1. Introduction

1.1 Details of the application

An application (Application A454) has been received from Anchor Products Limited, an infant formula and nutritional powder manufacturer in New Zealand (Waitoa), to amend Standard 1.6.1 – Microbiological Limits for Food. The application specifically proposes that the *Bacillus cereus* limit for infant formula in Standard 1.6.1 – Microbiological Limits for Food be amended from:

n = 5, c = 2, m = 10 cfu per gram, M = 100 cfu per gram

to:

1. n = 5, c = 3, m = 50 cfu per gram, M = 100 cfu per gram, or
2. such that infant formula powder should not contain more than 100 cfu per gram of *B. cereus* (no sampling plan specifed).

Where:

n means the minimum number of sample units which must be examined from a lot of food

c means the maximum allowable number of defective sample units

m means the acceptable microbiological level in a sample unit

M means the level, when exceeded in one or more samples would cause the lot to be rejected

1.2 Justification for the application

Application A454 argues that the limit of m = 10 set for *B .cereus* in infant formula in Standard 1.6.1 cannot consistently be complied with. This is because there can be seasonal variation in the level of *B. cereus* spores in the raw milk and which then survive the heat and processing conditions in manufacturing milk powder. Sufficient spores remain so that, at times, the count for *B. cereus* in dried milk products exceeds 10/g for a complete batch or succession of batches.

The following reasons are given by the applicant for a variation to the *B. cereus* standard for infant formula:

- The limit of m = 10/g is not always achievable using milk solids from pasture and silage fed animals in New Zealand and elsewhere;
- A higher limit of m = 50 per gram is not unsafe, with the margin of safety being about 20 000 times less than the toxic level under most product abuse models;
- The present limit of m = 10 per gram is set at the limit of measurement for *B. cereus*, giving the potential for misunderstandings between officials and commercial practitioners.

2. Regulatory Problem

2.1 Current Domestic Regulations

2.1.1 Transitional Standard for Infant Formula Products

Standard 1.1A.1 - Transitional Standard for Infant Formula Products came into effect on 20 December 2002. This standard incorporates Standard R7 – Infant Formula of the former *Australian Food Standards Code* (Division 2) and Regulation 242 of the *New Zealand Food Regulations* (Division 3). In Australia, Standard 1.1A.1 operates as a transitional alternative standard to Standard 2.9.1 – Infant Formula Products for a period of 2 years from the commencement of Standard 2.9.1 (until June 2004). During this time, infant formula products produced in or imported into Australia must comply with Division 2 of this Standard or Standard 2.9.1 of the Code.

In New Zealand, Standard 1.1A.1 also operates as a transitional alternative standard to Standard 2.9.1 for a period of two years until 20 June 2004. During this time infant formula products produced in or imported into New Zealand must comply with Division 2 or 3 of this Standard or Standard 2.9.1

Infant formula products complying with Division 2 of Standard 1.1A.1 must comply with the microbiological limits specified in Division 2. The microbiological standard for *B. cereus* in Division 2 is far more lenient than Standard 1.6.1 and specifies that infant formula powder shall have a *B. cereus* count not exceeding 100 microorganisms per gram such that:

"when 5 sample units each consisiting of at least 100g or more of infant formula powder are examined as detailed, the result shall be reported as 'not exceeding 100 microorganisms per gram of the food' when at least 4 of the 5 sample units have a *Bacillus cereus* count not exceeding 100 microorganisms per gram and the remaining sample unit has a *Bacillus cereus* count not exceeding 1000 microorganisms per gram." (clauses (4)(a)(v), (7)(e))

When written in a sampling plan format the standard for *B. cereus* in infant formula powder in Division 2 is: $n = 5, c = 1, m = 10^2, M = 10^3$

Infant formula products complying with Division 3 of Standard 1.1A.1 or Standard 2.9.1 must, however, comply with the microbiological limits specified in Standard 1.6.1 - Microbiological Limits for Food.

2.1.2 Standard 1.6.1 – Microbiological Limits for Food

Standard 1.6.1 – Microbiological Limits for Food lists the maximum permissible levels of foodborne microorganisms that pose a risk to human health in nominated foods or classes of foods. The sampling plan included in this standard for *Bacillus cereus* in infant formula (including formula with added lactic acid producing cultures) specifies an acceptable microbiological level in a sample unit (m) of 10 cfu per gram and a failing level (M) of 10^2 cfu per gram:

Food	Microorganism	n	c	m	M
Powdered infant formula	*Bacillus cereus* /g	5	2	10	10^2

(Schedule to Standard 1.6.1)

Where:

n means the minimum number of sample units which must be examined from a lot of food

c means the maximum allowable number of defective sample units

m means the acceptable microbiological level in a sample unit

M means the level, when exceeded in one or more samples would cause the lot to be rejected

(clause 1)

2.2 International Regulations

The Codex *Code of Hygienic Practice for Foods for Infants and Children* (CAC/RCP 21-1979) contains advisory microbiological specifications for infant formula which includes mesophilic aerobic bacteria, coliforms and Salmonella. Limits for *B. cereus* are not included.

The USA Food and Drug Administration have set a microbiological limit for *B. cereus* in infant formula of not more than 100 per gram[1] (no sampling plan available). In Canada, the Health Protection Branch have recommended microbiological guidelines for *B. cereus* in powdered infant formula of n=10, c=1, $m=10^2$, $M=10^4$. Within the European Union, the Netherlands seems to be the only country which has set a legislative "action" limit, which is 100 per gram.

3. Objective

In developing or varying a food standard, FSANZ has three objectives and must also have regard to several other matters which are set out in section 10 of the *Food Standards Australia New Zealand Act 1991*:

(1) The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:

(a) the protection of public health and safety; and
(b) the provision of adequate information relating to food to enable consumers to make informed choices; and
(c) the prevention of misleading or deceptive conduct.

(2) In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:

(a) the need for standards to be based on risk analysis using the best available scientific evidence;

[1] The microbiological limits provided for the USA and the Netherlands were supplied by the applicant.