological criteria.
- Infant-formula-equivalent preparation and handling scenarios, based on the current Code labelling requirements for microbiological safety, represented best practice in the assessment. Under these conditions, no microbial growth was assumed before a bottle was consumed:
    - Reconstitution using potable water that has been previously boiled and cooled.
    - Bottle fed immediately after preparation over a maximum of 2 h and any remaining formula is discarded and not reused.

    - If pre-prepared,
    - the bottle is stored before feeding in a refrigerator at no more than 5°C for a maximum of 24 h.
- Suboptimal scenarios represented plausible household deviations from best-practice preparation and handling. These scenarios assessed the impact of different time and temperature conditions:
    - Suboptimal reconstitution: using non-preboiled or non-potable water or poor hygiene which may introduce other contaminating microorganisms.
    - Suboptimal feeding time: bottle feeding extended beyond best practice, with most formula consumed after 4 h out of refrigeration at approximately 27 °C.
    - Suboptimal refrigerated storage: if pre-prepared, the bottle is stored before feeding in a refrigerator at 8 °C for 48 hours before feeding.
    - Suboptimal ambient storage: if pre-prepared, the bottle is left on the bench before feeding for 4 h at 27°C.
    - Worst case preparation scenario: combination of suboptimal preparation including reconstitution, feeding time and ambient storage.

The risk assessment showed that the severity and susceptibility associated with *Cronobacter* vary by age. Severe illness is predominantly associated with infants under six months of age. Susceptibility and severity are lower in children aged 1–3 years. Modelling indicated that, for young children, estimated *Cronobacter* risk remained well below the infant baseline across all scenarios assessed. This included scenarios without infant-formula-equivalent microbiological criteria. On this basis, microbiological criteria were not identified as a primary risk reduction measure for *Cronobacter* in young child formula when assessed on risk alone, although infant-formula-equivalent preparation and handling remain important controls.

In contrast, *Salmonella* poses a substantial risk across early childhood without the similar age-related reduction in susceptibility or severity to *Cronobacter*. Modelling showed that scenarios without infant-formula-equivalent microbiological criteria can result in increased risk for children aged 1–3 years. This was particularly evident when combined with suboptimal preparation steps inconsistent with infant formula expectations. Under these conditions, estimated risks approached or exceeded the infant baseline. The combined application of infant-formula-equivalent microbiological criteria for *Salmonella* and infant-formula-equivalent preparation steps resulted in lower estimated risk for young children relative to the infant baseline. This combination provided more robust levels of protection where consistent best-practice preparation cannot be assumed.

The existing non-regulatory infant formula product relevant guidance in FSANZ Compendium of Microbiological Criteria was reviewed for applicability to young child formula. This review examined whether the Compendium's non-regulatory process hygiene criteria, indicator organisms and verification testing guidance used for powdered infant formula are applicable to young child formula. Given the shared manufacturing processes and contamination risks, extending this non-regulatory framework to young child formula was considered appropriate.

Overall, this risk assessment provides a scientific basis to inform regulatory decisions under Proposal P1066. Under the specified model assumptions, applying infant-formula-equivalent microbiological criteria for *Salmonella* together with infant-formula-equivalent preparation steps to young child formula results in an estimated level of protection for Australian and New Zealand children aged 1–3 years that is comparable to the level of protection currently modelled for infants under existing Australia and New Zealand Food Standards Code requirements.

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1 Microbiological risk assessment

1.1 Purpose and introduction

Food Standards Australia New Zealand (FSANZ) has undertaken a microbiological risk assessment for powdered young child formula (formula for children aged 1–3 years) as part of Proposal P1066 (FSANZ 2025b).

This work builds on earlier FSANZ proposals P1039 (FSANZ 2016) and P1028 (FSANZ 2024) which introduced microbiological criteria and labelling requirements for powdered infant and follow-on formula to align with international benchmarks established by the Codex Alimentarius Commission (Codex) (Codex 2009, 2023, 2024). Young child formula was not in scope of those earlier proposals and is treated in the Australia New Zealand Food Standards Code (the Code) as a formulated supplementary food.

The assessment will help guide decisions about whether risk management measures for young child formula should align more closely with those already applied to powdered infant and follow-on formula, and whether such controls could provide an appropriate and proportionate level of public-health protection for young children.

1.2 International context and Codex framework

A detailed comparison of the Codex standard requirements relevant to microbiological safety has been provided in Appendix 1 for infant, follow-on and young child formula based on:

- Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants CXS 72-1981 amended in 2024 (Codex 2024), and
- The Codex Standard for Follow-up formula for Older Infants and Product for Young Children CXS 156-1987 revised in 2023 (Codex 2023).

In summary, the Codex requirements for infant, follow-on and young child formula are broadly aligned for labelling of best practice preparation instructions to reduce microbial risks. While the product definitions and target age groups differ, Codex applies the same overarching requirements across all three categories (Codex 2023, 2024). In terms of microbiologically safety the common required instructions for use cover:

- Ready to use products in liquid form should be used directly.
- Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use.
- Adequate directions for the appropriate preparation and handling should be in accordance with good hygienic practice.
- Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.
- The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.
- Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.

Only CXS 72-1981 for infant formula has an optional ingredient for L (+) lactic acid-producing cultures. CXS 72-1981 states only L (+) lactic acid-producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final product

should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk. The safety and suitability of the addition of specific strains of L (+) lactic acid-producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

The Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008) applies to powdered formula specifically manufactured to be used for infants[1] and young children[2] either as a breast milk substitute, to supplement infant formula or fortify human milk or in combination with other foods as part of the weaning diet for older infants and young children (Codex 2009). CAC/RCP 66-2008 recommends the following:

- Powdered infant formula, formula for special medical purposes and human milk fortifiers:
    - Microbiological safety criteria for
        - *Cronobacter* (not detected in 30 samples of 10 g)
        - *Salmonella* (not detected in 60 samples of 25 g)
    - Process hygiene criteria
        - Standard Plate Count (from 5 samples a batch fails if any sample exceeds 5,000 CFU/g or if two exceed 500 CFU/g)
        - Enterobacteriaceae (Ten 10-gram samples are tested as part of routine process hygiene monitoring. Results are acceptable if no more than two samples show detectable Enterobacteriaceae. Detection above this level indicates a loss of hygienic control and requires investigation and corrective action.)
- Powdered follow-up formula and formula for special medical purposes for young children*:*
    - Microbiological safety criteria *Salmonella* (sampling plans the same as infant formula).
    - Process hygiene criteria for Standard Plate and Enterobacteriaceae (sampling plans the same as infant formula).
- Emphasises the importance of Good Hygienic Practices (GHP) and Hazard Analysis and Critical Control Points (HACCP) systems in manufacturing.
- Provides guidance on environmental monitoring, especially in high-hygiene areas (food contact surfaces inside the equipment located after the dryer and prior to packaging and which present a higher risk), and outlines procedures for cleaning, sanitation and contamination control.

Food safety criteria are microbiological criteria that define the acceptability of a food or a batch of food with respect to consumer health. Codex recognises food safety criteria are appropriate where they contribute to consumer protection and are supported by scientific risk assessment. These criteria are generally mandatory when adopted into national legislation and are used by competent authorities for enforcement. However, Codex has only established recommendations for *Salmonella* for young child formula used for special medical purposes. Codex recommends that establishment of microbiological safety criteria for most young child formula should be undertaken by the competent authority guided by local risk assessments and Codex principles (CXG 21-1997, CXS 156-1987, CAC/RCP 66-2008, CXC 1-1969, CXS 193-1995).

[1] a person not more than 12 months of age.
[2] persons from the age of more than 12 months up to the age of three years (36 months).

In 2016, Proposal P1039 introduced microbiological safety criteria into the Code under Schedule 27 based on the Codex recommendations for:

- powdered infant formula products (excluding follow-on formula): *Cronobacter* not detected in 30 × 10 g samples, and
- powdered infant and follow-on formula products: *Salmonella* not detected in 60 × 25 g samples.

However, young child formula was not in scope for Proposal P1039 and there is no existing Australian New Zealand risk assessment to inform the need for microbiological criteria.

Key Message

Codex instructions for use relevant to microbiological safety are the same for infant, follow-on and young child formula. Codex leaves the establishment of microbiological safety criteria for most young child formula to national authorities, guided by local risk assessments and Codex principles[3]. Good hygienic practices, process controls and clear labelling are considered essential for ensuring product safety.

[3] See: CXG 21-1997, CXS 156-1987, CAC/RCP 66-2008, CXC 1-1969, CXS 193-1995.

1.3 Rationale for undertaking a microbiological risk assessment

Previous international risk assessments conducted by the Joint Food and Agriculture Organization of the United Nations and World Health Organization and (FAO and WHO) informed the development of microbiological criteria for powdered infant and follow-on formula (FAO and WHO 2006, 2008). These assessments focused on infants, reflecting their high susceptibility to severe illness.

Proposal P1066 builds in this evidence base by extending the assessment to young children formula for children aged 1-3 years. The FSANZ assessment applies internationally recognised risk-assessment principles to compare microbiological risks across age groups, microbiological criteria scenarios, and preparation practices, using estimates for infants aged < 6 months as the baseline.

1.4 Risk assessment approach and scope

FSANZ conducted this risk assessment in accordance with the Joint World Health Organization & Food and Agriculture Organization of the United Nations *Microbiological Risk Assessment Guidance for Food* (FAO and WHO 2021). Consistent with this guidance, a semi-quantitative risk-assessment approach was adopted for Proposal P1066. This approach is appropriate where data are limited but key exposure pathways, hazards and risk determinates are well characterised. The guidance also suggests explicit identification of data gaps and limitations relevant to the risk assessment.

1.4.1 Scope

This assessment compares the risk of illness associated with *Cronobacter* spp. and *Salmonella* spp. in powdered formula consumed by infants (0–6 months and 6–12 months) and young children (1–3 years) in Australia and New Zealand. Infants aged 0–6 months were used as the baseline population, reflecting the level of protection currently modelled under existing Code requirements. Comparing estimated risks for young children against this benchmark supports proportionate, risk-based regulatory decision-making for young child formula.

The scenarios assessed were combinations of:

- Estimated levels of hazards in the Australia and New Zealand formula supply were assessed under infant-formula-equivalent microbiological criteria.:
    - *Cronobacter*: not detected in 30 × 10 g
    - *Salmonella*: not detected in 60 × 25 g
- Estimated levels of hazards were also assessed under scenarios with no microbiological criteria.
- For *Salmonella*, additional sensitivity analyses were conducted using less stringent microbiological criteria.
- Infant-formula-equivalent preparation and handling scenarios, based on the current Code labelling requirements for microbiological safety, represented best practice in the assessment. Under these conditions, no microbial growth was assumed before a bottle was consumed:
    - Reconstitution using potable water that has been previously boiled and cooled.
    - Bottle fed immediately after preparation over a maximum of 2 h and any remaining formula is discarded and not reused.
    - If pre-prepared, the bottle is stored before feeding in a refrigerator at no more than 5°C for a maximum of 24 h.

- Suboptimal scenarios represented plausible household deviations from best-practice preparation and handling. These scenarios assessed the impact of different time and temperature conditions:
    - Suboptimal reconstitution: using non-preboiled or non-potable water or poor hygiene which may introduce other contaminating microorganisms.
    - Suboptimal feeding time: bottle feeding extended beyond best practice, with most formula consumed after 4 h out of refrigeration at approximately 27°C.
    - Suboptimal refrigerated storage: if pre-prepared, the bottle is stored before feeding in a refrigerator at 8°C for 48 hours before feeding.
    - Suboptimal ambient storage: if pre-prepared, the bottle is left on the bench before feeding for 4 h at 27°C.
    - Worst case preparation scenario: combination of suboptimal preparation including reconstitution, feeding time and ambient storage.

All references to *Salmonella* in this assessment refer to non-typhoidal *Salmonella enterica* (typhoidal *Salmonella enterica* includes human adapted pathogens transmitted via water or sanitation pathways not relevant to this assessment).

A semi-quantitative, spreadsheet-based model was used to integrate information on hazard presence, exposure patterns, preparation and handling practices, and illness severity. The approach was adapted from an internationally recognised semi-quantitative model (Ross and Sumner 2002) and risk assessments undertaken by FAO and WHO on infant and follow-on formula (FAO and WHO 2006, 2008).

1.4.2 Modelling approach, inputs and calculations summary

The model compared relative microbiological risk across hazards, age groups, microbiological criteria and preparation scenarios. A concise overview of model inputs, calculations and outputs is provided in Table 1. The model was adapted from Ross and Sumner (2002), and integrates information on hazard identification, hazard characterisation, exposure assessment and risk characterisation in a transparent manner. The following sections describe inputs and evidence for each section.

Table 1: Summary of model inputs and outputs used in the semi-quantitative microbiological risk assessment, with references to the sections describing how each input was derived.

Model outputs	Description	Calculation	Relevant Section
Prob_exp	Probability of exposure to the product per person per day.	= Frequency_consumption * Proportion_consuming	4.1
PDD	Probability of a disease-causing dose being present in the daily amount consumed	= Hazard_level * Illness_dose * Prep_effect The probability of a portion of food being contaminated with disease-causing dose cannot exceed 1. Accordingly, if the value of the above calculations exceeds 1,	4.2

		it is set equal to 1.	
Prob_ill_day	Probability of illness per consumer per day	= PDD * Pexp	5
Comparative_risk	The comparative risk estimate includes consideration of severity.	= ProbIll_day * Severity	5
Model Inputs	**Descriptor**	**Input examples from the baseline scenario**	**Relevant Section**
Hazard_severity	How severe is the outcome in the target population. This is a multiplier (1 most severe or < 1) based on information of severity of outcomes due to illness.	*Cronobacter* (infants 0–6 months) severe illness, high mortality and hospitalisation. Input = 1	3.1
Population_size	This is the total population size of interest, not just those that consumer the product.	Total number of infants aged 0 – 6 months in Australia and New Zealand. Input = 175,910	4.1
Proportion_consuming	This is the proportion of the total population of interest that consume the product.	72% of infants aged 0-6 months in Australia and New Zealand consume formula. Input = 0.72	4.1
Frequency_consumption	This is how frequently the product is consumed per unit of interest per person per year	Daily consumption assumed for infants aged 0–6 months. Input = 365	4.1
Hazard_level	This is the probability or proportion of contaminated product at the point of testing at end of manufacturing.	Probability of *Cronobacter* level with existing criteria calculated. Input = 0.007	4.2
Illness_dose	What is the increase in the hazard_level needed after manufacture to reach the average infectious dose for the consuming population? This is applied as a scaling	*Cronobacter* – infants 0–6 months baseline significant increase required (100,000-fold increase) Input = 0.00001	4.2

	factor (≤1).		
Prep_effect	What is the effect of preparation on the hazard. This is a multiplier (> 1 increase < 1 decrease) based on the amount of growth or inactivation of the hazard.	Baseline example: No net effect on the hazard = 1 (infant-formula-equivalent preparation and handling). Input = 1	4.2

2 Hazard identification

The microorganisms identified in P1039 (FSANZ 2016) and by the FAO and WHO in their expert meetings (FAO and WHO 2006, 2008), are not only relevant hazards to infant formula but also for young child formula. Young child formula shares the same characteristic with powdered infant formula because it is not sterile. As a result, contamination during manufacture, packaging or preparation can pose a health risk to children (FAO and WHO 2006, FAO and WHO 2008, Silano et al. 2016, Codex 2024, Donaghy et al. 2025).

