Ministry for Primary Industries
Manatū Ahu Matua

17 November 2015

Project Officer Proposal P1039
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

[redacted]

Dear Sir/Madam

Proposal P1039 – Microbiological Criteria for Infant Formula

Thank you for the opportunity to comment on this proposal. This submission is a joint submission from the Ministry for Primary Industries (MPI) and the Ministry of Health (MoH).

MPI and MoH welcome and strongly support this review of the microbiological limits for infant formula and the proposal to align all food safety criteria included in the Food Standards Code (FSC) standard 1.6.1-Microbiological Limits for Food with those in international standards (Codex Alimentarius [Codex]). These include microbiological criteria for *Cronobacter sakazakii* and *Salmonella* spp, which are bacteria known to cause illness in infants consuming infant formula.

We agree with the need for and value of having process hygiene criteria and believe that these will be a valuable tool for industry to verify that they have the manufacturing process under control.

However, we would like to raise the following points:

1. The microbiological criteria in the P1039 are not reflecting Codex guidelines. The Codex guideline (CAC/RCP 66-2008 (2008)) includes a 2-class sampling plan for *Enterobacteriaceae* which proposes a sample number (n) of ten (10) not five (5) as in the consultation. Amending the sampling plan will affect the operating characteristics if the number of acceptable units (c) is also not amended. This could have consequential effects for the sensitivity of the method especially where only 5 samples of 10g are sampled from a lot.

   We propose that the microbiological limits should reflect the Codex document:

Biosecurity Science, Food Science and Risk Assessment Directorate
Regulation and Assurance
Pastoral House, 25 The Terrace, PO Box 2526
Wellington 6140, New Zealand
Telephone: 0800 00 83 33, Facsimile: +64-4-894 0300
www.mpi.govt.nz

Powdered infant formula products	n	c	m	M
Mesophilic aerobic bacteria	5	2	500/g	5000/g
Enterobacteriaceae	10	2	0/10g	

It might have been considered that n= 5 is appropriate where there are other controls in place, e.g. a HACCP based food safety plan or environmental monitoring for Salmonella. If so, then it will be helpful to have a justification provided.

2. The Codex guidelines notes that the criterion for *Enterobacteriaceae* is not a true two-class sampling plan and provides a further explanation that added clarity to how the process hygiene criteria should be applied and used. To ensure clarity and consistency of approach MPI would like the text in footnote 22 of the Codex CAC/RCP 66 – 2008 adapted and included as an explanation in the Process Hygiene Criteria document, when it is finalised and published.

3. New Zealand surveillance data were misrepresented in the Supporting Document 1-Scientific evidence informing the proposed microbiological criteria for infant formula (Table 2). In 2004 a premature baby died of meningitis caused by *C. sakazakii* infection, four other infants in the same hospital were colonised, but did not become ill. Infants that were not sick cannot be called cases. We believe that this error should be corrected.

4. We are surprised that although the reference to the 2009 New Zealand survey (NZFSA (2009) Infant formula and *Cronobacter sakazakii* survey report) is included in the Supporting document 1-Scientific evidence informing the proposed microbiological criteria for infant formula, the results of this survey were not included in Table 4 (Prevalence of *Cronobacter* spp. in Powdered Infant Formula (PIF)). We would prefer the outcome of the New Zealand survey to be mentioned.

5. Advice on reconstitution of PIF is not included in the proposal. We fully support that this advice should not be a part of the requirements arising from proposal P1039. Therefore, the discussion of the WHO recommendations concerning PIF reconstitution in the Supporting document 1- Scientific evidence informing the proposed microbiological criteria for infant formula (part 4.1) looks out of place. We suggest that this discussion is excluded from the next version of the document. However, if FSANZ decide to keep this section, we would like to see a footnote that New Zealand guidance for PIF reconstitution is different.

Yours sincerely

[redacted]

Manager Food Science and Risk Assessment