

**08/03**  
**19 March 2003**

## **INITIAL ASSESSMENT REPORT**

### **APPLICATION A454**

### ***BACILLUS CEREUS* LIMITS – INFANT FORMULA**

**DEADLINE FOR PUBLIC SUBMISSIONS** to the Authority in relation to this matter: **30 April 2003** (See “Invitation for Public Submissions” for details)

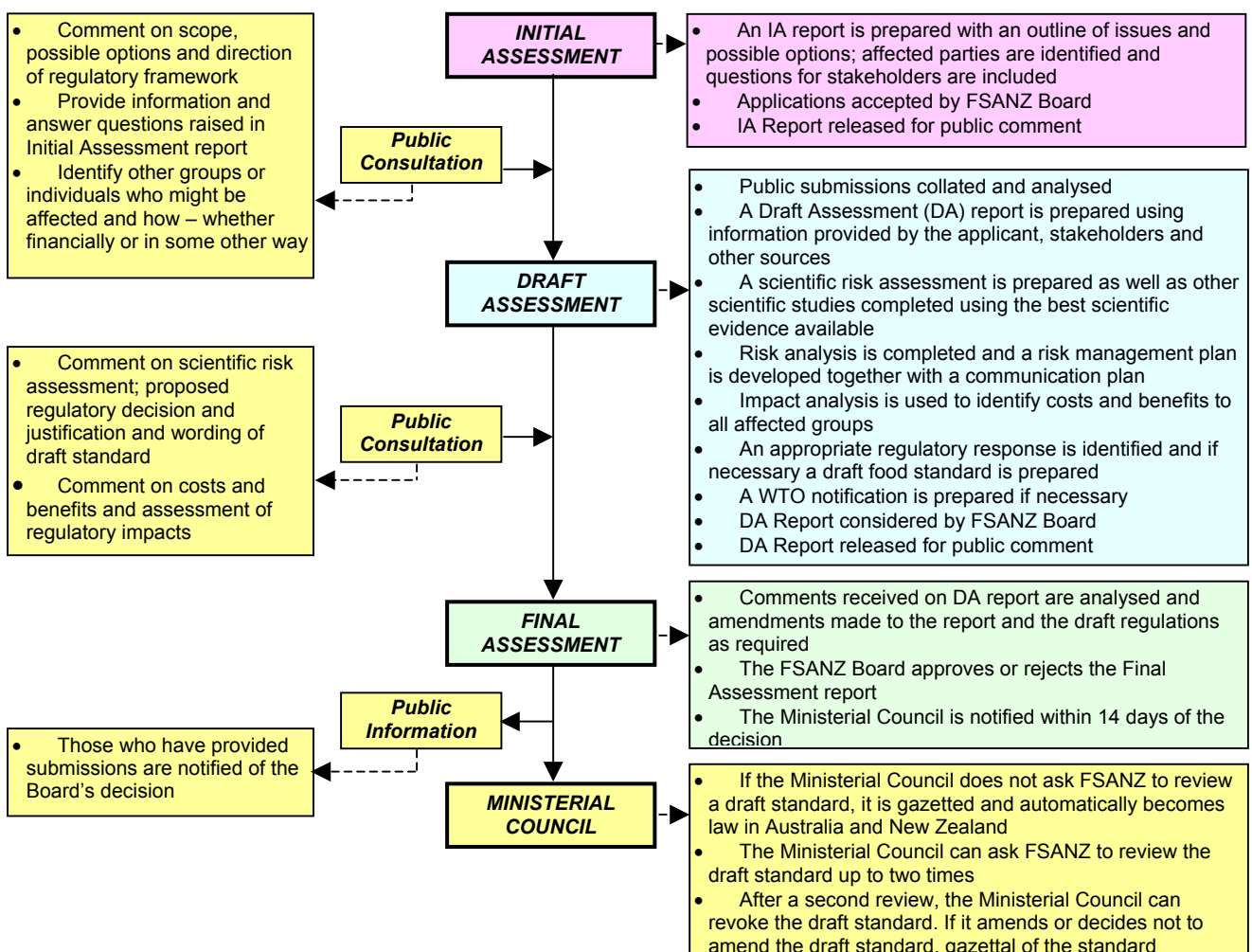
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of practice with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



## INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial Assessment Report of Application A454, which includes the identification and discussion of the key issues. The Authority now invites public comment on this Initial Assessment Report based on regulation impact principles for the purpose of preparing an amendment to the Food Standards Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Food Standards Code* (Code) from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority to treat in confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word "Submission" and quote the correct project number and name. Submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand**  
**PO Box 7186**  
**Canberra BC ACT 2610**  
**AUSTRALIA**  
**Tel (02) 6271 2222**  
**[www.foodstandards.gov.au](http://www.foodstandards.gov.au)**

**Food Standards Australia New Zealand**  
**PO Box 10559**  
**The Terrace WELLINGTON 6036**  
**NEW ZEALAND**  
**Tel (04) 473 9942**  
**[www.foodstandards.govt.nz](http://www.foodstandards.govt.nz)**

Submissions should be received by the Authority **by 30 April 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing [slo@foodstandards.gov.au](mailto:slo@foodstandards.gov.au).

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au) including other general enquiries and requests for information.

### **Further Information**

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Food Standards Australia New Zealand at one of the following addresses:

**Food Standards Australia New Zealand**  
**PO Box 7186**  
**Canberra BC ACT 2610**  
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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.

## 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 specified).

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 consisting 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	<i>Bacillus cereus</i> /g	5	2	10	10 <sup>2</sup>

(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<sup>1</sup> (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<sup>2</sup>, M=10<sup>4</sup>. 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;

<sup>1</sup> The microbiological limits provided for the USA and the Netherlands were supplied by the applicant.

- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair-trading in food;
- (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

The development of food standard(s) are also carried out in accordance with the competition policy principles which have been adopted by the Council of Australian Governments (COAG) and the draft Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to remove unnecessary obstacles to competition and an assessment of proposed regulation on all affected sectors of the community, and can be encapsulated in the phrase 'minimum effective regulation'.

## 4. Relevant Issues

### 4.1 *Bacillus cereus* occurrence in milk and infant formula

*B. cereus* is widely distributed in the environment and can be readily isolated from soil, dust and vegetation. *B. cereus* spores frequently contaminate milk, particularly if cows are fed with silage or are housed in barns.<sup>2</sup> Contamination can also occur from the udder, the environment and milking equipment.

Contamination of raw milk with *B. cereus* spores is generally at a very low level (<1 per ml). However, Application A454 states that there are seasonal increases in the level of *B. cereus* spores in raw milk, particularly during times when local farms need to supplement pasture feeding with silage and hay, which mean that a level of <10 cfu per gram in the finished formula product cannot be achieved. When higher levels of spores are present in the raw milk the *B. cereus* results in the finished product may range from 15 – 50 (and higher) cfu per gram despite good hygienic and manufacturing practices. While pasteurisation or other heat steps involved in the production of milk powder kill vegetative cells of *B. cereus*, spores are generally heat resistant and survive the processing steps into the final product.

Application A454 provides an example of how an increase in the level of *B. cereus* spores in raw milk to 4 cfu/ml would result in a level of 18 cfu per gram in the final formula. This level occurs because of the concentration effect during drying (total solids content of skim milk is 9.5%) resulting in a *B. cereus* level of ~ 42 cfu per gram in the dried milk powder. Infant formula produced contains 42% skim milk solids, giving a final level of ~ 18 cfu per gram.

Application A454 provides *B. cereus* test results for infant formula produced in the Waitoa production plant during the 2000 to 2001 season. These results show that while the majority of formula produced complies with a limit of m=10 cfu per gram a significant number of results greater than 10 are recorded each season. The number of higher results varies from season to season as the supplementary feed ratios change in response to the weather and growing conditions. The number of results between 10 and 90 cfu per gram occurs within a small number of batches of product. Levels in excess of 100 cfu per gram are also shown to

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<sup>2</sup> Jenson, I. & C, Moir. 1997. *Bacillus cereus* and other *Bacillus* species in *Foodborne Microorganisms of Public Health Significance*, AIFST Sydney.

occur, though no results over  $10^3$  cfu per gram were recorded (the upper limit specified in Transitional Standard 1.1A.1, Division 2).