The FAO and WHO classified *Cronobacter sakazakii* and *Salmonella* as Category A pathogens, meaning there is clear evidence linking them to illness in infants (FSANZ 2016). These pathogens have been responsible for severe infections such as meningitis, sepsis and gastroenteritis, which can lead to long-term complications or even death (FAO and WHO 2006, 2008). Although well-documented formula associated outbreak clusters in children aged 12–36 months are rare, there are several factors that affect the detection, identification and attribution of illness in this age group (FAO and WHO 2006, 2008). Evidence for young children is limited to a very small number of isolated cases rather than outbreaks. This pattern is consistent not only with pathogen-related differences in susceptibility and severity, but also with reduced exposure specificity and substantial challenges in attributing illness to formula once diets diversify beyond infancy. In older infants and young children, exposure pathways are more complex due to consumption of a wide range of foods. Accordingly, the limited documented outbreaks in young children must not be interpreted as absence of hazard or risk. For these reasons, *Cronobacter* and *Salmonella* are also key microbiological hazards for formula consumed by young child formula (FAO and WHO 2008, Paswan and Park 2020, Ling et al. 2022, Molina-Hernandez et al. 2025).

2.1 Australian and major international recalls of formula products

Salmonella, *Cronobacter*, *Clostridium botulinum* and cereulide toxin produced by *Bacillus cereus* have all been responsible for major recalls of formula since 2016. Table 2 provides an overview of major recalls of infant and young child formula that have occurred in Australia and internationally since 2016. While most events involve infant formula, they demonstrate the types of microbiological hazards that can arise in powdered formula products more broadly. Australia has experienced relatively few large-scale recalls, however, availability of imported products means that global contamination events can directly affect the Australian and New Zealand supply, as seen in 2025–2026. These recalls provide supporting context for the hazard identification and potential consequences of contamination events relevant to Proposal P1066.

Table 2: Overview of major recalls of infant formula and young-child drinks (including young child formulas and children's nutritional beverages) that have occurred in Australia and internationally since 2016.

Year	AU/NZ impact	Country / Region	Products affected	Reason for recall	Health impact reported	Sources
2017	No direct AU/NZ impact	Europe / global (Craon, France)	Infant	*Salmonella*	>35 confirmed infant salmonellosis cases in France; additional cases internationally; hospitalisations reported.	(WHO2017) (Eurosurveillance 2017)
2022	AU + NZ (recall action taken)	Australia; New Zealand; US/global	Infant	*Cronobacter Salmonella*	Total Adverse Events: 4 Hospitalizations: 4 Reported Deaths: Two deaths have been reported. *Cronobacter* infection may have contributed to the cause of death for both patients. AU/NZ: no local cases reported	(FDA 2022) (CDC 2025a) (FSANZ 2022) (NZMPI 2022)
2022	AU	Australia	Infant	*Cronobacter*	No illnesses reported	(New South Wales Health 2022)
2023	No direct AU/NZ impact	United States	Infant	*Cronobacter*	No illnesses reported	(FDA 2023)
2025 – 2026	No direct AU/NZ impact	United States	Infant	*Clostridium botulinum*	Cases: 48 Hospitalizations: 48 No deaths confirmed in official updates	(CDC 2025b) (FDA 2026b)
2025 – 2026	AU + NZ (recalls undertaken)	Multi-country (Europe + global expansion) Australia; New Zealand	Infant	Cereulide toxin produced by *Bacillus cereus*	EFSA: low exposure risk overall; some countries report symptomatic cases (vomiting, GI illness) No illnesses reported in AU or NZ at time of recall	(EFSA 2026) (FSA 2026) (FSANZ 2026b) (FSANZ 2026a) (NZMPI 2026)

At the time of drafting this assessment, Codex have noted the recent outbreaks and recalls associated with powdered formulae (JEMRA 2026). To address the issues and support a potential revision of the Code of Hygienic Practice for powdered Formulae for Infants and Young Children (CXC 66-2008), the fifty-fifth session of the Codex Committee on Food Hygiene requested the FAO and WHO Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) to:

(i) conduct a risk assessment on spore-forming pathogens, including *Clostridium botulinum* and *Bacillus cereus*, in powdered infant formula.
(ii) update existing risk assessments and scientific advice for *Cronobacter* spp. and *Salmonella* spp.; and

(iii) provide additional scientific advice to inform recommendations on strengthened control measures across the production environment, from primary production and packaging through to product reconstitution, including environmental monitoring programmes. This ongoing international work will help inform future risk management considerations as new evidence becomes available.

JEMRA has now issued a call for experts and data for this assessment (JEMRA 2026). The outcomes of this work will be monitored by FSANZ.

2.2 Consideration of spore forming bacteria

A recent outbreak of infant botulism in the USA caused by the presence of *Clostridium botulinum* Type A spores in powdered infant formula (2023-2025) has been linked to use of contaminated whole organic milk as an ingredient (CDC 2026, FDA 2026a). This is the first time since infant botulism was clinically distinguished more than 50 years ago, that it has been link to infant formula. Honey is the one known dietary reservoir of *C. botulinum* spores linked to infant botulism by both laboratory and epidemiologic studies, resulting in guidance to avoid feeding honey to infants under 12 months old, noting that the risk of illness decreases as the infant gut microbiome develops (Harris and Dabritz 2024). *C. botulinum* is a hazard to be identified and manged for powdered formula for all children (FDA 2026a).

C. botulinum is a spore-forming bacterium with extreme environmental persistence (FDA 2026a). Its spores are ubiquitous in the environment, resistant to routine heat treatments used in dairy and formula ingredient processing, and can survive for prolonged periods in dry foods, including powdered formula (FDA 2026a). The presence of spores does not necessarily indicate a direct health risk, as illness depends on spore viability, germination and in-gut toxin production, which primarily occurs in infants with immature gastrointestinal systems (FDA 2026a). Older children and adults with established gut microbiota are not considered susceptible to infant botulism but can still be at risk from botulinum toxin (FDA 2026a). Botulinum toxin production requires viable *C. botulinum* spores to germinate into vegetative cells under anaerobic, moist, low-acid, temperature-permissive conditions with limited microbial competition over sufficient time. Investigations into the outbreak remain ongoing, including ingredient- and environment-focused assessments by the FDA and affected manufacturers (FDA 2026a). Outcomes of these investigations, together with continued monitoring by regulatory agencies, will inform whether future risk-assessment are warranted. Outbreaks of botulism outbreaks are rare in Australia and only 2 notifications were reported between 2011 and 2015 (OzFoodNet Working Group 2025).

Recent detections of cereulide, an emetic toxin produced by the spore-forming bacteria *Bacillus cereus,* in infant formula and the potential link to illnesses in Europe has resulted in worldwide recalls of affected product (EFSA 2026). Cereulide found in arachidonic acid oil, an omega-6-fatty acid used in infant formula, is most likely the source of the toxin which is extremely stable and unlikely to be inactivated by further processing. The European Food Safety Authority (EFSA) conducted a rapid risk assessment to support risk management following the detection of cereulide in infant formula (EFSA et al. 2026). EFSA concluded that infants, particularly those below 16 weeks of age, are the most critical population for cereulide risk assessment due to their high formula consumption relative to body weight and immature metabolic and excretory capacity, and therefore derived an infant-specific acute reference dose (EFSA et al. 2026). While young children are less exposed because of lower relative formula intake and more diverse diets, EFSA recognised that they remain susceptible to cereulide toxicity and therefore also considered follow-on formulae and foods for special medical purposes for children in its assessment (EFSA et al. 2026). *B. cereus* is not a notifiable disease in Australia, however limits for the bacterium (not the toxin cereulide) are currently included in non-regulatory guidance for infant formula in the FSANZ

Compendium (FSANZ 2025a).

2.3 Justification for hazards included in the semi-quantitative assessment

The semi-quantitative assessment focuses on hazards for which sufficient evidence exists to support structured, comparative scoring of severity and likelihood of illness. *Cronobacter* and *Salmonella* were included because they have well-established associations with powdered formula, available data for hazard characterisation, available data for exposure assessment and remain priority hazards under Codex, FAO and WHO frameworks (FAO and WHO 2021).

Other microorganisms, including spore-forming bacteria such as *C. botulinum* and *B. cereus*, were not included in the semi-quantitative assessment because of the different exposure, limited hazard characterisation data, limited Australian data, and that these microorganisms are currently part of dedicated international risk-assessment work. These hazards are addressed qualitatively and will be reconsidered as new evidence becomes available. Specifically, guidance may be considered for the FSANZ Compendium (FSANZ 2025a). FSANZ will consider the outcomes of the JEMRA assessments and affected populations once published.

2.4 Risk profile differences for *Cronobacter* and *Salmonella* among infants and young children

The scope of the risk assessment was for *Cronobacter* and *Salmonella*. Recent reviews provide comprehensive insights into the biology, pathogenicity and risk factors associated with *Salmonella* spp. (Crump et al. 2015, Wen et al. 2017, Marchello et al. 2022, Takahashi et al. 2022) and *Cronobacter*. (Ling et al. 2022, Phair et al. 2022, Ortiz et al. 2023, Negi et al. 2024, Yan et al. 2024), including in vulnerable populations such as infants and young children.

Young children (1–3 years) have a different risk profile for foodborne pathogens in formula than infants under 12 months. In the first months of life, infants are uniquely vulnerable: some may rely exclusively on formula, have immature immune systems, and lack robust gut flora and stomach acid defences. By 12 months, many of these risk factors are reduced but are still not considered to be reduced as far as adults. Children less than 3 are still considered a vulnerable population to foodborne illness.

2.4.1 Age-related risk of Cronobacter infection

The risk of *Cronobacter* infection varies with age, with severe and invasive illness concentrated in very young infants and lower susceptibility observed in older infants and young children. Table 3 summarises recent epidemiological and clinical evidence reviews for age-related differences in susceptibility and severity used to inform the risk assessment for *Cronobacter*.

Table 3: Age-related differences in susceptibility and severity of Cronobacter infection in infants and young children, based on epidemiological and clinical evidence.

Age group	Susceptibility and severity	Key evidence and considerations	References
Infants <6 months	Very high susceptibility: severe	*Cronobacter* causes rare but severe infections in infants, including meningitis, sepsis and gastroenteritis.	(FAO and WHO 2006, 2008, Strysko et al. 2020, Morais

	outcomes reported	Reported case-fatality rates for neonatal meningitis range from approximately 30% to 80% The majority of severe invasive *Cronobacter* infections have occurred in infants under six months of age, especially <2 months	et al. 2022, Donaghy et al. 2025) .
Infants 6–12 months	Reduced susceptibility; severe illness uncommon	Susceptibility decreases after the neonatal period, consistent with maturation of immune and gastrointestinal defences. Invasive disease in this age group is uncommon, although sporadic cases have been reported, including in infants with underlying medical conditions. Continued consumption of powdered formula means exposure remains possible; reported illness is generally less severe than in infants under six months.	(FAO and WHO 2006, 2008, Holy and Forsythe 2014, Jason 2015, Donaghy et al. 2025).
Young children 12 months–3 years	Low susceptibility; infections rare and typically sporadic	Infections are rare and are more often reported in the context of underlying vulnerabilities. FAO and WHO (2008) identified two well-described invasive *Cronobacter* cases globally in children aged 12–35 months, both involving underlying medical conditions (posterior fossa dermoid cyst; Kasabach–Merritt syndrome with recent chemotherapy). One child had consumed a follow-up/young child formula marketed for 9–24 months.	(FAO and WHO 2006, 2008, Holy and Forsythe 2014, Jason 2015, Donaghy et al. 2025).

2.4.1.1 Cronobacter severity

Strysko et al. (2020) reviewed all US reported cases of invasive *Cronobacter* infections (bloodstream infection or meningitis) among infants from 1961 to 2018, drawing on CDC data and published literature. These data show that invasive *Cronobacter* infection occurs predominantly in the neonatal period. Of the 150 reported cases, 67% (100 cases) occurred in infants aged less than 28 days, and 95% (140 of 148 cases with age reported) occurred within the first two months of life. The median age at symptom onset was 13 days (interquartile range 7–28 days). Historically, invasive infections were most commonly reported in hospitalised and preterm infants, particularly outside the United States. The more recent US data indicate a shift toward a higher proportion of cases occurring in full-term and non-hospitalised infants. Prior to 2004, 22% (4/18) of reported cases involved full-term infants; this proportion increased to 56% (27/48) in cases reported between 2004 and 2018. Similarly, the proportion of non-hospitalised cases increased from 44% (8/18) before 2004 to 78% (42/54) in the later period. Outside the United States, reported cases remained more concentrated in hospitalised and preterm infants, with 31% (11/47) occurring in full-term infants and 15% (7/47) in non-hospitalised infants. Across all reported invasive cases with outcome data available, the overall case-fatality rate was 38% (42/112) and did not show a significant change over time. Collectively, these findings indicate that invasive *Cronobacter* infection remains strongly concentrated in neonates and very young infants, with severe

outcomes reported across settings, while also highlighting changes over time in the characteristics of affected infants in the United States.

Jason (2015) synthesised several decades of global surveillance data and outbreak investigations to characterise the epidemiology, clinical presentation and risk factors associated with invasive *Cronobacter* infections in infants. The review found that nearly all severe, invasive infections occur in infants under six months of age, with the highest risk concentrated in those less than two months old. Among previously healthy infants, 99% (95 of 96 cases) occurred in infants aged two months or younger, and 83% (80 of 96 cases) occurred in infants aged one month or younger. Clinical illness in this age group was frequently severe. Reported manifestations included meningitis (61% of cases) and bacteraemia (36% of cases), often accompanied by serious complications such as seizures, hydrocephalus, developmental delay and death. Earlier reports predominantly involved premature infants; however, more recent data indicate an increasing proportion of cases occurring in full-term infants. Feeding practices were identified as an important exposure factor, with 90% of invasively infected infants having received powdered infant formula prior to illness onset, while only 4% were exclusively breastfed. In contrast, invasive *Cronobacter* infection was extremely rare in infants aged 6–12 months, with only a single case identified in the dataset. No cases of severe, invasive *Cronobacter* infection were reported among previously healthy children aged 1–3 years, and the risk in this age group was considered substantially lower than that observed in infants under six months.

2.4.1.2 Data gaps and limitations

There are several data gaps and limitations that affect the interpretation of risk and severity estimates for *Cronobacter* disease in children:

- Most reported cases and severity data are concentrated in infants younger than two months of age, with very few documented cases in older infants or young children.
- As a result, estimates of risk and severity for the 6–12 month and 1–3 year age groups are based on a much smaller body of evidence and should be interpreted in that context.
- Much of the available information comes from historical studies and international datasets, which nevertheless show a consistent and marked decline in both incidence and severity with increasing age.
- The limited number of reported cases in older infants and children, together with the absence of routine surveillance for mild or sporadic infections, means that available data primarily reflect severe, clinically recognised disease rather than the full spectrum of infection.

2.4.2 Age-related risk of Salmonella infection

Age dependent susceptibility to *Salmonella* infection is less pronounced than *Cronobacter*, with young infants and young children remaining susceptible to illness and, in some cases, severe outcomes. Table 4 summarises recent epidemiological and clinical reviews informing age-related assumptions on susceptibility and severity used in the risk assessment.

Table 4: Age-related differences in susceptibility and severity of Salmonella infection in infants and young children, based on epidemiological and clinical evidence.

Age group	Susceptibility and severity	Key evidence and considerations	References
Infants <6 months	High susceptibility: more severe	*Salmonella* can cause illness across all age groups; however, severity is disproportionately higher in young	(FAO and WHO 2006, 2008, Ao et al. 2015, Wen et al.

	outcomes reported	infants. Contaminated powdered infant formula has been implicated in serious cases of gastroenteritis and, in some instances, sepsis in this age group. Multiple international outbreaks linked to powdered infant formula have been documented, collectively affecting large numbers of infants under 12 months of age.	2017)
Infants 6–12 months	Remain susceptible; illness generally less severe	Infants aged 6–12 months are still susceptible to salmonellosis, although reported illness is generally less severe than in younger infants. Disease typically presents as gastroenteritis, with invasive disease reported less often. Continued consumption of formula and transition to complementary foods mean exposure is still possible.	(FAO and WHO 2006, 2008, Wen et al. 2017, Marchello et al. 2022)
Young children 12 months–3 years	Remain susceptible; Illness usually self-limiting	Toddlers are still susceptible to salmonellosis. Illness is typically characterised by diarrhoea and fever and is less likely to require intensive care than neonatal infections. Fatal outcomes are rare (<1%). Healthy toddlers mostly recover without long-term consequences but still have moderate symptoms.	(FAO and WHO 2006, 2008, Wen et al. 2017, Sodagari et al. 2020)

2.4.2.1 Salmonella severity

For *Salmonella*, the Australian review by Wen et al. (2017) provides a comprehensive synthesis of evidence on non-typhoidal *Salmonella* infections in children, including epidemiology, clinical presentation, risk factors and management in the Australian and New Zealand context. Key findings from this review are summarised below.

