Fonterra Co-operative Group Limited Submission on:

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FSANZ Call for Submissions: Consultation Paper – Proposal P1028 Infant Formula

31 May 2016

Executive Summary

1. Fonterra welcomes the opportunity to provide comments and information to FSANZ on the Proposal P1028. We thank FSANZ for the consideration of the comments outlined in this submission

2. Fonterra strongly support the content and views of the Infant Nutrition Council (INC) P1028 submission. Along with other INC members, Fonterra have invested significant time in developing aligned industry positions on the key issues and questions posed through P1028, as outlined in the INC submission. In light of this, and rather than repeat INC responses, Fonterra have selected key areas of the P1028 Consultation where we are well placed to provide elaboration including Nutrition Composition, Nutritive Substances and Novel Foods, as summarized below;

Composition

3. On **protein**, specifically **Nitrogen Conversion Factor**, Fonterra does not support FSANZ's position to change the existing nitrogen conversion factor (NCF) of milk based infant formula from 6.38 to 6.25, however is supportive of the proposal for soy based infant formula whereby a NCF of 5.71 will be applied i.e. Fonterra supports a NCF of 6.38 applied to milk protein based infant formula and 5.71 for soy protein infant formula for scientific, nutritional, sustainability and economic reasons.

4. Regarding **protein quality**, Fonterra agrees with FSANZ preliminary conclusion that the amino acid (aa) breast milk reference pattern (with the suggested modifications as outlined by INC including alignment with Codex STAN 72-1981 minimums for tyrosine, phenylalanine, methionine, and cysteine) should remain within the FSANZ Infant Formula Std 2.9.1 (S29-6) for the time being. Fonterra is of the view that implementation of DIAAS as a protein scoring system, with suitable age related targets as recommended by the FAO at

such time as a supporting framework for implementation becomes available, will provide additional clarity to the formulation of IF, and ensure proteins used in IF will deliver bioavailable amino acids to the infant.

5. On **Fat**, Fonterra consider the **Trans Fatty Acids** limit in Standard 2.9.1 should not be reduced from a 4% limit to 3%, as proposed by FSANZ. Different definitions for TFA are defined in the Food Standards Code and Codex and therefore the same TFA limits can't be applied between the STAN 72-1981 and Standard 2.9.1. The 4% level should be retained to continue to allow the use of milkfat in infant formula, recognising also that Breast Milk contains TFA at levels of 2-5% (Larqué et al 2001) and the important components bovine milkfat contains. Fonterra does not support FSANZ's proposal to restrict **Phospholipid** content.

6. On **vitamins, minerals and electrolytes**, Fonterra strongly supports the continued use of non-binding GULs to serve as guidance for industry in designing formulations. Maximums should only be used when there is scientific evidence to support the need for an upper level. Regarding **folate**, Fonterra supports the use of **folic acid** to express the folate content of infant formula. Fonterra is supportive of increasing **iodine** levels for both nutrition and technical reasons, however considers full alignment with Codex including the use of a GUL appropriate. For reasons of alignment, flexibility for manufacture and avoidance of trade barriers Fonterra considers all **nutrient forms** permitted in Codex STAN 72-1981 should be permitted in Standard 2.9.1.

7. Regarding the current **optional substances L-carnitine** and **choline,** Fonterra is supportive of the proposal to mandate these nutrients, however has significant concerns with the feasibility and limited nutrition justification to support the proposed L-Carnitine maximum of 0.8mg/100kJ, noting that neither Codex or the EU include a limit. Fonterra is supportive of the proposal to increase the nutrient range for Choline to 1.7-12mg/100KJ, however considers a GUL not a maximum as outlined by Codex to be appropriate.

Safety and Food Technology

8. In relation to **nutritive substances** and **novel foods**, Fonterra considers Standard 2.9.1 should be included within the scope of Proposal P1024 (Proposal to revise the regulatory regime for nutritive substances and novel foods). Fonterra submits that, with appropriate differentiation and subject to improvements to the framework overall, the framework proposed in P1024 as Option 3 should be applied to Standard 2.9.1, including infant formula. Fonterra has raised several concerns regarding the application of the Option 3 framework to dairy ingredients, including that:

- the regime should reflect the long history of safe use of dairy ingredients and recognize that not all concentration or extraction steps create risk (i.e. create inbalance in total nutrient intake);
- the appropriate basis for comparison in a safety assessment is what can be delivered to a final product through typical dairy ingredients; and
- the Eligible Food Criteria do not provide clarity or allow an objective assessment of the "eligibility" of dairy ingredients.