#### 4.2 *Bacillus cereus* and foodborne illness<sup>3</sup>

While *B. cereus* may be present in a range of foods in low numbers (usually at concentrations  $< 10^3$  per gram), it generally does not cause illness unless time/temperature abuse of a food allows the organism to grow to high numbers ( $> 10^5 - 10^6$  cfu per gram).

There are two types of *B. cereus*-mediated intoxication – diarrhoeal syndrome and emetic syndrome. The first is characterised by diarrhoea after the ingestion of large numbers of cells. The diarrhoea is usually not severe and recovery typically occurs within 24 hours. A wide range of foods have been implicated in the diarrhoeal syndrome, in particular cereal or spice containing foods. The second type of infection is characterised by emesis (vomiting) after ingestion of toxin preformed in the food. This illness is also usually not severe and recovery occurs within 12 – 24 hours. Most foods implicated in emetic syndrome are rice based (cooked and fried rice).

*B. cereus* strains mainly associated with dairy products are psychrotrophic (cold tolerant) and are infrequently associated with food-borne illness. Outbreaks of food poisoning due to *B. cereus* have not been directly attributed to dry dairy products (milk powders), however temperature abuse of reconstituted product is a major concern. Infants are an especially vulnerable group because of their underdeveloped immune systems and because infant formula may represent their sole source of nutrition. If reconstituted infant formula containing low levels of *B. cereus* was temperature/time abused, there would be potential for unsafe counts to be reached. Diarrhoea illnesses in infants can be more severe than for the general population.

Nutricia, a large Netherlands-based infant nutrition and healthcare company, has published outcomes of predictive modelling work it has undertaken for abused reconstituted infant formula. The abuse conditions modelled were 2 hours at 30 °C followed by 24 hours at 10-12 °C. It was concluded that these conditions would result in a 5 generation increase in *B. cereus* in the made-up formula. This means that, even if formula powder before reconstitution had a level of 100 *B. cereus* per gram, the final level in the reconstituted formula after temperature abuse would still be less than 10 000 cfu per ml ( $3.2 \times 10^3$  per ml), a level which is not considered hazardous and unlikely to cause illness even in a vulnerable population group such as infants.

#### 4.3 Sampling plans

Sampling plans are used for determining when a lot or consignment of food should be accepted or rejected based on the possible risk posed to human health. Sampling plans presented in Standard 1.6.1 of the *Food Standards Code* are presented in the format devised

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<sup>3</sup> References for this section include: Jenson & Moir, 1997 (as above); ICMSF, 1996. *Microorganisms in Foods 5, Microbiological Specifications of Food Pathogens*, Blackie Academic and Professional, London.

by the International Commission on Microbiological Specifications for Foods (ICMSF). They indicate:

- the number of samples to be tested (n);
- the level of micro-organisms considered to be acceptable (m);
- the level of micro-organisms considered to be unacceptable (M)
- the number of samples which should conform to these limits (c)

Sampling plans are statistically based and provide a uniform basis for acceptance of a lot against defined criteria. The two widely accepted types of sampling plans defined by the ICMSF are the 2-class and 3-class plans. A 2-class sampling plan is used primarily for pathogens where a presence/absence test is to be used. Only one level of acceptance is provided – “m”. A 3-class plan is used where enumeration is required and the acceptance of the lot is based on a spread in distribution, such that two limits are given, “m” and “M”. In a 3-class plan, the number of samples allowed to exceed the lower limit is denoted by “c”. No samples are allowed to exceed “M”. In general, “m” is the level that is acceptable and attainable using good manufacturing practice (GMP) and “M” is the limit above which there is an unacceptable level of contamination caused by poor hygienic practice. Application A454 presents data that suggests that the “m” level currently set for *B. cereus* in infant formula in Standard 1.6.1 is not consistently attainable using GMP.

