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Fonterra Co-operative Group Limited Submission on:

FSANZ Consultation Paper – Completing the Review of Microbiological Criteria

16 February 2015

Fonterra Co-operative Group Limited

Fonterra is a leading global dairy nutrition business, owned by 10,500 New Zealand farmer shareholders. Fonterra is the world's leading exporter of dairy products and a preferred supplier of dairy ingredients to many of the world's leading food companies.

We are New Zealand's (NZ) largest company involved in large-scale milk procurement, processing and management, with a supply chain spanning more than 140 countries. The company has NZ$14.1 billion in total assets and revenues of NZ$16 billion, employing more than 16,000 people worldwide.

Fonterra is also a market leader in the consumer dairy segment with a portfolio of milk, cheese, butter and spreads, ice cream and yoghurt brands in Australia and New Zealand. Some of our consumer brands include Anchor, Bega, Fresh n' Fruity, Kapiti, Mainland, Perfect Italiano, Primo, Tip Top, Western Star and Nestle Ski. Fonterra also operates a dedicated sales channel for the foodservice industry which services restaurants, cafes, hotels and QSR operations.

Food safety and quality, and innovation are priorities to every part of the Fonterra business. Through its state-of-the-art research facilities in Palmerston North and Melbourne, and its global network of research and development facilities, Fonterra is a leader in dairy science and innovation. Fonterra products are synonymous with innovation in bone health, maternal health, child and infant nutrition and dairy goodness. Our products and ingredients are found in many types of manufactured food products, pharmaceuticals, food service outlets including bakeries, restaurants and hotels, and homes across Australia, New Zealand and around the world.

General Comments

- Fonterra undertakes a range of microbiological testing, both in-process and end-product testing, in order to meet internal food safety controls, regulatory and customer requirements.
- One of the challenges faced by Companies exporting globally is satisfying the wide variety, and sometimes over-lapping, microbiological testing requirements of different jurisdictions. Fonterra therefore prefers the flexibility to use a range of internationally recognised and validated methods for each microbiological test criteria. To have a locally prescribed testing regime will add complexity and costs without improving food safety outcomes.

- Fonterra supports an approach whereby separate criteria are set for food safety and process hygiene; with the former prescribed in the Food Standards Code (FSC) and the latter in a guidance document. The FSC is preferably outcomes based.
- Process hygiene criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs. We do not believe process hygiene criteria should be included in the FSC as this removes the ability for a Company to look at a range of effective situation-dependent options. A non prescriptive document allows the continuing adoption of best practices as the field develops.

Response to Specific Questions

Question	Comment
1a. What microbiological testing is currently undertaken by industry and government and why?	Typically, a company such as Fonterra will perform micro testing on dairy products it manufactures in order to meet the following requirements: 1. Regulatory (NZ): • Food Standards Code • Animal Products Act 1999, Tertiary Legislation and Guidance 2. Regulatory (Australia) • Food Standards Code • Australian States and Territories Legislation 3. Regulatory (Global): To satisfy the requirements of each country into which a product is being imported 4. Customer: To satisfy the specification requirements of each individual customer. 5. Company: To satisfy the Quality Control, Hazard Analysis Cricital Control Point (HACCP) verification, Internal Food Safety Requirements.
1b. How existing microbiological limits are used & any difficulties in their application	The various tests performed against (1-5) are used for the following purposes: • End-product testing to verify compliance with: ○ Animal Products Act & NZ (MPI) exporting country requirements. ○ Food Standards Code and associated Australian States and Territories Legislation ○ Customer specification requirements. • HACCP verification • Quality Control monitoring • Various indication roles e.g.: ○ Food Safety Management ○ Food Hygiene ○ Process Control
	One of the challenges faced by multi-national companies is satisfying the wide variety of different, and sometimes over-lapping, requirements of different parties e.g. • The same test (e.g. Salmonella) may be specified by different parties for the same product but with different test methods (e.g. ISO vs. FDA vs. GB China). This may see multiple testing of a particular product for the same criterion. • Ideally there should be international harmonisation of methods of analysis e.g. ISO, FDA, GB. • Fonterra prefers the flexibility to use a range of internationally

	accepted and accredited methods for each test criteria. Where appropriate, we suggest wording such as the methods employed should be internationally recognized and validated.. • Different tests may be applied for the same purpose (e.g. coliforms vs. Enterobacteriaceae for process hygiene) and this can lead to unnecessary and ineffective multiple testing. E.g. With respect to coliform monitoring, we do not believe this is required when Enterobacteriaceae testing is also being undertaken.

2. The proposed approach to include food safety criteria and process hygiene in the Code noting that each will have different corrective actions (i.e. response to not conforming to the criteria)	• Fonterra supports an approach whereby separate criteria are set for **food safety** and **process hygiene**; with the former being prescribed in the Code and the latter in a guidance document.
	