9. Fonterra submits that under the framework proposed as Option 3 in P1024, all substances for use in infant formula would undergo a pre-market assessment, but that not all pre-market assessments need to be undertaken by FSANZ. Fonterra also proposes specific differentiating factors for the Option 3 regime to address the vulnerability of the target population, and the unique role of infant formula as the sole source of nutrition for infants 0 to around 6 months where breastfeeding is not undertaken.

10. In relation to **contaminants**, Fonterra supports the FSANZ views in relation to acrylonitrile, tin, vinyl chloride, arsenic and lead and believes that further consideration is needed in relation to aluminium. Fonterra believes that the appropriate units for MLs relating to contaminants for infant formula should be based on mg/kg as sold.

11. **Food additives** are technologically necessary for the quality of the ingredients and finished product. To facilitate innovation and harmonisation of trade, Fonterra consider the list of food additives permitted in infant formula should be expanded to include those already permitted under Codex for which safety and technological justification have already been established. Fonterra supports continuation of the carry-over principle for food additives in infant formula.

12. Fonterra recognizes the importance of FSANZ objectives in revising and clarifying Standards related to infant formula in the Food Standards Code in light of international scientific and regulatory developments. Fonterra look forward to staying involved in the Consultation process. If there are any queries relating to this submission, please contact Jenny Campbell, Regulatory Manager – Group Food Safety, Quality and Regulatory (jenny.campbell@fonterra.com).

Yours faithfully

[redacted]

[redacted]

Group Director Food Safety Quality Regulatory

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Fonterra Co-operative Group Limited

13. Fonterra is a leading global dairy nutrition business, owned by 10,500 New Zealand farmers and supported by 16,000 staff, with a supply chain spanning more than 140 countries across Australasia, Asia, Africa, the Middle East and Latin America.

14. The world's largest exporter of dairy products and a preferred supplier of dairy ingredients to many of the world's leading food companies, Fonterra produces more than two million tonnes of dairy ingredients, specialty ingredients, foodservice products and consumer products every year.

15. As a market leader, Fonterra owns six global brands, including Anchor™, Anlene™ and Anmum™, and supplies dairy products to many of the world's largest consumer and foodservice brands.

16. Fonterra has a long history in the manufacture of paediatric nutrition, with more than 50 years of experience in producing world class infant and young child formulas globally. Fonterra produce formula and ingredients for large multinational and major regional paediatric companies and is one of the world's largest contract manufacturers of paediatric nutrition formula and ingredients.

17. Drawing on generations of dairy expertise, Fonterra is one of the largest investors in dairy-based research and innovation in the world. 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, New Zealand and Melbourne, Australia, and its global network of research and development facilities, Fonterra is a leader in dairy science and innovation.

Introduction

18. Fonterra welcomes the opportunity to provide comments and information to FSANZ on the Proposal P1028. We thank FSANZ for the consideration of the comments outlined in our submission.

19. Fonterra supports the continued protection of breastfeeding noting the many benefits this has for both mothers and infants. For non-breast fed infants that are fed infant formula, Fonterra supports a regulatory approach that ensures the best possible nutrition for such infants. This includes measures to ensure appropriate food safety and protection of public health, while allowing for continued innovation including scientific and technical development of infant formula. Fonterra supports harmonization with relevant Codex standards as a means of reducing trade barriers, unless there is strong scientific justification for a different approach.

20. Fonterra strongly supports the content and views of the Infant Nutrition Council (INC) P1028 submission. In conjunction with the Scientific and Technical INC working group, Fonterra have invested significant time in developing aligned industry positions on the key issues and questions through P1028 as summarized by the INC response. Rather than repeat the INC submission, Fonterra have selected key areas of P1028 Consultation where we are well placed to provide information on certain topics, or in the case of the one instance where there is a split INC position, we have elaborated on the Fonterra position.