The ICMSF publication *Microorganisms in Foods 7, Microbiological Testing in Food Safety Management* (2002), provides detailed discussion on choosing a suitable sampling plan when establishing microbiological criteria, based on the severity of the hazard and appropriate for the particular food.

#### 4.4 Enumeration methods

Application A454 suggests that the enumeration limit for *B. cereus* is 10 per gram (+/- 6 per gram) and that it is unwise to set regulatory limits close to the detection limit because of the disputes likely to arise over the testing uncertainties. The method referred to is a spread plate method that involves plating 1ml of a 1 in 10 dilution over 3 plates. This is not the Standards Australia reference method prescribed in Standard 1.6.1. Prescribed methods of analysis are included in the Code for the sampling plans given so that disputes won't arise over the analytical results because of variations in the testing method used.

Australian Standard 1766.2.6: Examination for specific organisms – *Bacillus cereus*, is the reference method prescribed in the Code. This method sets out two quantitative methods, a surface spread method and a most probable number (MPN) method. The surface spread method is a more precise method but the limit of detection using this method is 100 cfu per gram (0.1 ml spread plate of a 1 in 10 dilution). This method therefore cannot be used for analysis where the microbiological limit is less than 100, as is currently the case for infant formula (“m” = 10 cfu per gram).

The MPN method is more sensitive and can be used to determine low levels of *B. cereus* (<10), but is less precise. The MPN procedure provides an estimate of the count present and confidence limits are used to indicate the precision of the MPN estimates. For a 3 tube MPN estimate of 110 cfu per gram (the value closest to 100 provided in the Standards Australia MPN tables) the 95% confidence limits give a lower limit of 15 and an upper limit of 480.

This means that while the estimate is 110 cfu per gram, the true number of organisms lies between the lower and upper limits 95% of the time.

The limits of the reference analytical methods specified need to be considered in setting a microbiological limit.

#### **4.5 Matters prescribed in section 13 of the *FSANZ Act***

In making an initial assessment of an application, the Authority must have regard to the matters prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991*:

- (a) whether the application related to a matter that may be developed as a food regulatory measure, or that warranted a variation of a food regulatory measure, as the case required;
- (b) whether the application was so similar to a previous application for the development or variation of a food regulatory measure that it ought not to be accepted;
- (c) whether costs that would arise from a food regulatory measure developed or varied as a result of the application would outweigh the direct and indirect benefits to the community, Government or industry that would arise from the measure or variation;
- (d) whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application;
- (e) any other relevant matters.

With regard to (a), application A454 is concerned with the microbiological status and safety of a food and the method of sampling and testing the food to determine its composition and therefore relates to a matter that may be developed or varied as a food regulatory measure (section 9 (1)(a)(ii) & (iii) of the *FSANZ Act*).

With regard to (b), application A454 is not so similar to a previous application for the development of a food regulatory measure that it ought not to be accepted.

In relation to (c), a regulatory impact assessment will be undertaken during the assessment of A454 to determine the costs or benefits associated with any food regulatory measure developed or varied as a result of this application.

With regard to (d), application A454 is concerned with a variation to an existing food regulatory measure. The cost effectiveness of other measures compared to a food regulatory measure will not be considered in this case.

Other matters relevant to this application have been discussed above.

## **5. Regulatory Options**

The regulatory options posed by this application are to either amend the microbiological limit for *B. cereus* in infant formula in Standard 1.6.1 or to reject the application. An amendment to Standard 1.6.1 could include accepting the sampling plan proposed by the applicant or to propose another sampling plan that would be achievable, measurable and adequate to protect

public health and safety. Rejecting the application would result in no amendment to Standard 1.6.1.

- Option 1 – amend Standard 1.6.1

**(A). Accept the sampling plan proposed by the applicant:**

The sampling plan proposed by the applicant is based on industry data, supplied by an infant formula company operating under conditions of good hygienic and manufacturing practice. It is a fairly lenient sampling plan (c=3), allowing 3 samples in 5 to exceed 50 cfu per gram.

