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 precribed 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 Powdered infant formula with added lactic acid producing cultures	*Bacillus cereus* /g	5	3	50	10^2

(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 Powdered infant formula with added lactic acid producing cultures	*Bacillus cereus* /g	5	1	10^2	10^3

- 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	*Bacillus cereus* /g	5	2	10	10^2
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.