Salmonella is a major cause of infectious diarrhoea worldwide and can result in invasive disease, including bacteraemia, meningitis and osteomyelitis. Young infants, particularly those under three months of age, are at highest risk of invasive disease. In this age group, treatment is recommended for positive stool cultures regardless of clinical improvement or exposure history, reflecting the increased risk of serious complications. Invasive manifestations such as meningitis and osteomyelitis occur more frequently in young infants and typically require prolonged antibiotic treatment of 4–6 weeks. Bacteraemia is the most common systemic complication, reported in 2–47% of children with *Salmonella* gastroenteritis, with early age (especially under one year) and immunosuppression identified as key risk factors. Among infants under six months with *Salmonella* bacteraemia, meningitis has been reported in approximately 20–28% of cases, and *Salmonella* meningitis in infants is associated with high case-fatality rates (up to 50–70%).

In infants aged 6–12 months, the risk of invasive disease is lower than in younger infants but is still present. Clinical management differs by severity: well infants may be observed without antibiotics, while unwell infants are recommended to undergo blood culture and receive antibiotics. In children aged 1–3 years, *Salmonella* infections are generally less severe. Most

cases are self-limiting and do not require antibiotic treatment. When uncomplicated bacteraemia occurs, antibiotics are recommended. Chronic carriage (>1 year) is more common in children under five years (approximately 2.6%) than in older children (0.3%); however, antibiotic treatment is not recommended for prolonged carriage as it does not shorten symptom duration and may prolong bacterial shedding. Overall, the severity of *Salmonella* infection is greatest in infants under six months (Wen et al. 2017).

In New Zealand, age-specific notification and hospitalisation rate ratios for *Salmonella* have been reported for the period 1997–2015 (Jeffs et al. 2019). Notification rates were highest in young children, with infants under one year reported approximately 6.5 times more often than children aged 10–14 years. Children aged 1–4 years were reported about 5.3 times more often, and those aged 5–9 years about 1.6 times more often. Hospitalisation incidence rate ratios followed a similar pattern, with the highest rates observed in infants under one year. Compared with children aged 10–14 years (the reference group), infants under one year had hospitalisation rates 10.8 times higher, children aged 1–4 years had rates 4.23 times higher, and children aged 5–9 years had rates 1.44 times higher.

Notification and hospitalisation rates per 100,000 population reflect both how often salmonellosis occurs and how severe illness is, because more severe cases are more likely to be admitted to hospital. As a result, these rates cannot be used on their own to distinguish differences in severity between age groups. To better characterise illness severity among children who become infected, the proportion of notified cases requiring hospitalisation was examined. This approach helps separate differences in disease severity from differences in underlying incidence.

Data from the New Zealand annual foodborne illness reports were reviewed to compare notification and hospitalisation metrics for *Salmonella* infection in children between 2021 and 2023 (NZMPI 2021) (Table 5). Data for Australia has been received and will be considered for the 2nd Call for submissions.

Table 5: Notification and hospitalisation rates for Salmonella infection in New Zealand children, by age group, based on annual foodborne illness surveillance data reported between 2021 and 2023.

Age group	Notified No.	Notified Rate	Hospitalised No.	Hospitalised Rate	Deaths
<1	33–50	73.5–99.8	7–14	19.2–23.3	0
1–4	105–128	40.9–46.5	20–32	8.2–11.5	0
5–9	48–58	14.8–17.8	7–14	2.2–4.3	0
10–14	14–28	4.1–8.2	3–4	0	0

Maximum reported values were used as a conservative basis for estimating the proportion of notified cases requiring hospitalisation (Table 6). Because both rates are expressed per 100,000 population, dividing one by the other effectively cancels out population size. What remains is an estimate of the proportion of reported cases that are severe enough to require hospitalisation. This analysis shows that although salmonellosis is notified less frequently in older children, a similar proportion of notified cases require hospitalisation across age groups, suggesting a comparable likelihood that a reported infection is severe enough to warrant hospital admission.

Table 6: Estimated proportion of notified non-typhoidal Salmonella cases requiring hospitalisation in New Zealand children, by age group, calculated using maximum notification and hospitalisation rates reported between 2021 and 2023.

Age group	Notified rate per 100,000 children	Hospitalised rate per 100,000 children	Proportion of notified cases being hospitalised (%)
<1	99.8	23.3	23.3%
1–4	46.5	11.5	24.7%
5-9	17.8	4.3	24.2%

2.4.2.2 Data gaps and limitations

- Most available surveillance and clinical data group children broadly (e.g. <1 year, <5 years), which limits the ability to precisely estimate severity for narrower age bands (<6 months, 6–12 months and 1–3 years) used in this assessment.
- Severity categories in the semi-quantitative model rely primarily on indicators such as mortality and hospitalisation, as detailed clinical outcomes (e.g. ICU admission, invasive disease, complications, or length of stay) are not routinely available in surveillance datasets. Hospital admission therefore represents a pragmatic but coarse proxy for severity and does not capture the full spectrum of illness severity among hospitalised cases.
- Hospitalisation rates per 100,000 population reflect both disease incidence and the likelihood that cases are admitted to hospital. When hospitalisations are considered relative to notifications, they provide an approximate indication of severity among reported cases. However, similar proportions hospitalised across age groups (~20–25%) may be influenced by factors such as precautionary admission practices (particularly for infants), differences in clinical management and reporting practices, rather than true equivalence in clinical severity.
- Deaths and severe complications (e.g. meningitis, invasive disease) are rare in Australia and New Zealand, particularly outside early infancy. As a result, severity estimates for some age groups rely on small numbers of cases or international and historical data, which increases uncertainty.
- Treatment and management recommendations used to inform interpretation of severity are largely based on expert consensus and observational data, with limited robust clinical trial evidence, particularly for infants and young children.
- New Zealand surveillance data are currently used to supplement gaps in Australian reporting, which may introduce bias due to differences in healthcare systems, surveillance practices and admission thresholds between jurisdictions.
- Surveillance systems primarily capture notified and hospitalised cases, with limited information on mild or self-limiting infections managed in the community. This means available data are weighted toward more clinically apparent disease and may underestimate the full spectrum of illness.
- Severity scores applied in this assessment represent relative weightings to support comparison of risks across scenarios and age groups, rather than precise measures of clinical severity. These scores should be interpreted in conjunction with the underlying epidemiological evidence and with recognition of uncertainty arising from data availability and reporting limitations.

2.4.3 Age-related differences in exposure to microbiological hazards from formula preparation and use

Age-related differences in the preparation and consumption practices of formula vary between infants and young children and can also influence exposure to microbiological hazards. The contributing factors are summarised in Table 7.

Table 7: Age-related differences in formula preparation practices and implications for microbiological exposure.

Age group	Typical preparation and consumption practices	Implications for exposure risk	References
Infants <12 months	Formula is typically prepared with greater caution, including use of boiled water and sterilised bottles. Feeds are usually consumed soon after preparation under close supervision.	These practices reduce opportunities for microbial contamination and growth during preparation and holding, although infants remain highly susceptible to illness if contamination occurs.	(FAO and WHO 2006, Kalyantanda et al. 2015, Silano et al. 2016, Netting et al. 2022b)
Young children 12 months–3 years	Preparation practices may become less stringent after 12 months, with some caregivers discontinuing boiling water or sterilising feeding equipment. Formula or milk drinks may be consumed from cups or bottles over extended periods or intermittently throughout the day.	Less controlled preparation and longer holding times may increase opportunities for bacterial growth if contamination is present. While biological susceptibility is lower than in infancy, exposure risk may be elevated due to handling practices.	(Yockney and Comfort 2013, Netting et al. 2022b)
Across age groups	Labelling requirements for young child formula currently do not always mandate the same preparation instructions as infant formula (FSANZ 2025).	Clear, consistent preparation and handling instructions remain important to minimise exposure risk, particularly where products are consumed over extended periods or prepared under variable household conditions.	(Codex 2023, 2024)

3 Hazard characterisation

3.1 Model inputs for hazard severity

In the model, the severity input represents how serious the health outcome is when illness occurs and allows risks to be compared across hazards, age groups and scenarios. Severity does not affect the likelihood that illness occurs but it increases the overall risk score to account for more serious health outcomes.

This assessment applies severity scores to different health outcomes to reflect how serious illness from each hazard could be, using similar severity categories as defined by Ross and

Sumner (2002). Severity is applied as an order-of-magnitude weighting based on epidemiological and clinical evidence. Severity categories were adapted as outlined below:

- SEVERE hazard — causes death or hospitalisation in a considerable proportion of cases (e.g., >30% mortality rates or hospitalisation rate > 50%) = 1
- MODERATE hazard — requires medical intervention in most cases (e.g., >30% hospitalisation rate) = 0.1
- MILD hazard— some cases require medical attention (e.g., >5% hospitalisation rate) = 0.01
- MINOR hazard— cases rarely require medical attention (e.g., < 5 % hospitalisation rate) = 0.001

Where the severity of illness was considered to fall between categories, an intermediate value was applied. Severity categories and corresponding severity inputs are presented in Table 8 for *Cronobacter* and Table 9 for *Salmonella.*

3.1.1 Cronobacter severity model inputs

Table 8: Severity categories and corresponding severity model inputs for Cronobacter infection by age group, based on epidemiological and clinical evidence.

Age Group	**Severity** **Model input*	**Justification**	**References**
<6 months	Severe = 1	Very high mortality: • Neonatal meningitis: 38–80% mortality • Infant septicaemia: 15–25% mortality High risk of invasive disease in infants, particularly < 2 months of age. Causes severe invasive infections. Affects previously healthy infants. Serious long-term outcomes among survivors. Recognised by WHO as a high-risk pathogen with potential for death and permanent disability	(FAO and WHO 2006, 2008, Strysko et al. 2020, Morais et al. 2022, Donaghy et al. 2025) .
6–12 months	Moderate/Mild = 0.03	Moderate risk of invasive disease, some severe cases. While most cases occur in infants <2 months, there is one documented case of invasive infection in a previously healthy infant older than 2 months. Full-term, normal birthweight infants living at home became increasingly represented in cases after 2004, suggesting risk persists beyond the neonatal period. Documented cases are fewer but still significant.	(FAO and WHO 2006, 2008, Holy and Forsythe 2014, Jason 2015, Donaghy et al. 2025).
1–3 years	Mild = 0.01	Low risk, mostly self-limiting	(FAO and WHO

		gastroenteritis. Only two documented cases in this age group. These were sporadic, not linked to outbreaks, and harder to trace due to lack of surveillance and lower severity.	2006, 2008, Holy and Forsythe 2014, Jason 2015, Donaghy et al. 2025).

3.1.2 Salmonella severity model inputs

Table 9: Severity categories and corresponding severity model inputs for Salmonella infection by age group, based on epidemiological and clinical evidence.

Age Group	**Severity** *Model input	**Justification**	**References**
<6 months	Moderate = 0.1	High risk of invasive disease and meningitis. Severe illness or death is more likely in this group but reported deaths are rare in Australia and New Zealand. Treatment is always recommended The proportion of hospitalization to notifications is about 20% for this age group.	(FAO and WHO 2006, 2008, Ao et al. 2015, Wen et al. 2017, NZMPI 2021)
6–12 months	Moderate/Mild = 0.03	Moderate risk of invasive disease, and some severe cases. In France (2005), 104 infants <12 months were infected with *Salmonella* Agona; 37% were hospitalised. Treatment only recommended if unwell. The proportion of hospitalization to notifications is estimated at about 20% for this age group in NZ. To account for this severity was not set at mild.	(FAO and WHO 2006, 2008, Wen et al. 2017, NZMPI 2021, Marchello et al. 2022)
1–3 years	Moderate/Mild = 0.03	Low risk, mostly self-limiting gastroenteritis Generally, no treatment required. The proportion of hospitalisation to notifications in NZ is estimated at about 20% for this age group. To account for this severity was not set at mild.	(FAO and WHO 2006, 2008, Wen et al. 2017, Sodagari et al. 2020, NZMPI 2021)

3.2 Estimates of infectious dose for exposure assessment

To support estimating the probability that a disease-causing dose is present in the daily amount consumed, the assumed infectious dose (ID) values were defined for *Cronobacter* spp. and *Salmonella* spp. across the age groups assessed.

Assumed ID values were informed by international dose–response models for *Cronobacter* and *Salmonella* (Table 10). These ID values are used in later calculations (section 4.2) to determine the increase in hazard level required for a daily intake to result in illness.

Table 10: Infectious dose (ID) values for Cronobacter and Salmonella by age group used in the exposure assessment.

	Infectious dose (ID) (number of cells)	
	Cronobacter	*Salmonella*
0-6 month old	1,000	1,000
6-12 month old	10,000	
1-3 years old	100,000	

The data and information considered for these estimates is summarised below.

3.2.1 Cronobacter dose-response models considered and justification

Reported incidence rates of *Cronobacter* illness vary substantially by age group, with the highest rates observed in neonates and infants under 6 months of age (FAO and WHO 2006, 2008). In England and Wales, neonates (<1 month) had an incidence of 17.6 per million, while infants aged 1–11 months had a rate of 2.06 per million, and children aged 1–4 years had a rate of 0.70 per million (FAO and WHO 2006, 2008). Adults, by comparison, had a reported incidence of 0.22 per million (FAO and WHO 2006, 2008). These figures suggest that the burden of reported illness is concentrated in the youngest age groups, particularly in the first months of life. However, it is important to note that incidence data reflect reported cases and do not directly measure biological susceptibility. Differences in exposure (e.g. use of powdered infant formula), immune system maturity, healthcare access and surveillance sensitivity may all influence observed incidence. For example, neonates are known to have transitory immunodeficiency, including reduced gastric acidity and immature immune responses, which may contribute to their higher observed rates (FAO and WHO 2006, 2008). Conversely, the lower incidence in older children and adults may reflect both reduced exposure and more robust immune defences.

The FSANZ model incorporates age-specific illness dose (*ID*) values to reflect varying susceptibility across age groups based on international dose–response models that describe the probability of cells causing illness using an exponential form (FAO and WHO 2006, Paoli and Hartnett 2006):

$$P_{ill} = 1 - e^{-r*dc}$$

Here, P_{ill} is the probability of illness, r is the per-cell infectivity, and d_c is the number of cells consumed. At low doses, this model simplifies to a linear approximation: $P_{ill} \approx r * d_c$, which is particularly relevant for low-level contamination scenarios. The model does not apply this exponential formula. Instead, it uses a semi-quantitative approach to approximate the same risk dynamics adapted from Ross and Sumner (2002) where r values can be used to approximate the dose with a 50% probability of causing illness (ID50). In summary, the spreadsheet provides a streamlined, scenario-based interpretation of the WHO exponential dose–response model.

Table 11 shows the *r* values for *Cronobacter* reported by FAO and WHO (2006) and converted to an ID50 for each age. To ensure values are conservative each ID was reduced by a factor of 10 to represent the assumed *ID*. The lower *ID* for infants reflects their increased vulnerability, while the higher values for older children suggest a logical progression in tolerance to infection.

