

## Supporting document 2

### Process hygiene criteria in powdered infant formula products (at Approval) – Proposal P1039

#### Microbiological Criteria for Infant Formula

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## 1 Introduction

FSANZ is undertaking a review of microbiological criteria contained in the *Australia New Zealand Food Standards Code* (Code) and associated documents. Proposal P1039 has been prepared to align microbiological food safety criteria for *Salmonella* and *Cronobacter* in powdered infant formula and powdered follow on formula in Schedule 27 in the *Australia New Zealand Food Standards Code* with Codex principles. These criteria apply for regulatory testing purposes. To meet the stringency of the sampling plans specified for these pathogens it would be expected that infant formula manufacturers utilise routine microbiological sampling and testing as part of monitoring and verification of the food safety control system they have in place.

The Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66 – 2008) provides guidance on the hygienic manufacture of powdered infant formula and on the subsequent hygienic preparation, handling and use of reconstituted formula products.

FSANZ is developing a single guidance document titled *Compendium of Microbiological Criteria for Food* to provide guidance on appropriate process hygiene criteria for specific commodities or food types. This supporting document provides the proposed process hygiene criteria for powdered infant formula products, to be included in the *Compendium of Microbiological Criteria for Food*.

## 2 Process Hygiene Criteria

### 2.1 Powdered infant formula products

Safe production of powdered infant formula products is dependent on maintaining a high level of hygiene control to prevent entry and establishment of pathogens such as *Salmonella* and *Cronobacter* in processing areas. The Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66 – 2008) provides guidance on the hygienic manufacture of powdered infant formulae and on the subsequent hygienic preparation, handling and use of reconstituted formula products.

Microbiological food safety criteria for *Salmonella* and *Cronobacter* in powdered infant formula and powdered follow on formula are specified in Schedule 27 in the *Australia New Zealand Food Standards Code*. These criteria apply for regulatory testing purposes.

To meet the stringency of the sampling plans specified for these pathogens it would be expected that infant formula manufacturers utilise routine microbiological sampling and testing as part of monitoring and verification of the food safety control system they have in place. This may include testing of ingredients, the processing environment, in process samples and final product testing.

### 2.1.1 Process hygiene criteria

Testing for Enterobacteriaceae and Mesophilic Aerobic Bacteria is useful to verify that the hygiene measures in place within a manufacturing facility are working as intended. This provides assurance that the potential for pathogens such as *Salmonella* and *Cronobacter* to be in the processing environment and to cross-contaminate infant formula products is being controlled.

Process hygiene criteria for Enterobacteriaceae and Mesophilic Aerobic Bacteria in powdered infant formula products are provided below.

<b>Powdered Infant formula products</b>	<b>(n)</b>	<b>(c)</b>	<b>(m)</b>	<b>(M)</b>
Mesophilic Aerobic Bacteria	5	2	500/g	5000/g
Enterobacteriaceae	10	2 <sup>1</sup>	0/10g	-

**n** = number of sample units

**c** = the number of sample units allowed to exceed m

**m** = the acceptable microbiological limit

**M** = the limit which must not be exceeded

These process hygiene criteria apply to the finished product or at any other point in manufacture that provides the information necessary to verify process control. They are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs.

Mesophilic aerobic bacteria counts provide useful indications on the hygienic status of wet processing steps. A trend in counts above the recommended limits may be indicative of build-up of bacteria in equipment such as evaporators or contamination due to leaks in plate-heat exchangers (Codex, 2008). These limits shouldn't be applied to powdered infant formula products that contain lactic acid producing microorganisms.

Failure to consistently meet criteria for Enterobacteriaceae may be a trigger to examine environmental and process hygiene controls and to evaluate product safety through increased sampling of final product for *Cronobacter* and *Salmonella*. Finding 1 or 2 positives should indicate a trend toward potential loss of process control. Finding 3 or more positives should signal loss of process control and appropriate actions should be taken including:

- Evaluation of product safety through increased sampling of final product for *Cronobacter* and *Salmonella* before release of the product

<sup>1</sup> Codex proposed a 2 class sampling plan for Enterobacteriaceae on the basis that a 3 class sampling plan would not be practical analytically given the low levels of Enterobacteriaceae that occur when stringent hygiene conditions are maintained. This criterion assumes that:

- the product is sufficiently homogenous so that high level contaminations will fail (more than two samples would exceed "m")
- in practice, positives would not normally be found if strict hygiene measures are in place. If occasional positives are found, the manufacturer would take appropriate actions.

- Evaluation of environmental and process hygiene controls to confirm they are suitable and are able to maintain hygiene control on an ongoing basis before production is resumed.

### ***Microbiological specifications***

Critical ingredients that do not undergo a heat treatment during processing (e.g. dry mix ingredients) need to be able to meet microbiological requirements for the final product. The ICMSF (2011) suggest sampling and testing for *Salmonella* and *Cronobacter*, as well as Enterobacteriaceae, should be considered either for acceptance or as monitoring, depending on the confidence level in the supplier.

#### *Additional considerations*

FAO/WHO Expert Consultations (2004, 2006) categorised *Staphylococcus aureus* and *Bacillus cereus* as “Microorganisms for which causality with illness is less plausible or not yet demonstrated” (Category C). It is generally accepted that low levels (<100 cfu/g) of these microorganisms may be present in powdered infant formula products and should be managed and monitored by the manufacturer as appropriate.

## **References**

Codex (2008) *Code of hygienic practice for powdered infant formulae for infants and young children* (CAC/RCP 66 – 2008), [http://www.codexalimentarius.org/standards/list-standards/en/?no\\_cache=1](http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1) accessed 28 July 2015.

International Commission on Microbiological Specifications for Foods (2011) *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*. Springer, New York.

FAO/WHO (2006) *Enterobacter sakazakii* and *Salmonella* in powdered infant formula: Meeting Report

FAO/WHO (2004) *Enterobacter sakazakii* and microorganisms in powdered infant formula: Meeting Report