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Attachment 1 – Microbiological safety of powdered infant formula: Effect of water temperature on risk

Supporting document 1

Safety and food technology

Proposal P1028 – Infant formula

Executive summary

The *Australia New Zealand Food Standards Code* (the Code) contains requirements for the manufacture, storage and use of infant formula to help ensure the microbiological safety of the product. The focus of those provisions is to ensure that the information and instructions on the label for the preparation and use of infant formula are clear and easy to follow for the general community.

FSANZ has undertaken microbiological safety assessments relating to the preparation, use and storage of powdered infant formula (PIF). In the FSANZ 2016 Consultation paper¹ (FSANZ 2016 CP1), the microbiological risk management strategies were reviewed with a particular focus on the temperature of water used for reconstitution of PIF and the storage time of prepared formula.

In the FSANZ 2021 Consultation paper 1 (FSANZ 2021 CP1), FSANZ reported the findings from additional modelling that investigated a wider range of preparation and storage times for PIF reconstituted with water between 10–50°C and refrigerated before use. The modelling indicated the water temperature used for reconstitution of PIF has a greater influence on risk than the time reconstituted PIF spends under refrigerated storage. FSANZ noted the relative risk increased when the temperature of water used to reconstitute PIF was 40°C or higher.

Clarity was sought in some submissions to FSANZ 2021 CP1 on whether ‘lukewarm’ water (around 40°C) presented a safety risk if used to reconstitute PIF that is fed immediately and discarded within 2 hours.

FSANZ has undertaken further modelling to consider the effect of ambient temperature and duration of feeding on risk when PIF is reconstituted with lukewarm water and used immediately for feeding. FSANZ concludes that infant formula that is prepared with boiled water that has been cooled to a lukewarm temperature (20–42°C) and fed within 2 hours at ambient temperatures up to 32°C, presents no heightened risk of infection to infants.

¹ <https://www.foodstandards.govt.nz/code/proposals/Pages/P1028.aspx>

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1 Introduction

In FSANZ 2021 CP1 for Proposal P1028, FSANZ analysed a range of preparation and storage time scenarios for powdered infant formula (PIF), to estimate the relative risk posed to infants by PIF intrinsically contaminated with *Cronobacter* spp. (formerly known as *Enterobacter sakazakii*). That assessment used the FAO/WHO Risk assessment model for *Cronobacter sakazakii* in powdered infant formula.² The model estimates the risk of illness from *Cronobacter* spp. posed to infants from intrinsically contaminated PIF, and does not consider post-manufacture contamination or recontamination from the preparation environment or other sources. The model is particularly useful in comparing the risk of different preparation and handling scenarios.

Our 2021 modelling indicated that the relative risk was significantly influenced by the temperature of the water used for reconstitution of PIF and by the period of time reconstituted formula spends under refrigerated storage before rewarming and feeding. In particular, as the water temperature for PIF reconstitution was increased above 40°C and the length of refrigerated storage increased, the relative risk of illness increased, mainly due to *Cronobacter* spp. being able to grow while the reconstituted PIF cooled to refrigeration temperature (modelled as 6°C).

In response to feedback in submissions to FSANZ 2021 CP1, we have now undertaken further modelling to consider the effect of ambient temperature and duration of feeding on risk when PIF is reconstituted with lukewarm (up to 42°C) water and used immediately for feeding.

2 Model Inputs

To enable direct comparison, the baseline scenario selected was the same as was used in the FSANZ 2021 CP1 (Table 1). That scenario included a total of 45 minutes preparation plus rewarming/cooling time, followed by a 30 minute feeding period. In our current modelling (Table 2) we have considered scenarios where formula is reconstituted quickly (6 minutes) in previously boiled and cooled lukewarm water, followed by feeding over 1 or 2 hours.

The outputs are expressed as *relative risk reduction* compared to the baseline scenario (which is assigned a relative risk of 1.00). The outputs (Table 3) provide a comparison of risk across the range of water temperatures used for reconstitution of PIF, ambient temperatures, and feeding periods.

Table 1: *Baseline scenario model inputs*

Stage	Temperature (°C)	Duration (h)
Water for reconstitution	37	
Preparation of formula	20	0.5
Holding/Cooling	6	0
Active rewarming/cooling	37	0.25
Feeding period	25	0.5

² <http://tools.fstools.org/esakmodel/ESAKRAModelWizard.aspx>

Table 2: Risk assessment model inputs

Stage	Temperature (°C)	Duration (h)
Water for reconstitution	20, 37, 42	
Ambient temperature during formula preparation and feeding	20, 25, 32	
Preparation of formula		0.1
Holding/Cooling		0
Active rewarming/cooling		0
Feeding period		1.0, 2.0

3 Results

All modelled scenarios returned a relative risk reduction of 1.00, indicating no increased risk compared to the baseline scenario (summarised in Table 3). This indicates that there is no increase in relative risk, compared to baseline, when formula is reconstituted with lukewarm water (modelled at 20°C, 37°C and 42°C) and feeding occurs immediately thereafter at an ambient temperature of 20–32°C for up to 2 hours.

Table 3: Summary of model outputs. Baseline scenario bolded

Reconstitution temperature (°C)	Ambient temperature (°C)	Duration of feeding (h)	Relative Risk Reduction*
37	20–25	0.5	1.00
20, 37 or 42	20, 25 or 32	1 or 2	1.00

* Compared to the baseline: A relative risk reduction of less than 1 represents an increased relative risk

3.1 Discussion

Since there is insufficient data to estimate the actual dose-response relationship for *Cronobacter* spp. in infants (Paoli and Hartnett, 2006), the model returns estimates of relative risk of illness compared to a baseline scenario for the reconstitution, holding and feeding of infant formula. The relative risk is calculated on the potential for growth or decline in the level of *Cronobacter* contamination, starting from an assumed level of 1 cell per serving.

The baseline scenario we have chosen is assumed to permit no-to-minimal growth during preparation and feeding. We compared scenarios where formula is reconstituted with lukewarm water (modelled at 20°C, 37°C and 42°C) and feeding occurs immediately thereafter at an ambient temperature of 20–32°C for up to 2 hours. None of the scenarios modelled presented a heightened risk of illness compared to the baseline scenario.

4 Conclusion

Based on the analysis, FSANZ concludes that infant formula that is prepared with boiled water that has been cooled to lukewarm (20–42°C) and fed for up to 2 hours at ambient temperatures up to 32°C presents no heightened risk of infection to infants.

5 References

Paoli G, Hartnett E (2006) Overview of a risk assessment model for *Enterobacter sakazakii* in powdered infant formula. Available at www.who.int/foodsafety/publications/micro/RA_Overview.pdf. Accessed 20 December 2021.