Table 11: FAO and WHO (2006) Cronobacter dose–response (r) values and derived ID_{50} estimates, with conservative assumed infectious doses applied in the model.

	r values (FAO and WHO 2006)	ID50 (ID50 = ln2/r)	FSANZ model assumed Infectious Dose (ID)
0-6 months	0.00001	69,300	1,000 (0.001)
6-12 months	0.000001	693,000	10,000 (0.0001)
1-3 year	0.0000001	6,930,000	100,000 (0.00001)
3 - 6 years	0.00000001	69,300,000	NA
6 - 12 years	0.000000001	693,000,000	NA
Adults	0.0000000001	6,930,000,000	NA

3.2.2 Salmonella dose-response models considered and justification

There is no validated dose response model that characterises age-specific responses to different doses of *Salmonella*. Consequently, risk assessments typically apply a general dose–response model and adjust assumptions as needed.

The FAO and WHO risk assessment for *Salmonella* in eggs and broiler chickens (FAO and WHO 2002) developed a beta-Poisson dose–response model using human outbreak data. Only two infant cases were available, reflecting the limited age-specific evidence: a 9-month-old infant with cystic fibrosis exposed to an estimated 44.8 cells per day, and a 1-year-old infant exposed to a single dose of approximately 200 cells. These cases were incorporated into the broader outbreak dataset used to characterise illness at low doses. To address uncertainty in outbreak data, FAO and WHO derived beta-Poisson dose–response parameters using Monte Carlo resampling, fitting models to approximately 5,000 resampled datasets (FAO and WHO 2002). The resulting parameters and associated ID50[4] values are presented in Table 12.

Table 12: Beta-Poisson dose–response model parameters for non-typhoidal Salmonella, including expected and uncertainty-bound estimates and corresponding ID50 values (FAO and WHO 2002).

Bound	Alpha	Beta	ID50
Expected Value	0.1324	51.45	9,609.63
Lower Bound	0.0763	38.49	339,348.48
2.5th Percentile	0.094	43.75	69,687.08
97.5th Percentile	0.1817	56.39	2,501.87
Upper Bound	0.2274	57.96	1,163.61

For infant and young child risk assessment, use of the upper-bound parameter set is appropriate as a conservative modelling choice (approximately 1,164 cells). Selecting the upper bound ensures that uncertainty and variability in the outbreak data are explicitly incorporated and provides a protective basis for assessing risk in vulnerable populations. The FSANZ assessment used 1,000 CFU as the *ID* for *Salmonella* for all infants and young children.

[4] Reported as N50 by FAO and WHO (2002).

4 Exposure assessment

4.1 The probability of exposure (Prob_exp)

In the model, the probability of exposure to the product per person per day (Prob_exp) is used to describe how often individuals are exposed to formula based on consumption behaviour across the population.

Prob_exp is derived from two inputs:

- how frequently the formula is consumed per person per year (Frequency_consumption)
- the proportion of the total population of interest that consume formula (Proportion_consuming)

Together, these inputs capture differences in consumption patterns across age groups and scenarios.

Specifically, Frequency_consumption and Proportion_consuming are combined in the semi-quantitative spreadsheet to calculate Prob_exp using the model structure described by Ross and Sumner (2002):

$$\text{Prob\_exp} = \text{Frequency\_consumption} \times \text{Proportion\_consuming}$$

Prob_exp reflects exposure behaviour only and is not itself a measure of risk.

4.1.1 Model inputs for population size, proportion consuming, and frequency of consumption: Combined Australia and New Zealand estimates

For the risk assessment, combined Australia and New Zealand population estimates were used to derive the exposure inputs. This approach provides the required single, representative point estimate for exposure while reflecting the total population potentially affected across both countries. The following were estimated and presented in Table 13:

- Total number of children consuming formula: This is the sum of all infants consuming formula across Australia and New Zealand for each age group.
- Proportion of the population consuming formula = Total number of children consuming formula ÷ Total population estimate.

The following estimated and presented in Table 13 and Table 14:

- Frequency of consumption = how frequently in number of days per year formula is consumed.
- Total amount of formula consumed (mL/day) = This is the sum of all formula consumed per day by all infants in both countries for high and low use.
- Average formula consumed (mL/day) = Total amount of formula consumed (mL/day) ÷ Total number of children consuming formula.
- Daily Formula Powder (g/day) = average daily intake converted to powder using an assumed preparation ratio of 13 g per 100 mL of prepared formula (rounded to the nearest multiple of 10).

Table 13: Combined Australia and New Zealand population estimates used for the model inputs and to derive other relevant values.

Aus + NZ formula consumption population	**AUS + NZ population estimates (persons)** **Model input – Population size*	**Total number of children consuming formula (persons)**	**Proportion of the population consuming formula** **Model input – Proportion consuming*
0-6 month old	175,910	126,021	0.72
6-12 month old	175,910	126,021	0.72
1-3 years old	1,102,547	220,509	0.20

Table 14: Combined Australia and New Zealand exposure estimates used for the model inputs and to derive other relevant values.

Aus + NZ formula consumption population	**Frequency of consumption** **Model input – Frequency of consumption*	**Total amount of formula consumed (mL/day)**	**Average formula consumed (mL/day)**	**Average powder consumed (g/day/person)** **Required for determining increase in hazard needed to cause illness)*
0-6 month old	Daily	69,780,375	554	70
6-12 month old	Daily	74,271,750	589	80
1-3 years old	Daily	85,447,393	388	50

4.1.2 Method of deriving the combine exposure estimates

To inform the combined values in Table 13 and Table 14, best-estimate consumption scenarios were first estimated separately for Australia and New Zealand. Exposure was characterised under two consumption scenarios:

- high use, representing exclusive or predominant formula consumption, and
- low use, representing mixed feeding or less frequent consumption.

For each country, age group and consumption scenario, the following were calculated:

- Total children consuming formula = Total population estimate × Proportion of the population consuming formula
- Total Amount (mL per Day) = Total infants consuming × average volume per day

These country-specific estimates were then summed to derive the combined Australia–New Zealand values used in Table 13 and Table 14. The high- and low-use best-estimate consumption scenarios are presented in Table 15. The sections that follow describe the data sources, assumptions and calculations used to derive these best estimates.

Table 15: Best-estimate formula consumption inputs used to derive the combined Australia and New Zealand model inputs, showing population size, proportion consuming formula, average daily intake, and total daily formula consumption for high- and low-use scenarios.

Country	Total population estimates	Formula Use	Proportion of the population consuming formula	Average volume (mL/day/person)	No. persons consuming formula (persons)	Total amount consumed (mL/ day)
0-6 month						
Australia	147,070	High	0.20	925	29,414	27,207,950
		Low	0.50	375	73,535	27,575,625
New Zealand	28,840	High	0.40	925	11,536	10,670,800
		Low	0.40	375	11,536	4,326,000
Combined estimates	**175,910**				**126,021**	**69,780,375**
6-12 months						
Australia	147,070	High	0.30	750	44,121	33,090,750
		Low	0.40	450	58,828	26,472,600
New Zealand	28,840	High	0.50	750	14,420	10,815,000
		Low	0.30	450	8,652	3,893,400
Combined estimates	**175,910**		**0.72**		**126,021**	**74,271,750**
1-3 years						
Australia	925,677	High	0.10	525	92,568	48,598,043
		Low	0.10	250	92,568	23,141,925
New Zealand	176,870	High	0.10	525	17,687	9,285,675
		Low	0.10	250	17,687	4,421,750
Combined estimates	**1,102,547**				**220,509**	**85,447,393**

4.1.2.1 Step 1: Determine the Aus + NZ population estimates

Table 16 presents the most recent government estimates of the resident population by age, which are used as inputs to the risk assessment model. These values are point estimates and require assumptions to align available population data with the specific age bands used in the assessment (e.g. splitting single-year age groups). While population sizes are expected to change over time, the use of current estimates is considered appropriate for comparative risk assessment. Future quantitative analyses could incorporate projected population changes over the life of a proposed standard.

Table 16: Most recent government resident population estimates by age group used as inputs to the risk assessment model, including data sources and assumptions applied to align available population data with the assessment age bands.

Australia	**Size (Persons)**	**Data Source**	**Assumptions**
0-6 months	147,070	ABS Estimated resident population, by age and sex– at 30 June 2023 (ABS 2025)	Half the reported ABS data for 0 year population represent 0 – 6 months (294,140/2)
6-12 months	147,070		Half the reported ABS data for 0 year population represent 6 – 12 months (294,140/2)
1-3 years	925,677		Combined ABS data for 1 year (314,380) + 2 year (306,475) + 3 year (304,822)

New Zealand	**Size (Persons)**	**Data Source**	**Assumptions**
0-6 months	28,840	Group: Population Estimates - DPE Table: Estimated Resident Population by Age and Sex (1991+) (Annual-Jun) Statistics New Zealand (Statistics New Zealand 2025)	It was assumed that half the 0 year population represent 0 – 6 months (57,680/2)
6-12 months	28,840		It was assumed that half the 0 year population represent 6 – 12 months (57,680/2)
1-3 years	176,870		Stats NZ combined data for 1 year (56,910) + 2 year (57,630) + 3 year (62,330)

4.1.2.2 Step 2: Estimate the proportion of 0 – 6 month olds consuming formula and the amount

4.1.2.2.1 Proportion consuming formula

The data available for Australia and New Zealand describe exclusive breastfeeding as common at birth but declines over the first months of life, with increasing use of formula either exclusively or in combination with breastmilk. However, estimates vary by data source, study design and definition of feeding categories.

Australia

Data reported in P1028 (FSANZ 2024) describe feeding practices at six months of age as follows:

- 38% of infants were exclusively breastfed to 6 months and did not consume formula
- 9% of infants never receive any breastmilk and for this risk assessment are assumed to be formula-fed from birth.
- 53% are infants that have consumed some infant formula in addition to breastmilk.

Findings from the Australian Feeding Infants and Toddlers Study (OzFITS 2021) (Netting et al. (2022a)) provide additional context on early feeding patterns for Australian children from birth to two years of age:

- less than 1% of infants were reported as exclusively breastfed to six months.
- by 6 months, 56% of infants had received formula and
- 40% of infants had been introduced to formula during the first month of life.

Day-of-record dietary data from (Moumin et al. 2022b) reported that among infants aged 0–5.9 months:

- 70.7% consumed breastmilk on the day of the record, and
- 82.6% consumed infant formula on the day of the record.
- These data reflect intake on a single day and do not represent habitual feeding patterns. No use of follow-on formula or young child formula was reported for this age group.

New Zealand

P1028 reported (FSANZ 2024) 2006 feeding data for New Zealand infants at six months of age:

- 25% were exclusively breastfed,
- 40% were exclusively formula-fed, and
- 35% received both breastmilk and formula.

More recent data indicate lower rates of exclusive breastfeeding at later ages in infancy. National monitoring data show that exclusive breastfeeding decreases from 93% at birth to 59% by one month, 51% by three months, and less than 1% by six months of age (NZBA 2024). The Growing Up in New Zealand study (birth cohort 2009–2012) reported that 16% of infants were exclusively breastfed to six months (NZMPI 2018). However, this study did not disaggregate breastmilk and formula consumption for other exposure-relevant metrics. As a result, these data provide limited information on volumes or frequency of formula intake.

4.1.2.2.2 Estimated daily consumption amounts

Direct data on the frequency and volume of formula consumption among infants aged 0–6 months are limited. In the absence of detailed intake distributions, estimated formula requirements for exclusively formula-fed infants reported by the National Health and Medical Research Council (NHMRC 2012) were used to inform consumption assumptions.

Guidance indicates that infants up to six months of age typically require approximately 150 mL/kg body weight per day, with reported ranges extending higher or lower depending on individual growth and feeding patterns (NHMRC 2012). Using an indicative mid-range body weight of 5.5 kg, this corresponds to an average intake of approximately 825 mL/day, which is consistent with values reported internationally (EFSA NDA (European Food Safety Authority Panel on Dietetic Products Nutrition and Allergies) 2013, SACN 2018).

For mixed-fed infants (receiving both breastmilk and formula), intake volumes are not well

characterised. For the purposes of this assessment, it was assumed that mixed-fed infants typically consume more than one formula feed per day. A daily intake of 375 mL was therefore used as a pragmatic estimate, equivalent to approximately 1.5 feeds of 250 mL.

4.1.2.2.3 0–6 months best-estimate justification

Taken together, the data sources described above indicate the proportion of infants in Australia and New Zealand that consume infant formula by six months of age, either exclusively or in combination with breastmilk. However, estimates vary by data source, study design and feeding definitions, and direct measures of habitual intake, frequency and volume are limited. As a result, assumptions are required to translate the available evidence into exposure inputs suitable for the risk assessment. The best estimates are summarised in Table 17. High use was defined as infants who are exclusively formula-fed or where breastmilk is only provided occasionally (e.g., 800–1,100 mL/day). Low use was defined infants who are mixed fed (receive both breastmilk and formula; typically consume lower daily volumes, e.g., ~375 mL/day).

Table 17: Best-estimate formula consumption assumptions for infants aged 0–6 months in Australia and New Zealand, defining high- and low-use exposure scenarios applied in the semi-quantitative risk assessment.

0 – 6 month old formula consumption	Proportion of the population consuming formula	Typical formula volume consumed (mL/day/person)
Australia		
High Use	20%	965
Low Use	50%	375
New Zealand		
High Use	40%	965
Low Use	40%	375

Australia

The 20% high use estimate is a conservative, rounded value that reflects the range of exclusive formula feeding reported in national data. Importantly, this group is intentionally defined to be conservative and protective: it not only includes infants who are exclusively formula-fed from birth, but also those who are predominantly formula-fed with only very occasional or token breastfeeding (such as a few feeds in the early days or weeks). This reflects real-world feeding patterns and acknowledges that survey definitions and recall periods often do not distinguish between strict exclusive formula feeding and predominant formula feeding with rare breastmilk exposure. Including these infants in the high use group ensures the risk assessment does not underestimate the number of infants with high formula exposure, especially given the variability in feeding practices and reporting.

The 50% low use (mixed feeding) value is supported by data (53% had some formula in addition to breastmilk) and aligns with the majority of infants who are not exclusively formula-fed but have regular formula exposure.

New Zealand

The 40% high use estimate value is consistent with available data (40% exclusively formula-fed at 6 months) and more recent studies showing a decline in exclusive breastfeeding.

The 40% low use (mixed feeding) value is consistent with available data (35% combined

feeding) and allows for a conservative, protective approach given the uncertainty and lack of recent, granular data. These values ensure that the risk assessment does not underestimate exposure, especially in the context of data variability and the need to protect public health.

Formula volumes

High Use: 965 mL/day: This value is the midpoint of the observed intake range for exclusively formula-fed infants (825–1,100 mL/day). This is supported by Australian and international feeding guidelines.

Low Use: 375 mL/day: This value is based on the typical intake for mixed-fed infants, as supported by dietary recall studies and international feeding guidelines (e.g., 1.5 × 250 mL serves per day). It reflects the assumption that mixed-fed infants typically receive more than one formula feed per day, with the remainder of their intake from breastmilk.

Uncertainties and Data Gaps

- Australia: Proportions consuming formula are supported by multiple data sources; however, volumes consumed by mixed-fed infants are assumed rather than directly measured.
- New Zealand: More recent data suggest lower exclusive breastfeeding rates than older studies, but detailed information on formula volumes and frequency is limited.
- Both countries: Habitual daily formula intake among mixed-fed infants is poorly characterised; assumptions are based on guidance values and typical feeding patterns rather than measured intake distributions.

4.1.2.3 Step 3: Estimate the proportion of 6 – 12 month olds consuming formula and the amount

4.1.2.3.1 Proportion consuming formula

Australia

The NHMRC recommends the introduction of solid foods at around 6 months of age when infants are developmentally ready (NHMRC 2012). Consequently, reductions in breastfeeding prevalence in this age group do not necessarily indicate increased formula use, unlike in the 0–6 month age group.