	• We are strongly supportive of the process being guided by / and consistent with the Codex / ICMSF approach as set out below:
	  • CAC/GL 21-1997: Principles & Guidelines for the Establishment & Application of Microbiological Criteria for Foods (revised 2013)
	  • ICMSF (2006). Micro-organisms in Foods 7: Microbiological Testing in Food Safety Management (2002). Kluwer Academic /Plenum Publishers, NY.
	  • ICMSF (2011). Microorganisms in Foods 8: Use of Data for Assessing Process Control. Springer, NY.
	
	• Fonterra is supportive of an outcome based regulatory framework that delivers safe food. Process hygiene criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs. Fonterra are supportive of process hygiene criteria being contained in Guidance and not in the Code as this removes the ability for a Company to look at a range of effective situation- dependent options. As outlined in the Codex Code of Hygienic Practice for Powdered Formula, process hygiene criteria are intended to be used by the manufacturer not the Regulator.
	  • We are interested in the process that FSANZ will use in defining the hygiene indicators to be included in the guidance document as well as the process by which the limits will be set.
	
	• Fonterra wishes to see consistency in the application of appropriate test criteria across similar food products e.g.
	  • Food Safety Criteria should be selected from a standard list e.g.:
	  Salmonella
	  L. monocytogenes
	  S. aureus (coagulase positive staphylococci)
	  B, cereus
	  C. perfringens
	  Campylobacter
	  etc
	  • Hygiene criteria should be selected from a standard list e.g.:
	  APC
	  Enterobacteriaceae
	• A discussion of product groupings is covered in the response to Section 3b.
	• Fonterra do not support the application of *E. coli* as a food safety test for pasteurized milk products. This is because the results of *E. coli* testing are

	widely misinterpreted: • In the case of *drinking / potable water*, it is *correct* to interpret the presence of *E. coli* as indicating the occurrence of recent faecal contamination – the implication being that enteric pathogens could also be present. • In the case of *dairy products made from pasteurized milk* it is *incorrect* to interpret the presence of *E. coli* as indicating the occurrence of recent faecal contamination. Their source is almost invariably *not* associated with faecal matter. Rather, their source is almost exclusively associate with hygiene issues (see the bullet point below where coliforms and Enterobacteriaceae are mentoned) • From a pathogen perspective, since most *E. coli* strains are not pathogenic, it is not really appropriate to apply a food safety 'tag' to *E. coli*. • In relation to process hygiene for pasteurized products, the Coliform or Enterobacteriaceae tests are more effective indicators than *E. coli* which forms a single species sub-set of both.
3 FSANZ seeks input for prioritizing the work. Information that may assist includes: a) **whether the proposed order of review is appropriate**	• Fonterra is supportive of the Infant Formula product criteria being reviewed first in early 2015 as outlined in the Consultation paper, and notes the other product categories including dairy, seafood and meat are also planned for review in 2015. We suggest a review of the Dairy Category follow shortly after the IF review given the need for consistency between these categories.
b) Issues related to specific commodities/ commodity groups that should be considered under this review and the rationale	We believe there is significant room for improvement in the current Standard 1.6.1 (and the associated Use Guide to Standard 1.6.1). For example, the descriptions of food groups in Column 1 of the schedule are not user 'friendly' e.g. product groupings are not clear (e.g. what products are included under the Dried Milk heading) or consistent; products are not alphabetical and many products are not mentioned (e.g. pasteurized milk / cream; yoghurt, acid beverages, quark, whey powders, casein etc). • The output of the review should be in the form of tables of microbiological criteria which are intuitive, easy to use / covering all food groups / able to be extrapolated to cover specific foods that are not mentioned. • Fonterra is supportive of the adoption of Codex microbiological criteria where these exist (e.g. those given in Appendix 1 of the 'Code of Hygienic Practice for Powdered Formulae for Infants & Young Children' (CAC/RCP 66 – 2008). Unfortunately most of the Codes published by Codex do not included specific microbiological criteria as illustrated by the Code of Hygienic Practice for Milk & Milk Products (CAC/RCP 57-2004) which states 'Where they are employed, microbiological criteria…… should be developed in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods, CAC/GL 21-1997……' • Fonterra would like to see 'sensible' broad groupings and definitions within the 'dairy product' category. One possible solution would be to group dairy products using factors such as:

	○ Pasteurised / Unpasteurised ○ Characteristics that bestow stability on groups of products e.g. products where microbial stability is reliant on refrigeration and short shelf life; products where low water activity is the reason for the inherent microbial stability of the product; products where microbial stability is reliant on low pH etc
3c) Resources available to assist in the application of microbiological criteria.	If required, Fonterra is able to provide expertise in relation to the following: • The statistics of sampling and testing (Calibration & Statistics Team) • Risk assessment (Food Assurance team) • Developing microbiological criteria (Food Assurance and Calibration & Statistics teams)

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Yours faithfully

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