

Further Information

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Executive Summary

Anchor products limited, a New Zealand infant formula manufacturer, has made an application (A454) to FSANZ to vary the microbiological limit for *Bacillus cereus* in infant formula currently specified in Standard 1.6.1 of the *Food Standards Code*. This application to amend the limit is made on the basis that the current standard (n=5, c=2, m=10, M=100) is too restrictive and cannot be complied with consistently under good manufacturing and hygienic practice.

B. cereus spores can occur in milk at very low levels. Processing of the milk into powder to be used in infant formulations will not eliminate the spores present. There is evidence to support that there may be seasonal increases in the level of *B. cereus* spores present in milk due to, for example, supplementary feeding of dairy cattle with silage, such that the level of spores in the dried milk powder will result in the final infant formula exceeding the limit of 10 cfu per gram (the "m" limit currently set in Standard 1.6.1) for some batches. The applicant proposes that a sampling plan in which the lower limit is raised to 50 cfu per gram (n=5, c=3, m=50, M=100) would be achievable and safe. In addition the applicant emphasises that the limit set should also consider the limit of enumeration of the analytical method to be used.

In addition to the microbiological limits for infant formula in Standard 1.6.1, Division 2 of Standard 1.1A.1 - Transitional Standard for Infant Formula Products also specifies microbiological limits for infant formula (Standard R7 of the "old" *Australian Food Standards Code*). The *B. cereus* limits in this standard are more lenient than those contained in Standard 1.6.1 or proposed by the applicant: n=5, c=1, m=100, M=1000. Standard 1.1A.1 will operate as an alternative standard until 20 June 2004.

The options in dealing with this application are to either amend the microbiological limit for *B. cereus* in infant formula in Standard 1.6.1 (Option 1) or to reject the application (Option 2). An amendment to Standard 1.6.1 could include (A) accepting the sampling plan proposed by the applicant or (B) proposing an alternative sampling plan that would be achievable, measurable and adequate to protect public health and safety. The sampling plan specified in Standard 1.1A.1 could be considered as an alternative sampling plan.

FSANZ has made an initial assessment of Application A454 in accordance with section 13 of the *Food Standards Australia New Zealand Act 1991* and has accepted it. Prior to FSANZ making a draft assessment of application A454, it is seeking public comment on matters relevant to the application, including the regulatory options proposed by the application and the costs and benefits of those regulatory options.