Among infants aged 6–11 months, 54% were still receiving some breastmilk; 37% had received breastmilk previously but had ceased by this age; and 10% had never been breastfed (ABS 2023). Data from the OzFITS 2021 study indicate that by 6 months of age, 56% of infants had been introduced to formula, increasing to 65% by 12 months. (Moumin et al. 2022b) reported that in the 6–11.9 month age group, 221 infants (77.3%) received breastmilk, 39 (13.6%) received infant formula, and 59 (20.6%) received follow-on formula, while young child formula was not consumed on the day of dietary recording.

New Zealand

A recent study reported that at 9 months of age, 96.3% of children consumed breastmilk or infant formula at least once per day (NZMPI 2018). Another study reported at 7 months of age:

- 51% of infants were breastfed,
- 24% were fed formula
- 25% received both breast milk and formula.

By age 1:

- breastfeeding rates declined to 43%,
- 33% of infants were formula-fed,
- 11% received both, and
- 13% were not fed any infant milk.

The First Foods New Zealand (FFNZ) was an observational study of 625 New Zealand infants aged 6.9 to 10.1 months and reported that 47% were fed infant formula on one or more of the 24 h diet recall days (McLean et al. 2024).

4.1.2.3.2 Estimated daily consumption amounts

Specific Australian consumption volume data for infants aged 6–12 months are limited. Indicative formula requirements are commonly cited as approximately 100 mL/kg/day for infants around 6–9 months of age, decreasing thereafter, although actual intake varies substantially with the introduction and increasing contribution of complementary foods (NHMRC 2012).

In New Zealand, reported median daily formula intakes of approximately 300–510 mL/day at 7 months and 319–402 mL/day at 12 months are reported (Daniels et al. 2018). The FFNZ study reported that among the total sample (n = 625), 319 infants (51.0%) did not consume any formula; 73 infants (11.7%) consumed <1000 kJ/day (equivalent to 0.0 to <357.1 mL/day); 167 infants (26.7%) consumed 1000 to <2500 kJ/day (357.1 to <892.9 mL/day); and 66 infants (10.6%) consumed ≥2500 kJ/day (≥892.9 mL/day) (McLean et al. 2024).

These findings are consistent with international reports indicating that infants in this age group typically consume 1–4 formula feeds per day, corresponding to approximately 500–800 mL/day (EFSA NDA (European Food Safety Authority Panel on Dietetic Products Nutrition and Allergies) 2013, SACN 2025).

Potential variability in formula intake is further illustrated by qualitative research examining caregiver perceptions and use of follow-on and young child formulas for children aged 6–36 months in Australia and New Zealand (Yockney and Comfort 2013). Reported intakes ranged from approximately 450 mL/day to 800 mL/day. The lowest reported intake scenario involved three 150 mL bottles per day (450 mL/day), while most scenarios reflected higher intakes of 600–800 mL/day.

To reflect observed variability in feeding patterns and uncertainty in intake estimates, the 0–6 month formula consumption data were adjusted by ±10% for high-use and low-use scenarios for both Australia and New Zealand.

4.1.2.3.3 6 – 12 months old best-estimate consumption scenarios

Best-estimate formula consumption assumptions for infants aged 6–12 months in Australia and New Zealand, defining high- and low-use exposure scenarios applied in the semi-quantitative risk assessment are presented in Table 18.

High use was defined as infants who receive formula as their only milk source or receive large daily volumes (typically >500 mL/day).

Low use was defined as infants who are mixed fed (receive both breastmilk and formula, or receive formula less frequently/lower volumes, typically <500 mL/day).

Table 18: Best-estimate formula consumption assumptions for infants aged 6–12 months in Australia and New Zealand, defining high- and low-use exposure scenarios applied in the semi-quantitative risk assessment.

6 - 12 month old formula consumption	Per cent of the population consuming formula	Typical Formula Volume consumed (mL/day/person)
Australia		
High Use	30%	800
Low Use	40%	400
New Zealand		
High Use	50%	800
Low Use	30%	400

The prevalence estimates for high- and low-use formula consumption in Australia (30% high use; 40% low use) and New Zealand (50% high use; 30% low use) are based on the best available national survey data and published studies for infants aged 6–12 months. These values reflect the proportion of infants who are exclusively formula-fed or have transitioned to predominantly formula feeding (high use), as well as those who are mixed-fed consuming breast milk/formula/other foods (low use).

For Australia, the 30% high-use estimate aligns with evidence indicating the proportion of infants predominantly receiving formula (ceased breastfeeding), while the 40% low-use estimate reflects the continued prevalence of mixed feeding. For New Zealand, the higher high-use estimate is supported by both older and more recent studies demonstrating greater reliance on formula feeding in this age group.

The high-use category is intended to capture not only infants who are exclusively formula-fed, but also those with other high-intake patterns. These assumptions are conservative and designed to avoid underestimation of exposure, particularly in the context of data variability and potential under-reporting.

Typical daily formula volumes of 800 mL/day for high use and 400 mL/day for low use are consistent with reported intake ranges from Australian and New Zealand studies, international feeding guidance and qualitative data. The 400 mL/day estimate represents a reasonable midpoint for mixed-fed infants who typically consume one to two formula feeds per day. Use of fixed-point estimates provide a transparent and practical approach for exposure modelling where detailed intake distributions are unavailable and is consistent with FAO and WHO MRA guidance.

Uncertainties and data gaps

- Australia: Overlap between infant formula and follow-on formula categories; reliance on single-day dietary records may misrepresent habitual intake.
- New Zealand: Recent data suggest lower formula use than indicated in older studies; “any formula” categories include both exclusive and mixed feeding.
- Both countries: Considerable variability in intake among mixed-fed infants; a proportion of infants may receive no infant milk by 12 months of age.

4.1.2.4 Step 4: Estimate the proportion of 1 – 3 year olds consuming formula and the amount

4.1.2.4.1 Proportion consuming formula

The studies below demonstrate variability in young child formula consumption by age, survey method (ever-use, day-of-record, or weekly use) and population subgroups as defined in the original studies.

Australia

Across Australian studies (Table 19), day-of-record data indicate that approximately 14–20% of children aged 12–24 months consume formula or young child formulas (Moumin et al. 2022a) (Moumin et al. 2022b), while weekly-use data suggest higher prevalence (≈32%) among children aged 12–36 months (Willcox et al. 2021). Additionally, there is variance in population subgroups that was beyond the scope of this assessment (Bolton et al. 2018, Zahra et al. 2022).

Table 19: Summary of Australian studies reporting the prevalence of formula and young child formula consumption among children aged 12–36 months, based on day-of-record and weekly-use data across different population groups.

Year	Australian Population Group	Child Age Range	Sample Size	Consumption (%)	What was consumed/reported	Study
2020–2021	General population	12–18 months	233	20.20%	Reported to consume some formula or young child formulas on the day of the food record	(Moumin et al. 2022a)
2020–2021	General population	18–24 months	242	17.40%	Consumed some formula or young child formulas on the day of the food record	(Moumin et al. 2022a)
2020–2021	General population	12–23.9 months	475	13.50%	Consumed young child formula on the day of the food record	(Moumin et al. 2022b)
2017	Major metropolitan areas (Sydney, Melbourne, Brisbane)	12–36 months	252	31.80%	Consumed ‘growing up milk’ at least once per week	(Willcox et al. 2021)

New Zealand

New Zealand data were limited, with no recent nationally representative day-of-record intake data available for young children. In a 2010–2011 New Zealand cohort, 6% of children aged 2–5 years had ever consumed young child formula (Cairncross et al. 2017)

4.1.2.4.2 Estimated daily consumption amounts

The OzFITS 2021 study reported that among toddlers who consumed formula or young child formula:

- Median intake was 423 g/day for children aged 12–18 months
- Median intake was 354 g/day for children aged 18–24 months

This corresponds to approximately 1.35 and 1.31 servings per day, respectively, assuming one serving equals 250 mL prepared volume (Moumin et al. 2022).

Potential for variation is well illustrated in a qualitative research report on caregivers' perceptions and usage of follow-up formula young child formulas for children aged six to 36 months in New Zealand and Australia (Yockney and Comfort 2013). Low use ranged from 220 mL to 300 mL/day and high use to 450 to 600 mL/day.

4.1.2.4.3 1 – 3 years old best-estimate consumption scenarios

High use was defined as children who consume young child formula regularly (e.g., daily or several times per week, typically at higher daily volumes: 450–600 mL/day).

Low use was defined as children who consume young child formula infrequently or in small amounts (e.g., less than daily, or <300 mL/day).

The following best estimates were assumed:

Table 20: Best-estimate formula consumption assumptions for children aged 1–3 years in Australia and New Zealand, defining high- and low-use exposure scenarios applied in the semi-quantitative risk assessment.

1 – 3 year old formula consumption	Per cent of the population consuming formula	Typical Formula Volume consumed (mL/day/person)
Australia		
High Use	10%	525
Low Use	10%	250
New Zealand		
High Use	10%	525
Low Use	10%	250

Justification

10% high use; 10% low use: Australian day-of-record data indicate that approximately 13–20% of toddlers consume formula or young child formula on a given day (Moumin et al. 2022a, b), while weekly consumption may reach ~32% in some subgroups (Willcox et al. 2021). Allocating 10% each to high- and low-use groups provides a conservative and rounded estimate that captures regular consumption without over-representing infrequent or subgroup-specific use.

In the absence of contemporary, nationally representative New Zealand intake data, applying the same prevalence assumptions is considered conservative and protective, and consistent with guidance when local data are limited.

A value of 525 mL/day was selected for high use as it represents the midpoint of the

observed high-use range (450–600 mL/day) reported across studies.

For low use, a value of 250 mL/day was selected, reflecting approximately one typical serving and the midpoint of the observed low-use range (220–300 mL/day). Use of midpoint values provides a pragmatic and transparent basis for exposure modelling where detailed intake distributions are not available.

These assumptions are suitable for regulatory risk assessment purposes, providing realistic yet protective estimates of consumption in the presence of uncertainty, and are consistent with international best-practice guidance.

4.1.2.5 Step 5: Combine best estimate scenarios and derive combined estimates for Australia and New Zealand

The country-specific estimates for high and low formula use presented in Table 17, Table 18, and Table 20 were then summed to derive the combined Australia–New Zealand values presented earlier in Table 13 and Table 14. The high- and low-use best-estimate consumption scenarios are presented in Table 15 along with the combined estimates.

4.2 The probability of an illness-causing dose (PDD)

In the model, the probability that a disease-causing dose is present in the daily amount consumed (PDD) is used to describe how microbiological contamination at manufacture, preparation practices, and dose–response considerations together influence the likelihood that consumption results in illness.

PDD integrates three components:

- the probability that the consumed amount contains at least one organism (hazard_level), which reflects contamination levels in the powder supply under different microbiological criteria
- the likelihood that the amount consumed is sufficient to cause illness (illness_dose), which reflects the gap between expected exposure and an illness-relevant dose
- the effect of preparation, storage and handling practices (prep_effect), which can increase or reduce the hazard prior to consumption

PDD which is calculated using the model structure (Ross and Sumner 2002):

PDD = Hazard_level * Illness_dose * Prep_effect

PDD does not account for how often consumption occurs or the severity of illness; these factors are incorporated in later steps of the model.

4.2.1 Model inputs for the probability that the daily amount of formula consumed by infants and young children is contaminated with 1 CFU of Cronobacter or Salmonella under different microbiological criteria scenarios (Hazard_level)

The input for the for the probability that a daily intake of powdered formula contains at least 1 CFU of *Cronobacter* or *Salmonella* (hazard_level) is varied on the model to describe how different microbiological safety criteria influence risk. To determine the model inputs the following are estimated:

- the concentration of *Cronobacter* or *Salmonella* in powdered formula at the point of product testing at end of manufacture.
- the probability that the daily amount of powdered formula that is reconstituted contains 1 CFU of *Cronobacter* or *Salmonella*.

The existing regulatory safety criteria considered for the infant baseline were:

- *Cronobacter* – infant-formula-equivalent microbiological criteria (30 × 10 g)
- *Salmonella* – infant-formula-equivalent microbiological criteria (60 × 25 g)

These scenarios were assessed for the other age groups and also included:

- *Cronobacter* – no microbiological criteria
- *Salmonella* – no microbiological criteria
- *Salmonella* sensitivity analysis for additional less stringent sampling plans (30 × 10 g, 10 × 25 g, 5 × 25 g) to assess how reductions in microbiological control affect risk for young children.

The estimates and model inputs for the different scenarios are presented in Table 21. The following sections describe how these values were derived.

Table 21: Estimated probability that the daily amount of powdered formula consumed contains at least one CFU of Cronobacter or Salmonella (hazard_level), by age group and microbiological criteria scenario, based on assumed concentrations in the powder supply and average daily powder consumption.

Aus + NZ: Formula consumption population	Concentration in powder supply (CPS) (CFU/g)	Daily powder consumption (g/day)	Probability daily powder consumption contains 1 CFU
Cronobacter - without microbiological criteria			
0-6 month olds	0.000671	70	0.0470
6-12 month olds	0.000671	80	0.0537
1-3 year olds	0.000671	50	0.0338
Cronobacter - with infant-formula-equivalent microbiological criteria (30 x 10g)			
0-6 month olds	0.000321	70	0.0225
6-12 month olds	0.000321	80	0.0257
1-3 year olds	0.000321	50	0.0162
Salmonella without microbiological criteria			
0-6 month olds	0.00546	70	0.3822
6-12 month olds	0.00546	80	0.4368
1-3 year olds	0.00546	50	0.2750
Salmonella with infant-formula-equivalent microbiological criteria (60 x 25g)			
0-6 month olds	0.000399	70	0.0279
6-12 month olds	0.000399	80	0.0319
1-3 year olds	0.000399	50	0.0201
Salmonella sensitivity analysis for 1-3 year olds			
30 x 10g	0.00109	50	0.0549
10 x 25g	0.00140	50	0.0705
5 x 25g	0.00210	50	0.1058

4.2.1.1 Step 1 – Estimate concentration of Cronobacter and Salmonella in the powdered formula supply under different microbiological criteria scenarios

An understand how microbiological standards and sampling strategies influence contamination estimates is required to determine risk (Paoli and Hartnett 2006). This requires insight into contamination levels within the manufacturing setting, ideally reflecting the concentration at the time of sampling lots at the end of manufacture (Paoli and Hartnett 2006). However, no recent publicly available data from manufacturers in Australia and New Zealand was identified. Consequently, the semi-quantitative assessment draws on estimates from the international quantitative risk assessment model for *Cronobacter* in powdered infant formula that informed the development of the Codex recommended criteria for infant and follow-on formula Paoli and Hartnett (2006).

4.2.1.1.1 Cronobacter data considered

The *Cronobacter* model[5] developed by Paoli and Hartnett (2006) can be used to explore the impact of microbiological criteria upon the level of contamination in powder supply. The model provides the following estimates based on a Poisson-lognormal model:

[5] https://tools.fstools.org/esakmodel/ESAKRAModelWizard.aspx

- Mean pre-sampling concentration = average contamination across all lots *before sampling*
- Mean concentration after sampling = reflects the average concentration among *accepted lots*
- Lot rejection rate = the proportion of lots excluded due to positive samples.

The *Cronobacter* model[6] (Paoli and Hartnett 2006) was used to simulate an infant-formula-equivalent sampling plan for *Cronobacter* of no detections in 30 samples of 10g. Paoli and Hartnett (2006) used 60 records of raw manufacturing data to determine the mean log concentration of *Cronobacter* was approximately −3.91 $\log_{10}$ CFU/g, with a standard deviation of 0.67, however recent data were not available to generate country specific estimates, therefore, a mean concentration of −3.91 $\log_{10}$ CFU/g and a standard deviation of 0.8 for both between-lot and within-lot variation were applied to represent conservative estimates of variability. The outputs from the model are presented in Table 22.

Table 22: Estimated reduction in mean Cronobacter concentration in powdered formula and lot rejection rates associated with alternative microbiological sampling plans, based on outputs from the Paoli and Hartnett (2006) model.

