Comments from Dairy Food Safety Victoria and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources.

Due date of submission – 20 November 2015

Dairy Food Safety Victoria (DFSV) and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments), welcome the opportunity to provide comments on Proposal P1039 – Microbiological criteria for infant formula.

DFSV and the departments agree that the review of Standard 1.6.1 of the Code, and of the user guide for ready-to-eat foods, should be underpinned by the *Codex principles and guidelines for the establishment and application of microbiological criteria in foods.*

In line with the Codex principles, DFSV and the departments support including only food safety criteria in the Code, with appropriate process hygiene criteria to be moved into the *Compendium of Microbiological Criteria for Food,* which is currently under development by FSANZ with input from jurisdictions (including Victoria).

It is understood that the assessment of Proposal P1039 will provide a model for the remaining review of microbiological limits.

Specific issues raised by Proposal P1039 are set out below:

(i) *Cronobacter* species

The addition of food safety criteria for *Cronobacter* species in powdered infant formula products (PIFs) is supported.

(ii) Sampling plans

The International Commission on Microbiological Specifications for Foods (ICMSF) recommends taking into account a number of factors when choosing a sampling plan, including the risk posed by the hazard. The risk comprises the severity of the hazard **and** the likelihood of occurrence.

FSANZ's report appears to focus on the severity of the hazard rather than considering both the hazard and the likelihood of occurrence. FSANZ proposes increasing the number of sample units to be taken to test for *Salmonella* in PIFs from ten to sixty. This is of concern because sampling at n=60 is highly onerous, and according to ICMSF (Volume 7, 2002), n=60 is for the most dire situation (Case 15).

The report argues that:

> "These sampling plans are based on the premise that the history of the lot is unknown. Alternate sampling criteria would be appropriate where the history of the product is known *e.g.* it is produced under a validated and verified food safety system such as HACCP where manufacturers apply integrated sampling plans with in-process and environmental samples."

Further the report further states under final product:

> "For example any positive results for *Salmonella* in the processing environment or in-process should result in increasing sampling regime in the finished product."

The Code sets requirements for the minimum number of sample units to be tested. These requirements are not discretionary.

DFSV and the departments maintain that the principle of minimum effective regulation should be applied. There is no evidence of regulatory failure with the current sampling plan requirement for *Salmonella* in PIFs. The history of these products in Australia and New Zealand is well known.

In Victoria PIFs are produced under validated and verified food safety programs and therefore alternative criteria should be applied as the minimum requirement. While the FSANZ report states, "All feedback received from the industry has indicated that they are already undertaking testing as per the criteria outlined in the proposed changes in order to meet international standards", we consider this to be at the discretion of a business, and it should not be the determinant for setting minimum effective sampling levels appropriate for Australia and New Zealand.

A large part of the cost of testing for Salmonella is in the pre-enrichment media. Increasing costs by six-fold (from ten sample units to sixty sample units) is not "machinery in nature". DFSV and the departments are of the view that these changes will have a significant material impact on businesses and regulators contrary to statements under 'Cost benefit analysis' in FSANZ's report.

DFSV and the departments recommend maintaining the current (Standard 1.6.1) sampling plan for *Salmonella* in PIFs.

A similar situation arises with the proposed sampling plan for *Cronobacter* species. Hence DFSV and the Departments recommend reducing the number of sample units from thirty to ten, based on the reasoning set out above.

(iii) *Bacillus cereus*

The deletion of *Bacillus cereus* from the list of food safety criteria for PIFs is not supported.

The FSANZ assessment report includes the statement:

> "The FAO/WHO expert consultations found that, while *B. cereus* may be present at low levels, it does not represent a direct threat to the health of infants. It is generally accepted that low levels are acceptable (<100cfu/g) and will not lead to illness as long as the product is prepared and handled according to the recommendations. As such, food safety criteria for *B. cereus* are not necessary and limits will be removed from the Code."

DFSV, the regulator responsible for manufacturers of PIFs in Victoria, has reported that FSANZ raised the limit for *B. cereus* in infant formula to the current level in 2004. See: (http://www.foodstandards.gov.au/code/applications/Documents/A454_B_cereus_FAR.pdf). The assessment at the time stated:

> "*Although there is very little epidemiological evidence linking B. cereus to illness in infants, diarrhoea is a significant cause of ill health and death among infants and children in developed countries*".

The assessment found:

> "*Powdered infant formula containing up to 100 cfu/g of B. cereus and reconstituted using* [appropriate practices] *would not expose infants to an infectious dose of B. cereus".*

The inverse is also correct – mishandling and temperature abuse of powdered infant formula may cause food poisoning when emetic *B. cereus* is present. So this raises the following questions:

- Is the absence of any burden of illness data a reflection of the value of the current microbiological limit?
- Do we have data from manufacturers showing their ability to meet this limit on a consistent basis?

This may be an example of where microbiological criteria serve a useful regulatory purpose, and without it there will be no testing and manufacturers would have little evidence that a potential problem may arise.

DFSV has data that show *B. cereus* may be detected in pasteurised milk near the end of its shelf-life, at a prevalence of up to 14.8%. The presence of this organism in milk demonstrates the plausibility that it may also be in found powdered infant formula, and possibly at high levels because of concentration.

It is therefore recommended that criteria for *B.cereus* remain in the Code.

(iv) Other draft variations to the Code

It is proposed that Standard 1.1.1 is varied by omitting from subsection 1.1.1-2 (2) the words "Standard Microbiological limits in food", substituting "Standard 1.6.1 Food Safety microbiological criteria".

This proposed amendment is premature and is not supported as Standard 1.6.1 will still include process hygiene criteria up until the time that all foods in the current schedule are reviewed.

(v) Process hygiene criteria

It is proposed that the process hygiene criteria for PIFs should include *Enterobacteriaceae* and Mesophilic Aerobic Bacteria.

The term Mesophilic aerobic bacteria is not generally as well understood as Standard plate count (SPC or aerobic plate count) which is documented in AS 5013.5—2004 Food microbiology – Method 5: Microbiology of food and animal feeding stuffs—Horizontal method for the enumeration of microorganisms—Colony count technique at 30°C. The SPC is a term currently in use in Standard 1.6.1, and also in the revised code:

S27—2 Definitions
Note In this Code (see section 1.1.2—2):
SPC:
(a) means a standard plate count at 30°C with an incubation time of 72 hours; and
(b) in relation to powdered infant formula products with added lactic acid producing organisms—means that standard plate count prior to the addition of the microorganisms to the food.

The SPC (which will include yeast and mould) is often used as a basic indicator of total microbial load and therefore an indicator of process performance or raw material quality. There are decades of data based on SPC and, even though the mesophilic aerobic bacteria count may often yield similar results, to introduce a new term will confuse many, and will require regulators to also work with the laboratories to ensure they are using the correct method and are reporting accordingly. The continuity and comparison of performance data will also be compromised.

The proposal to change to Mesophilic aerobic bacteria is not supported at this time.

With the removal of SPC for PIFs from Standard 1.6.1, it is logical to also delete part (b) of the definition of SPC. However, the same qualification regarding SPC and added lactic acid bacteria should be made in the process hygiene criteria for PIFs.

DFSV and the departments request an opportunity to discuss these matters further with FSANZ and other jurisdictions to ensure that the 'model' for ongoing review of microbiological criteria is appropriate.