Food	Microorganism	n	c	m	M
Powdered infant formula	<i>Bacillus cereus</i> /g	5	3	50	10 <sup>2</sup>
Powdered infant formula with added lactic acid producing cultures					

**(B). Accept an alternative sampling plan:**

The applicant proposes that a regulatory limit for *B. cereus* should be set:

- at a level which is at least one step above good manufacturing practice;
- at a level which is sufficiently safe for the consumer even when substantial customer abuse occurs, and
- at a level which is sufficiently far away from the measurement limits that unnecessary disput about the results is avoided.

The applicant proposes that this may be met by accepting the sampling plan outlined in (A) above, or an alternative such that an absolute limit of 100 *B. cereus* per gram is set.

It should be noted that there are currently two *B. cereus* limits for infant formula in the Code - one specified in Standard 1.6.1 and the other in Transitional Standard 1.1A.1. The limit in Standard 1.1A.1 (formerly Standard R7 – Infant Formula of the old *Food Standards Code*) is technically achievable and though more lenient than the sampling plan in Standard 1.6.1, has been adequate in protecting the health and safety of infants to date (indicated by the absence of foodborne illness data linking *B. cereus* food poisoning to the consumption of infant formula). It specifies a GMP limit (“m”) of 100 cfu per gram which is at the limit of detection for the spread plate method for *B. cereus* specified by Australian Standard 1766.2.6.

Food	Microorganism	n	c	m	M
Powdered infant formula	<i>Bacillus cereus</i> /g	5	1	10 <sup>2</sup>	10 <sup>3</sup>
Powdered infant formula with added lactic acid producing cultures					

- Option 2 – reject the application

Rejecting Application A454 would mean that no amendment to Standard 1.6.1 would be made. The sampling plan currently in Standard 1.6.1 (below) isn't technically feasible during certain manufacturing periods according to the information supplied by Anchor Products. It is also considerably more stringent than the standard for *B. cereus* in infant formula in Transitional Standard 1.1A.1, though both would be in effect concurrently at least until the end of 2004.

Food	Microorganism	n	c	m	M
Powdered infant formula	<i>Bacillus cereus</i> /g	5	2	10	10 <sup>2</sup>
Powdered infant formula with added lactic acid producing cultures					

## 6. Impact Analysis

The assessment of Application A454 will include an analysis of the costs and benefits of the regulatory options proposed to affected parties. The parties likely to be affected by A454 are:

- the food industry – infant formula manufacturers and suppliers;
- health care professionals/consumers – particularly involved with infant health care
- government agencies.

Anchor Products produces infant formula for export and the New Zealand and Australian market. About 10-15% of production from the Waitoa plant is sold on the Australia and New Zealand market, representing 60 – 85% of this market (a total of about 3300 – 4600 tonnes per annum). The applicant estimates that between 2 and 10 batches of infant formula would be lost each year (would “fail”) because they would not comply with the *B. cereus* limit in Standard 1.6.1. This would be considered by the company to be a serious economic loss and would cause Anchor Products to review their continued involvement in the supply of infant formula to the New Zealand and Australian market.

## 7. Consultation

FSANZ is inviting public comment on Application A454 in order to assist in the assessment of this application. Comment is particularly sought from organisations involved in the manufacture and supply of infant formula; public health agencies; consumer groups and any other interested party. Information is specifically sought in relation to:

- the issues raised above in section 5;
- the regulatory options proposed (Option 1(A), Option 1(B), Option 2); and
- costs and benefits of the regulatory options.

It will be recommended to the agencies responsible that the WTO be notified under the SPS agreement in accordance with Australia and New Zealand's obligations as members of the

WTO, in order to enable other member countries to comment on proposed changes to standards which may have a significant impact on them.

## **8. Conclusion and Recommendation**

Application A454 fulfills the requirements for initial assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991*. It is recommended that application A454 is accepted and public submissions are sought in order for FSANZ to make a draft assessment of this application.