Sampling Plan	Mean pre-sampling concentration (CFU/g)	Mean concentration after sampling (CFU/g)	Proportion of Lots Rejected
No plan	0.000671	0.000671	0
30 of 10g	0.000671	0.000321	0.10

4.2.1.1.2 Cronobacter– best estimate for concentration in the powder supply at end of manufacture under different microbiological criteria scenarios

FSANZ assumed the following values are applicable to both infant and young child formula due to shared manufacturing lines, ingredients, and as other data is not available for Australia or New Zealand:

- Without regulatory criteria the concentration in powdered formula supply = 0.000671 CFU/g,
- With regulatory criteria (30 samples of 10 g, reject if any are positive) the concentration in powdered formula supply = 0.000321 CFU/g

Although *Cronobacter* can slowly decline in powder, FSANZ did not included this or recontamination potential before preparation by the caregiver because doing so would introduce additional uncertainty and complexity without materially improving the robustness or conservatism of the risk assessment. It is noted Paoli and Hartnett (2006) applied a reduction of 0.014 Log_{10} units per day for different storage durations ranging from 0 – 365 days.

4.2.1.1.3 Salmonella data considered

FAO and WHO (2006) did not report data for concentration of *Salmonella*. However, the risk assessment did describe the effects of different contamination scenarios (mean log concentration −3, −4, −5 Log_{10} CFU/g; between-lot standard deviation 0.5 and 0.8; within-lot standard deviation: 0.1, 0.5, 0.8). Plans with more samples and larger sample sizes showed

[6] https://tools.fstools.org/esakmodel/ESAKRAModelWizard.aspx

the greatest relative risk reduction.

It has been recently estimated that after a 2 log_{10} CFU *Salmonella* contamination breach on an 8.4 cm² stainless steel surface, the median number of contaminated milk powder units (300 g each) was 72 out of 100,000, with an average contamination concentration of -2.33 log_{10} CFU/g (Daeschel et al. 2025). In a more severe 6 log_{10} CFU breach scenario, contamination increased to 688 units with an average concentration of 0.689 log_{10} CFU/g. The authors noted that the modelled concentrations align with real-world contamination levels found in recalled dry powder products, which typically range between -2.82 and -1.62 log_{10} CFU/g.

In the absence of contemporary data from Australia and New Zealand, simulations were generated using the same tool used for *Cronobacter*[7] (Paoli and Hartnett 2006) with conservative parameters: mean log concentration -3 log10 CFU/g, and standard deviations of 0.8 for both between-lot and within-lot variation (Table 23).

Table 23: Estimated impact of alternative microbiological sampling plans on Salmonella contamination in powdered formula, showing exposure-reduction factors, mean pre-sampling and accepted concentrations, and the proportion of lots rejected under each sampling scenario.

Sampling Plan	Mean pre-sampling concentration (CFU/g)	Mean accepted concentration (CFU/g)	Proportion of Lots Rejected
No plan	0.00546	0.00546	0
60 of 25g	0.00546	0.000399	0.64
30 of 10g	0.00546	0.00109	0.35
10 of 25g	0.00546	0.00140	0.29
5 of 25g	0.00546	0.00210	0.19

4.2.1.2 Salmonella – best estimate concentration in the powder supply (CPS) at end of manufacture under different microbiological criteria scenarios

It was assumed the following values are applicable to both infant and young child formula due to shared manufacturing lines, ingredients, and as other data is not available for Australia or New Zealand:

- Without microbiological criteria the concentration in the powder supply = 0.00546 CFU/g,
- With microbiological criteria (60 samples of 25 g, reject if any are positive) the concentration in powdered supply = 0.000399 CFU/g

Data gaps and limitations

[7] https://tools.fstools.org/esakmodel/ESAKRAModelWizard.aspx

- There is a lack of recent, representative contamination data specific to Australia and New Zealand; estimates rely on international data and published models.
- Assumptions are made that contamination levels and sampling plan performance are the same for both infant and young child formula, despite possible differences.
- The simulation models are based on limited manufacturing records and may not capture rare high-contamination events or changes over time.
- Real-world effectiveness of sampling plans may differ from modelled performance due to operational or laboratory variability.
- For *Salmonella*, there is no direct local concentration data; estimates are based on international studies and modelled scenarios.
- The models assume stable, long-run mean concentrations and risk reduction factors, which may not reflect sporadic contamination or outbreak situations.
- Conservative assumptions are used in the absence of data, which may overestimate risk in some scenarios but are necessary for public health protection.

4.2.1.3 Step 2 – Estimates for the probability that the daily amount of powdered formula that is reconstituted contains 1 CFU of Cronobacter or Salmonella.

The probability that a daily formula powder consumption contains 1 CFU (hazard level) was calculated as:

Hazard_level = CPS × DPC where

- Concentration in powder supply (CPS): the estimated concentration of the hazard (CFU/g) in powdered formula at the end of manufacture under each microbiological criteria scenario.
- Daily powder consumption (DPC): the average amount of powder consumed per day (g/day), as described in Model inputs for population size, proportion consuming, and frequency of consumption: Combined Australia and New Zealand estimates (page 26).

This is mathematically and internationally justified because it is the expected number of cells in the daily amount of powder based on assuming random distribution of bacteria in the powder (FAO and WHO 2006, Paoli and Hartnett 2006, FAO and WHO 2008). When contamination is rare, such as for infant formula, a valid approximation of the probability that at least 1 CFU is present is the mean concentration multiplied by the serving size (FAO and WHO 2006, Paoli and Hartnett 2006, FAO and WHO 2008).

4.2.1.4 Spreadsheet implementation

Hazard_level is used in the semi-quantitative spreadsheet to determine the probability of a disease-causing dose (PDD) which is calculated using the model calculation (Ross and Sumner 2002):

PDD (Probability of a disease-causing dose being present in the daily amount consumed)
= Hazard_level * Illness_dose * Prep_effect

Illness_dose and Prep_effect inputs are described in the following sections.

4.2.2 Model inputs for the increase in the hazards needed at the point of release needed to reach the average infectious dose for the consuming population (Illness_dose)

In the model, the input representing the probability that a contaminated daily intake results in illness (illness_dose) is varied to describe how differences between the expected daily dose

and an illness-relevant dose influence risk under different microbiological safety criteria and preparation scenarios (Ross and Sumner 2002).

To determine the model inputs for illness_dose, the following were estimated:

- the expected daily dose of the hazard at the concentration in the powder supply (hazard_level), which differs according to the microbiological criteria applied at manufacture
- the assumed infectious dose (ID) for *Cronobacter* or *Salmonella*, based on published dose–response information
- approximate $\log_{10}$ increase (ALI) which represents the order-of-magnitude increase in contamination required for the daily consumed amount, under each microbiological criteria scenario, to reach the assumed infectious dose after manufacture. ALI is calculated as the base-10 logarithm of this increase.
- The reciprocal of ALI is then used as a multiplicative factor to estimate the probability of a disease-causing dose (P_DD) being present in the daily powder (Ross and Sumner 2002). This factor represents the decreasing likelihood that a contaminated daily intake contains a disease-causing dose as the gap between the expected dose and the infectious dose increases.

The estimates and model inputs for the different scenarios are presented in Table 24.

Table 24: Estimated inputs for the probability that a disease-causing dose is present in the daily amount of formula powder consumed (PDD), showing hazard_level, assumed infectious dose, approximate $\log_{10}$ increase required to reach the infectious dose, and the corresponding illness_dose scaling factors by age group, hazard, and microbiological criteria scenario.

Aus + NZ: Formula consumption population	**Probability daily amount of formula powder contains 1 CFU (hazard_level)** **Model input = hazard_level)*	**Assumed infectious dose (ID) (cells)**	**Approximate $\log_{10}$ increase (ALI) needed to reach the AID**	**10^{-ALI}** **Model input = illness_dose)*
Cronobacter - without microbiological criteria				
0-6 month olds	0.0470	1,000	4.3	0.0000470
6-12 month olds	0.0537	10,000	5.3	0.00000537
1-3 year olds	0.0338	100,000	6.5	0.000000338
Cronobacter - with microbiological criteria 30 x 10g				
0-6 month olds	0.0225	1,000	4.6	0.0000225
6-12 month olds	0.0257	10,000	5.6	0.00000257
1-3 year olds	0.0162	100,000	6.8	0.000000162
Salmonella without microbiological criteria				
0-6 month olds	0.3822	1,000	3.4	0.000382
6-12 month olds	0.4368	1,000	3.4	0.000437
1-3 year olds	0.2750	1,000	3.6	0.000275
Salmonella with microbiological criteria 60 x 25g				
0-6 month olds	0.0279	1,000	4.6	0.0000279

6-12 month olds	0.0319	1,000	4.5	0.0000319
1-3 year olds	0.0201	1,000	4.7	0.0000201
Salmonella sensitivity analysis for 1-3 years old only				
30 x 10g	0.0549	1,000	4.3	0.0000549
10 x 25g	0.0705	1,000	4.2	0.0000705
5 x 25g	0.1058	1,000	4.0	0.000106

This section describes how the increase in microbiological hazard required from the point of testing to cause illness was estimated, based on assumed infectious doses, consumption levels, and potential changes in hazard levels prior to consumption.

4.2.3 Model inputs for the effect that different formula preparation steps have on Cronobacter and Salmonella (prep_effect)

This step captures what happens after purchase but before consumption. In the model, the input representing the effect of preparation, storage and handling practices on microbiological hazards (prep_effect) to evaluate how different Codex aligned preparation scenarios influence the level of microbiological hazard at the point of consumption.

Multipliers of values less than 1 represent inactivation or reduction of the hazard (e.g. use of hot water), while values greater than 1 represent potential growth associated with suboptimal preparation or extended storage and feeding times. The multipliers are not intended to represent precise predictions of growth or inactivation, but rather to provide order-of-magnitude estimates of how specific practices may influence exposure. Values were estimated based on consideration of published growth and survival data, international risk-assessment guidance, and previous FSANZ and FAO/WHO assessments.

This approach allows the semi-quantitative model to compare the relative effect of different preparation scenarios on risk in a transparent and internally consistent manner, without requiring detailed growth modelling. Suboptimal scenarios were included in accordance with Codex principles (CXG 21-1997; CXC 1-1969; CXC 66-2008) which require microbiological risk assessment and management to consider foreseeable conditions of use rather just idealised preparation practices. The scenarios assessed were:

- Infant-formula-equivalent preparation and handling scenarios, based on the current Code labelling requirements for microbiological safety, represented best practice in the assessment. Under these conditions, no microbial growth was assumed before a bottle was consumed:
    - Reconstitution using potable water that has been previously boiled and cooled.
    - Bottle fed immediately after preparation over a maximum of 2 h and any remaining formula is discarded and not reused.
    - If pre-prepared, the bottle is stored before feeding in a refrigerator at no more than 5°C for a maximum of 24 h.
- Suboptimal scenarios represented plausible household deviations from best-practice preparation and handling. These scenarios assessed the impact of different time and temperature conditions:
    - Suboptimal reconstitution: using non-preboiled or non-potable water or poor hygiene which may introduce other contaminating microorganisms.
    - Suboptimal feeding time: bottle feeding extended beyond best practice, with most formula consumed after 4 h out of refrigeration at approximately 27 °C.
    - Suboptimal refrigerated storage: if pre-prepared, the bottle is stored before feeding in a refrigerator at 8 °C for 48 hours before feeding.

- Suboptimal ambient storage: if pre-prepared, the bottle is left on the bench before feeding for 4 h at 27°C.
- Worst case preparation scenario: combination of suboptimal preparation including reconstitution, feeding time and ambient storage.

The derived inputs for each scenario are presented in Table 25. The following sections describe how these scenarios and inputs were estimated.

Table 25. Preparation scenarios and corresponding Cronobacter and Salmonella prep_effect multipliers applied in the semi-quantitative risk assessment, illustrating the relative impact of reconstitution, storage, and feeding practices on microbiological risk at the point of consumption.

Preparation scenario	Reconstitution of formula	Storage of prepared bottle before feeding	Duration of feeding	Overall effect of preparation
Infant-formula-equivalent baseline scenario	Cooled boiled water (no inactivation no growth assumed)	No storage (fed immediately) or kept in fridge at 5°C for 24 h before feeding	2 h	
Cronobacter	1	1	1	1
Salmonella	1	1	1	1
70°C water reconstitution	Boiled water at 70°C is used for reconstitution (inactivation estimated)	No storage (fed immediately) or kept in fridge at 5°C for 24 h before feeding	2 h	
Cronobacter	0.00001	1	1	0.00001
Salmonella	0.00001	1	1	0.00001
Suboptimal reconstitution	Cooled boiled water used	No storage (fed immediately) or kept in fridge at 5°C for 24 h before feeding	4 h at 27°C	
Cronobacter	1	1	76	76
Salmonella	1	1	220	220
Suboptimal fridge storage	Cooled boiled water used	Bottle in fridge at 8°C for 48 h before feeding	2 h	
Cronobacter	1	20	1	20
Salmonella	1	11	1	11
Suboptimal ambient storage	Cooled boiled water used	Left on bench for 4 h at 27°C before feeding	2 h	
Cronobacter	1	76	1	76
Salmonella	1	220	1	220
Worst case	Ambient tap water/non-potable water/poor hygiene for reconstitution	Left on bench for 4 h at 27°C before feeding	4 h at 27°C	
Cronobacter	10	76	76	57,652
Salmonella	10	220	220	483,351

Defining the baseline scenario: infant-formula-equivalent preparation methods

The objective of Proposal P1066 is to identify risk-management measures that provide young children with a level of microbiological protection equivalent to that afforded to infants consuming formula.

To support this comparison, a baseline scenario was defined assuming all microbiological safety-related preparation steps described in the current labelling instructions required for infant formula in the Code are undertaken when formula is prepared. The microbiological safety relevant instructions are:

- each bottle must be prepared individually
- previously boiled and cooled potable water must be used
- if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours
- formula left in the bottle after a feed must be discarded within 2 hours.

The parameters considered representative of this baseline scenario are presented in Table 26.

Table 26: Baseline (infantformulaequivalent) preparation scenario assumptions applied in the semiquantitative risk assessment, defining reference conditions for reconstitution, storage, and feeding against which alternative preparation scenarios are compared.

Scenario – *Cronobacter* and *Salmonella*	**Reconstitution water**	**Storage time and temperature**	**Feeding time**	**Overall effect of preparation**
Infant-formula-equivalent baseline scenario	Cooled boiled water reconstituted (no inactivation no growth)	No storage or 5°C for up to 24 h before feeding	All consumed within 2 h	1

The volume instruction was considered qualitatively. Preparing powder in bulk would mean that there is an increased risk of all bottles then subsequently prepared being contaminated at high levels if unsafe practices are followed. This effect could manifest in situations such as daycares or hospitals if large volumes of powdered formula exposed to poor handling could make large numbers of children sick. Preparation of individual bottles reduces the chance of a single cell being present and thus reduces the likelihood of exposure during daily consumption.

4.2.3.1 Justification for sub-optimal preparation and handling scenarios

FAO and WHO powdered formula risk assessments identify feeding time and storage temperature after preparation as key drivers of microbiological risk (FAO and WHO 2006, 2008). Consequently, WHO-aligned guidance emphasises immediate consumption where possible, limits on feeding duration, storage at low refrigeration temperatures and short refrigerated holding times as critical controls to minimise risk. Minimal deviations from infant-formula-equivalent preparation practices were selected for modelling for the following reasons:

- **Use of tap water, non-potable, or non-boiled water for reconstitution:** FAO and WHO powdered formula risk assessments recognise that powdered formula is not sterile and that reconstitution water can introduce additional microorganisms if it is not

adequately treated. While potable tap water is generally safe, FAO and WHO note that household practices vary and that water may not always be boiled or handled hygienically.

