(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.[2] 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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[2] 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[3]

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 (3.2×10^3 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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[3] 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.