- **Extended feeding time or storage at ambient temperature (e.g. 4 hours at ~27 °C):** FAO and WHO identify time between preparation and consumption as a major driver of microbiological risk. Reconstituted formula can support rapid growth of *Cronobacter* and *Salmonella* at ambient temperatures, and risk increases substantially when feeding is prolonged or bottles are offered intermittently over several hours. Extended feeding times and delayed consumption are recognised as a common household practice.
- **Sub-optimal refrigerated storage (e.g. ~8 °C for up to 48 hours):** FAO and WHO note that refrigeration slows but does not stop bacterial growth, and that growth can occur at refrigeration temperatures above optimal conditions. Domestic refrigerators frequently operate above the recommended ≤5 °C, and longer storage durations further increase the potential for bacterial multiplication. Storage at approximately 8 °C for extended periods therefore represents a plausible sub-optimal household scenario rather than best practice.
- **Worst-case preparation scenario:** FAO and WHO emphasise that microbiological risk increases cumulatively when multiple deviations from best practice occur together. Combining non-boiled water, extended feeding times, and ambient storage represents a worst-case but plausible household scenario that allows both introduction and amplification of contamination.

4.2.4 Cronobacter growth estimates

The minimum growth temperature reported for *Cronobacter* is 5.5–8.0°C, and the maximum is 41–45°C. Relative growth factors were derived from the maximum growth rates for *Cronobacter sakazakii* in reconstituted powdered infant formula reported by Pina-Pérez, Rodrigo and Martínez (2012), expressed as the slope of log10 cfu/ml versus time (Table 27).

The change in microbial concentration over time was estimated by assuming exponential growth. The increase in the base-10 logarithm of cell numbers was calculated as the product of the maximum growth rate (expressed in $\log_{10}$ units per hour) and the exposure time (in hours). The corresponding relative growth factor was then calculated by raising 10 to the power of the product of the growth rate and time. This growth factor represents the multiplicative increase in cell numbers over the specified period.

As shown in Table 27, at 8 °C, the reported growth rate of 0.027 $\log_{10}$/h was applied over 24 h and 48 h to represent suboptimal feeding delay and extended refrigerated storage, resulting in relative increases of approximately 4-fold and 20-fold, respectively. For ambient storage, a growth rate at 27 °C was estimated by interpolation between the reported values at 25 °C and 37 °C, giving an approximate rate of 0.47 $\log_{10}$/h; applied over 4 h, this corresponded to a relative increase of around 75-fold. These factors were used as conservative, temperature- and time-dependent multipliers to estimate relative changes in hazard across multiple initial exposure scenarios.

Table 27: Temperature- and time-dependent growth multipliers applied for Cronobacter under suboptimal preparation and storage scenarios, showing assumed maximum growth rates, exposure durations, and resulting multiplicative increases used to conservatively estimate relative changes in hazard across exposure scenarios.

Temperature (°C)	Maximum growth rate (log_{10}/h)	Time (h)	Multiplicative factor F
8	0.027	24	4
8	0.027	48	20
27	0.47	4	76

4.2.4.1 Salmonella growth

Growth of *Salmonella* can occur at temperatures between ~5.2 - 46.2 °C, pH 3.8-9.5, and minimum water activity aw ~0.93 under near-optimum conditions (FSANZ 2016). The assumed generation times selected in the table below were conservative and determined using the ComBase broth-based growth model for *Salmonella* with no lag phase (ComBase 2024).

Relative growth factors for *Salmonella* were derived using maximum growth rates obtained from the ComBase predictive growth model under laboratory broth conditions, using the same calculations as for Cronobacter (Table 28). At 8 °C, the ComBase-derived maximum growth rate of 0.02164 log_{10}/h was applied over 24 h to represent suboptimal feeding delay, resulting in an approximate 3-fold increase, and over 48 h to represent extended refrigerated storage under worst-case conditions, resulting in an approximate 11-fold increase. For ambient temperature exposure, a maximum growth rate of 0.585 log_{10}/h at 27 °C was applied over 4 h, corresponding to a relative increase of approximately 220-fold. These multiplicative factors were used as conservative, temperature- and time-dependent estimates of relative hazard increase across multiple initial exposure scenarios.

Table 28: Temperature- and time-dependent growth multipliers applied for Salmonella under suboptimal preparation and storage scenarios, showing assumed maximum growth rates, exposure durations, and resulting multiplicative increases used to conservatively estimate relative changes in hazard across exposure scenarios.

Temperature (°C)	Max growth rate (log_{10}/h)	Time (h)	Multiplicative factor F
8	0.02164	24	3
8	0.02164	48	11
27	0.58546	4	220

4.2.4.2 Inactivation

For the assessment reconstituting powdered infant formula with water at 70 °C was considered to provide a 5 log_{10} reduction of *Cronobacter* and *Salmonella* (FAO and WHO 2006, 2008). FAO and WHO explicitly recognises that powdered infant formula is not a sterile product and may contain low levels of pathogenic bacteria. Consequently, while reconstitution with water at approximately 70 °C can reduce microbial risk, it does not guarantee complete inactivation of pathogens. WHO further acknowledges that preparation practices vary widely across care settings and households, leading to substantial variability in

the actual temperatures and exposure times achieved during formula preparation. As a result, WHO emphasises that effective risk reduction relies on a combination of control measures, including hygienic handling, appropriate time–temperature management, rapid cooling, and proper storage, rather than reliance on preparation temperature alone. Therefore, the minimum of 5 $\log_{10}$ reduction was modelled. In addition, use of very hot water introduces secondary hazards, including scalding risk and potential nutrient degradation, which must be balanced against the microbiological benefit (FSANZ 2016). Overall, the 70 °C control is effective in principle but variable in real-world application, and its performance depends on correct implementation and risk communication.

5 Risk characterisation

Risk characterisation integrates exposure, dose–response and severity components described in earlier sections to derive severity-weighted comparative risk estimates. This section focuses on interpretation of the risk estimates.

5.1 Analysis of comparative risk estimates

Figure 1 and 2 present $\log_{10}$ changes in severity-weighted comparative risk relative to the infant (0–6 month) baseline. Values below zero indicate lower estimated risk than the infant baseline; values above zero indicate higher estimated risk. Differences between scenarios mainly reflect whether infant-formula-equivalent microbiological criteria are applied and whether preparation practices follow infant-formula-equivalent guidance.

In Figure 1, for *Cronobacter* (yellow bars), estimated risk for children aged 1–3 years is consistently below the infant baseline across all scenarios, including worst-case preparation scenarios. This does not indicate absence of risk. It reflects a substantially lower relative risk in this age group. Infant-formula-equivalent preparation practices further reduce estimated risk. Infant-formula-equivalent microbiological criteria are not critical to producing estimate of risk for 1 – 3 year olds below or equivalent to the infant baseline.

In contrast, estimated *Salmonella* risk (blue bars), does not decline consistently with age. For children aged 1–3 years, estimated risk falls below the infant baseline only when infant-formula-equivalent microbiological criteria are applied together with infant-formula-equivalent preparation practices. When such criteria are not applied, estimated risk increases under suboptimal and worst-case preparation and storage scenarios and exceeds the infant baseline. These results show that, for *Salmonella*, preparation practices reduce risk, with microbiological criteria providing additional risk reduction, particularly where best-practice preparation cannot be assumed.

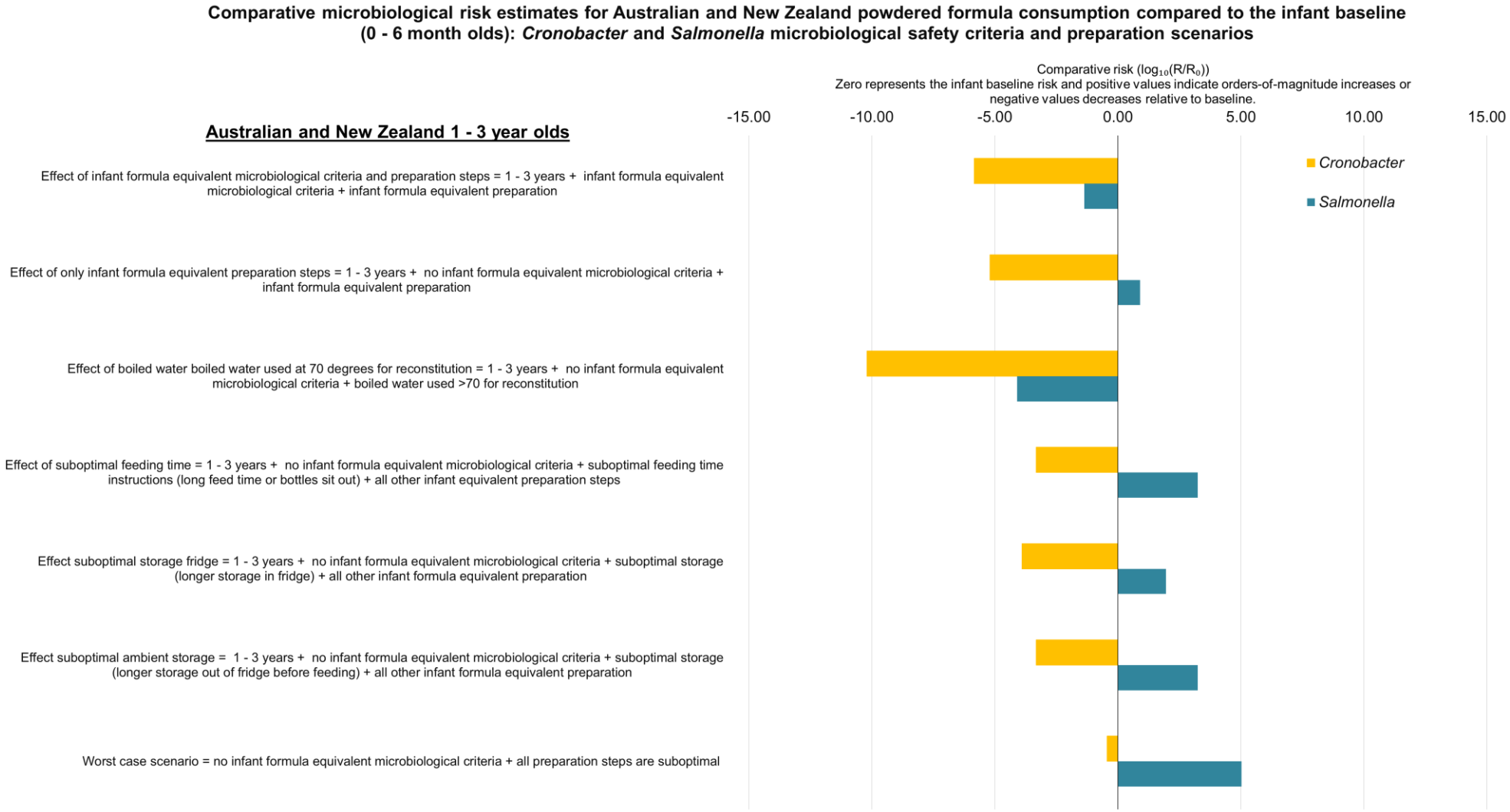

Figure 1. Comparative microbiological risk estimates for Australian and New Zealand powdered formula consumption compared to the infant baseline (0 - 6 month olds): Cronobacter and Salmonella microbiological safety criteria and preparation scenarios

5.2 Key insights for risk manager and how uncertainty was addressed by the model for *Cronobacter*

Strong age-related reduction in risk: Available evidence indicates that children aged 1–3 years have substantially lower susceptibility to, and severity of illness from, *Cronobacter* than infants aged 0–6 months, with the highest risk concentrated in infants under 2 months of age.
Uncertainty: Age-specific susceptibility is inferred from surveillance and clinical data rather than controlled dose–response studies.
Model assumptions: This uncertainty is addressed by applying conservative assumptions for exposure and by benchmarking all scenarios against the most vulnerable 0–6 month infant group.

Very low observed incidence in young children: *Cronobacter* illnesses are rarely notified in the 1–3 year age group in Australia or New Zealand, and cases in older infants and children are rare.
Uncertainty: Surveillance systems primarily capture severe or clinically recognised illness; mild or sporadic infections may be under-reported.
Model treatment: The assessment does not rely on absence of reported cases alone, but incorporates conservative hazard and exposure assumptions to avoid underestimating risk.

Estimated comparative risk is consistently below the infant benchmark: Modelling indicates that, for 1–3 year olds, estimated *Cronobacter* risk remains well below the infant baseline across all scenarios assessed, including scenarios without infant-formula-equivalent microbiological criteria, but infant-formula-equivalent preparation is important for reducing risk.
Assumption: Infant-formula-equivalent preparation is undertaken every time a bottle is prepared.
Uncertainty: There is variation in how consistently bottles will be prepared in accordance with any instructions.
Model treatment: Additional scenarios representing selective or suboptimal preparation have been explicitly modelled to demonstrate sensitivity.

Limited incremental benefit of infant-formula-equivalent microbiological criteria for this age group: Based on the risk assessment alone, applying infant-formula-equivalent microbiological criteria is not identified as a critical risk-reduction measure for *Cronobacter* in young child formula.
Uncertainty: This conclusion is based on semi-quantitative modelling and available evidence rather than precise quantitative risk estimates.
Model treatment: Conservative inputs (e.g. higher assumed hazard levels and growth multipliers) were used to ensure that potential risk is not underestimated.

Comprehensive preparation practices are a key control: Scenarios assuming infant-formula-equivalent preparation result in the lowest estimated *Cronobacter* risks and provide the greatest margin below the infant benchmark.
Uncertainty: Household practices vary in reality.
Model treatment: Worst-case and partial-compliance scenarios were included to capture plausible deviations from ideal preparation or absence of certain preparation instructions.

5.3 Key insights for risk managers and how uncertainty was addressed by the model for *Salmonella*

Limited evidence of age-related reduction in susceptibility: Unlike *Cronobacter*, there is limited evidence that susceptibility to *Salmonella* infection decreases substantially with age during early childhood. The dose required to cause illness is therefore assumed to be broadly similar across infants and young children.
Uncertainty: Age-specific dose–response data for non-typhoidal *Salmonella* are sparse.
How uncertainty is addressed in the assessment: A single, conservative infectious-dose assumption is applied across age groups to avoid underestimating risk in young children.

Greater risk at comparable contamination levels: Because the infectious dose for *Salmonella* is generally lower than for *Cronobacter*, similar levels of contamination in powdered formula result in a higher likelihood of illness.
Uncertainty: The precise dose–response relationship at low exposure levels is uncertain.
How uncertainty is addressed in the assessment: Conservative dose–response assumptions and upper-bound growth estimates are used to reflect potential illness at low doses.

Severity does not decline markedly across early childhood: Surveillance data from New Zealand indicate similar proportions of hospitalisation among children aged 0–3 years, suggesting comparable severity of illness across this age range.
Uncertainty: Hospitalisation data reflect reported cases and may be influenced by healthcare-seeking behaviour and admission practices rather than severity alone.
How uncertainty is addressed in the assessment: Severity weighting is applied consistently across scenarios so that relative differences in risk are driven by exposure and hazard control rather than assumed reductions in severity.

Key pathogen of concern for young children: *Salmonella* disproportionately affects children under five years of age in Australia and New Zealand, making it a priority hazard for risk management in young child formula.
Uncertainty: Surveillance data do not capture all infections, particularly mild cases.
How uncertainty is addressed in the assessment: Risk is benchmarked against the infant baseline and evaluated across a wide range of preparation and handling scenarios to test sensitivity.

Infant-formula-equivalent microbiological criteria and preparation are critical controls: Modelling shows that a combination of microbiological criteria (not detected in 60 × 25 g samples) and infant-formula-equivalent preparation reduce estimated risk for 1–3 year olds below the infant baseline.
Assumption: Infant-formula-equivalent preparation is undertaken every time a bottle is prepared.
How uncertainty is addressed in the assessment: Additional scenarios representing selective or suboptimal preparation have been explicitly modelled to demonstrate sensitivity.

Additional sensitivity analysis for *Salmonella*

Additional modelling was undertaken for Salmonella to support risk-management decision-making. The analysis examined how sensitive estimated risk is to different microbiological sampling plans and preparation practices. Unlike earlier analyses, this sensitivity analysis tests whether preparation practices alone, different microbiological criteria alone (as represented by alternative sampling plans), or combinations of both provide a level of protection comparable to that afforded to infants.

The analysis focused on children aged 1–3 years. Severity-weighted comparative risk estimates were compared against the 0–6-month infant baseline. Results are provided in Figure 2. This allows direct comparison of risk-management options across a range of microbiological control, from no sampling through to increasingly stringent sampling plans.

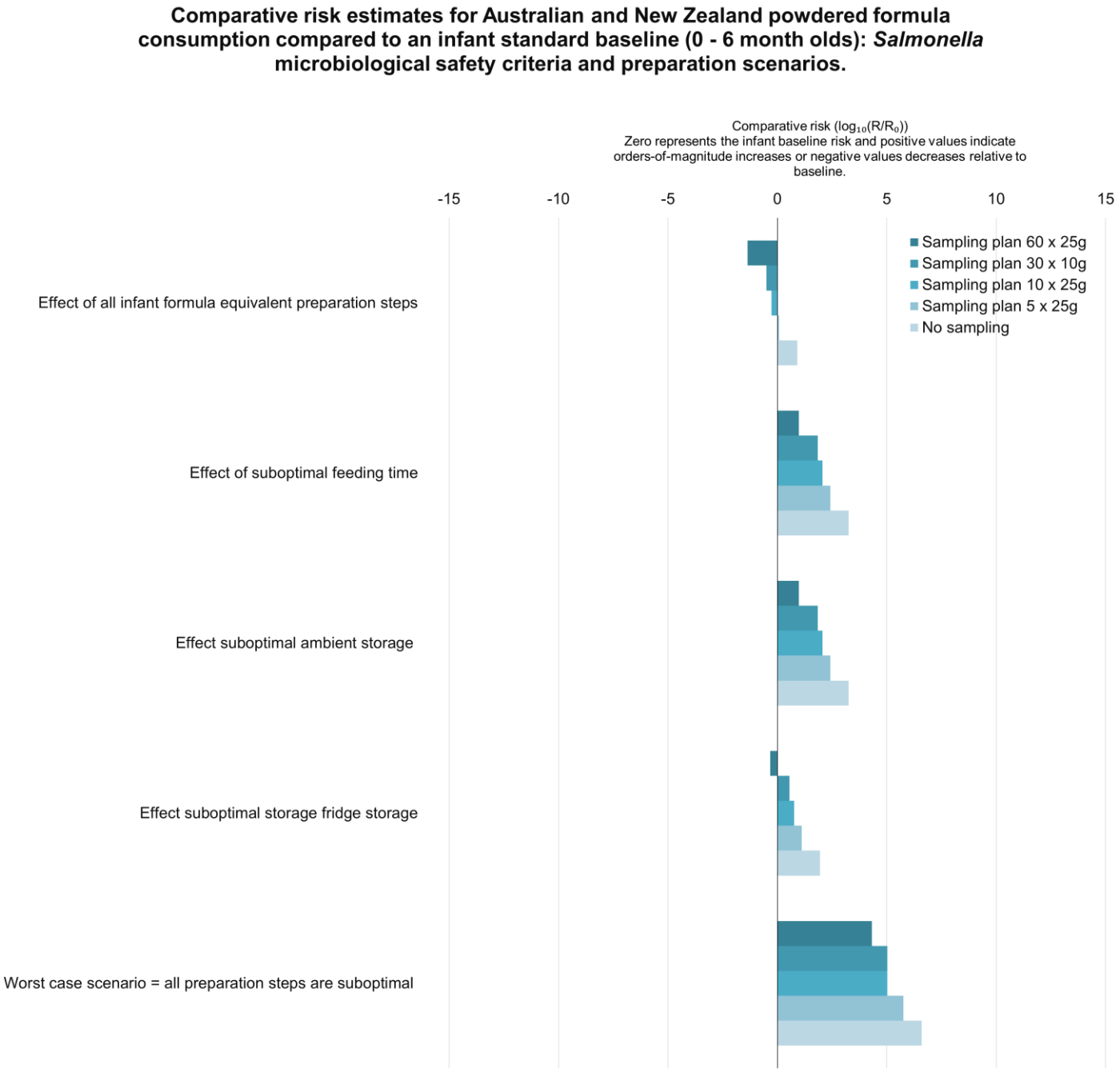

Figure 2. Log_{10} comparative risk estimates for Salmonella from powdered infant formula consumption in Australia and New Zealand, shown relative to the 0–6-month infant baseline. Bars illustrate the effect of preparation practices under different microbiological sampling plans, from optimal preparation to worst-case handling.

Under the most stringent sampling plans (e.g. 60 × 25 g and 30 × 10 g), estimated risk remains close to, or below, the infant baseline. This remains the case even when preparation or storage practices deviate from best practice.

Intermediate sampling plans (e.g. 10 × 25 g and 5 × 25 g) reduce risk but are more sensitive to suboptimal feeding times and storage conditions. As preparation practices worsen, estimated risk increases under these plans.

In contrast, scenarios with no microbiological sampling show the greatest sensitivity to preparation practices. Suboptimal feeding, storage, and worst-case handling result in large increases in risk above the infant baseline.

These findings show that preparation practices contribute to risk reduction, but the level of protection achieved depends strongly on the microbiological sampling plan. More stringent sampling plans provide a robust baseline level of protection and limit increases in risk under real-world variation in preparation and handling. Less stringent sampling plans place greater reliance on caregiver behaviour to control *Salmonella* risk.

Overall, equivalence to infant-level protection for *Salmonella* is most consistently achieved through the application of sufficiently stringent microbiological sampling plans. Preparation practices remain important secondary risk-reducing measure.

Actionable risk assessment outcomes

Modelling indicates that, under the specified assumptions, infant-formula-equivalent microbiological criteria for *Salmonella* and preparation steps to young child formula results in an estimated level of protection for Australian and New Zealand children aged 1–3 years that is comparable to the level of protection currently modelled for infants aged 0–12 months under the existing Code requirements for *Cronobacter* and *Salmonella*.

Question to submitters:

Q4.1 FSANZ seeks stakeholder comment, supported by data or other evidence where available, on the need for microbiological criteria in Schedule 27 for young child formula, specifically:

(a) criteria for *Salmonella*; and

(b) criteria for *Cronobacter*.

6 Review of microbiological guidance for powdered formula products

6.1 Introduction

The FSANZ Compendium of Microbiological Criteria for Food (the Compendium) (FSANZ 2025a) plays a key role in microbiological risk management by providing guidance to support microbiological testing and verification of hygienic control. Consistent with Codex *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXG 21-1997), both FSANZ and Codex recognise that microbiological testing has inherent statistical limitations, particularly for low-prevalence hazards and non-sterile foods, and that end-product testing alone cannot reliably assure food safety.

Within this framework, FSANZ applies a tiered, Codex-aligned approach. Mandatory food safety criteria in the Australia New Zealand Food Standards Code define acceptability of food in relation to public-health protection and are applied at the point of release or sale. In contrast, the Compendium provides process hygiene guideline criteria to support routine monitoring, trend analysis, and early detection of loss of hygienic control during manufacture. These guideline criteria are particularly important for high-risk foods such as powdered formula, where statistically meaningful verification of safety for every pathogen by testing alone is impractical, and where indicators of hygienic performance provide more reliable and actionable signals.

Aligning Compendium guidance for these products with that applied to infant formula can strengthen preventive control by improving the usefulness of microbiological testing, supporting timely corrective action, and ensuring consistent interpretation of results.

6.2 Existing guidance for infant and follow-on formula in the FSANZ Compendium of Microbiological Criteria for Food and applicability to young child formula

The FSANZ Compendium treats powdered infant formula as a high-risk food, recognising that pathogens such as *Salmonella* spp. and *Cronobacter* spp. can persist in dry processing environments and contaminate product following lethality steps. Mandatory food safety criteria for these hazards are established in the Food Standards Code (Standard 1.6.1), requiring their absence in powdered infant and follow-on formula at the point of sale.

Consistent with the Codex-aligned framework described above, the Compendium complements these food safety criteria with non-regulatory microbiological guideline criteria to verify hygienic process performance during manufacture. Process hygiene indicators, including Enterobacteriaceae and Standard Plate Count (SPC), are used to assess the effectiveness of hygienic controls rather than the safety of individual lots. While Codex and ICMSF recommend lower SPC guideline values (m = 500 CFU/g; M = 5,000 CFU/g), FSANZ has retained the existing Australian guidance values (m = 1,000 CFU/g; M = 10,000 CFU/g).

The Compendium also sets out process hygiene expectations across all stages of manufacture, including wet processing, drying, dry blending and packing, and links each stage to appropriate preventive controls, verification activities and corrective actions. Sampling plans, testing frequencies and responses to adverse trends support a systems-based, through-process approach to microbiological safety, consistent with the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008).

Given the close alignment in manufacturing processes, contamination risks and intended vulnerable populations, these principles are equally applicable to powdered young child formula. Extending the Compendium's process hygiene framework to young child formula under Proposal P1066 therefore represents a logical and proportionate application of established Codex-aligned principles, strengthening early detection of hygienic failures and supporting consistent protection across powdered formula products intended for children.

Question to submitters:

Q4.2 FSANZ seeks comment on the need to extend the Compendium of Microbiological Criteria for Food to include young child formula.

6.3 Potential updates and considerations

6.3.1 Limits for SPC in powdered formula

The SPC is included in the FSANZ Compendium as a non-regulatory guidance value. FSANZ proposes to align with Codex/ICMSF guidance for all powdered formula (m = 500 CFU/g; M = 5,000 CFU/g).

However, as mentioned in P1039 FSANZ retained the existing Australian criteria in the Compendium (m = 1,000 CFU/g; M = 10,000 CFU/g). P1066 provides an opportunity align with Codex guidance or retain the current process hygiene criteria.

Reducing SPC limits would align domestic guidance with international norms, strengthen hygiene monitoring, and support trade. However, retaining current limits avoids unnecessary compliance burden and focuses on risk-based priorities.

- Option 1: Align with Codex/ICMSF (m = 500 CFU/g; M = 5,000 CFU/g)
- Option 2: Retain Current FSANZ Limits (m = 1,000 CFU/g; M = 10,000 CFU/g)

Question to submitters:

Q4.3 FSANZ seeks comment on aligning or retaining the Standard Plate Count for all powdered formula in the Compendium of Microbiological Criteria for Food.

6.3.2 Spore formers

Recent outbreaks and recalls involving *C. botulinum* and *B. cereus* (cereulide) have prompted the international community to reconsider existing guidance for these pathogens (CDC 2026, EFSA 2026, EFSA et al. 2026, FDA 2026a, JEMRA 2026).

EFSA's 2026 rapid risk assessment establishes a science-based acute reference dose (ARfD) for cereulide in powdered formula and identifies indicative cereulide concentrations in reconstituted formula that may pose concern (EFSA et al. 2026). While out of scope for this assessment, this information could be considered in the future for referencing the EFSA ARfD as contextual international guidance, and informing risk-screening or incident response.

In relation to *C. botulinum,* spores are ubiquitous, their presence does not directly predict illness, and powdered formula cannot be sterilised without compromising product quality (Harris and Dabritz 2024, FDA 2026a, JEMRA 2026). Existing testing is impractical for food

safety application and control relies on application of specific or combined steps depending on the product (e.g., ingredient quality, product formulation, packaging conditions and/or storage conditions through chain). Additional specific international guidance for powdered formula is still evolving (FDA 2026a, JEMRA 2026). FSANZ will monitor the release of specific international guidance for *Clostridium* in powdered formula from Codex and JEMRA. However, it should be reinforced that effective HACCP and robust GHP/GMP are of critical importance throughout the manufacture of powdered formula. The US FDA's March 2023 Letter to Industry identified key focus areas and emphasised that manufacturers must identify and manage all known or reasonably foreseeable biological hazards (including *Cronobacter* spp., *Salmonella* and spore formers) for the safe manufacture of all foods for infants and young children (FDA 2026a).

7 Conclusions

This assessment examined the microbiological risks associated with *Cronobacter* and *Salmonella* in powdered young child formula for children aged 1–3 years, using a semi-quantitative approach consistent with international risk-assessment guidance. The purpose of the assessment was to support characterisation of risks across age groups and risk-management scenarios, rather than to estimate absolute risk.

The assessment indicates that *Cronobacter* risk is more age-dependent, with severe illness predominantly affecting very young infants. Under the model assumptions applied, estimated *Cronobacter* risk for children aged 1–3 years was lower than the infant benchmark across the scenarios assessed. Infant-formula-equivalent preparation and handling practices remain relevant to managing exposure.

For *Salmonella*, the assessment indicates that risk does not decline to the same extent with age during early childhood. Modelling suggests that a combination of infant-formula-equivalent microbiological criteria and preparation practices both reduce risk for young children to below the infant baseline.

For other microbiological hazards, including spore-forming bacteria such as *C. botulinum*, data limitations and the absence of internationally agreed criteria preclude quantitative assessment at this time. In this context, the assessment notes the ongoing importance of HACCP based whole-of-chain food safety management systems and good manufacturing practices for powdered formula for all children.

8 Appendix 1 – Codex requirement comparison

Section	Infant formula (CXS 72-1981 Section A + B)	Follow-on formula (CXS 156-1987 – Section A)	Young child formula (CXS 156-1987 – Section B)
Definitions:	Infant formula means a breastmilk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding. The product is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold. OR Formula for special medical purposes intended for infants means a substitute for human milk or infant formula that complies with Section 2 (Description) of the Standard for the labelling of and claims for foods for special medical purposes (CXS 180-1991)14 and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding. Other definitions The term infant means a person not more than 12 months of age.	Follow-up formula for older infants means a product, manufactured for use as a breastmilk-substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced. 2.1.2 Follow-up formula for older infants is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold. 2.2 Other definitions 2.2.1 The term infant means a person of not more than 12 months of age. 2.2.2 The term older infant means a person from the age of 6 months and not more than 12 months of age.	Drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children means a product manufactured for use as a liquid part of the diversified diet of young children. i 2.1.2 Drink for young children with added nutrients or product for young children with added nutrients or drink for young children or product for young children is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage, and distribution in the country where the product is sold. 2.2 Other definitions 2.2.1 The term young child means a person from the age of more than 12 months up to the age of three years (36 months).
Purity: All ingredients shall be clean, of good quality, safe and suitable for ingestion	Yes	Yes	Yes
HYGIENE: It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of	Yes	Yes Additional: and in the case of liquid formula that has been commercially sterilized should also consider the	Yes Additional: and in the case of liquid formula that has been commercially sterilized should also consider the

the General principles of food hygiene (CXC 1-1969), and other relevant Codex texts such as the Code of hygienic practice for powdered formulae for infants and young children (CXC 66-2008).		appropriate sections of the Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40-1993)8 and the Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23-1979), as applicable.	appropriate sections of the Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40-1993)8 and the Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23-1979), as applicable.
HYGIENE: The products should comply with any microbiological criteria established in accordance with the Principles and guidelines for the establishment and application of microbiological criteria related to food (CXG 21-1997).	Yes	Yes	Yes
LABELLING – Date marking and storage; The date marking and storage instructions shall be in accordance with Section 4.7 of the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985). Where practicable, storage instructions shall be in close proximity to the date marking.	Differs	Yes	Yes
Labelling - Information for use – water: Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with good hygienic practice.	Yes	Yes	Yes
Labelling: Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label.	Yes.	Yes	Yes
The label shall carry clear graphic instructions illustrating the method of preparation of the product.	Yes	Yes	Yes
The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use	Yes	Yes	Yes

Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.	Yes	Yes	Yes

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