21. Our submission focuses on aspects of Nutrition Composition, Contaminants and Food Additives, and Nutritive Substances and Novel Foods, with responses to select questions covered in the text.

Nutrient Composition

Protein

22. ***Protein Content***: *FSANZ notes that protein amounts are generally aligned with Codex but that there is growing interest in lowering the requirements to potentially lower the risk of obesity in childhood. FSANZ considers that more evidence is required to demonstrate the advantages of lower protein intakes for infants.*

23. Regarding alignment with Codex protein levels, Fonterra refers to the INC submission which suggests a minor technical amendment to the per 100kJ values to align with Codex which stipulates on per 100kcal basis. We support FSANZ conclusions that more evidence is required to demonstrate the advantages of low protein infant formula. Fonterra note that support for the early protein hypothesis mostly comes from one large RCT (Koletzko et al. 2009a,b). While follow-up data of this trial showed a significantly higher BMI in the higher protein vs lower protein group, there was no significant difference in BMI between the higher protein and breastfed control groups (Weber et al. 2014). Three other RCTs designed to test the early protein hypothesis do not consistently support a negative effect of higher protein levels in early life on anthropometric measures in young children (Inostroza et al. 2014, Putet et al. 2015, Larnkjaer et al. 2009). RCTs investigating the safety of lowering protein levels, mostly by simultaneously changing the protein quality, and so which were not set up to test the early protein hypothesis, did not suggest that higher protein levels had adverse effects on growth velocity or body weight (Lien et al. 2004; Davis et al. 2008; Trabulsi et al. 2011; Rozé et al. 2012; Fleddermann et al. 2014; Timby et al. 2014; Ziegler et al. 2015). The Patro-Golab (2016) systematic review concluded that current evidence is too limited to draw conclusions on the effects of reducing protein concentration in infant formulas on long-term outcomes.

24. ***Calculation of protein: Nitrogen Conversion Factors***: *Currently Standard 2.9.1 specifies two conversion factors: 6.38 for milk proteins and 6.25 for all other protein sources. FSANZ proposes that only two factors should continue to be specified: the conversion factor of 6.25 should apply to mammalian milk and the conversion factor for soy protein sources should be 5.71.*

25. The proposal of FSANZ to adopt a nitrogen conversion factor (NCF) of 5.71 for soy protein infant formula aligns with the figures published in the scientific literature (recently reviewed in IDF Bulletin 482, 2016). Hence, Fonterra supports this proposal.

26. The proposal of FSANZ to remove the NCF=6.38 for milk protein infant formula and to replace it with NCF=6.25 is not science based (see IDF Bulletin 482, 2016 and Maubois & Lorient, 2016). Accordingly, Fonterra disagrees with this proposal and submits that the NCF of 6.38 should be retained for milk based infant formula.

27. Rationale for this position is outlined as follows;

28. <u>Consistency of application of decision principles</u>

FSANZ proposes a change in NCF for soy protein based infant formula which is science based and a change in NCF for milk protein based infant formula which is not science based. The NCF=6.25 is incorrect and scientifically flawed for both soy based and milk based infant formula (IDF Bulletin 482, 2016). However, it is used as a generic factor for all infant formulas in several jurisdictions and

as such has been in use in international trade. To apply a consistent decision principle, the choice is to either use a scientifically flawed NCF=6.25 for all infant formula, OR to use science based, specific, NCFs for soy protein based and milk protein based formula. To use a science based NCF for soy based infant formula, but not for milk protein based infant formula, would mean an inconsistent approach.

29. Specific factors for different protein based products are recommended by the vast majority of scientific publications

The general consensus of scientific publications on the use of NCFs across a variety of foods, including infant formula, is that, based on scientific grounds, specific NCFs should be used and a generic NCF=6.25 should be rejected (IDF Bulletin 482, 2016). This conclusion agrees with the recommendation of FAO (2003).

30. Scientific basis for NCF=5.71 for soy protein based infant formula and NCF=6.38 for milk protein based infant formula

The NCF=5.71 for soy protein products and NCF=6.38 for milk protein products have been well-established (see reviews of the scientific literature in IDF Bulletin 405, 2006; IDF Bulletin 482, 2016; Maubois & Lorient, 2016). For milk protein based infant formula, the NCF=6.38, used generically for other milk products, is the appropriate NCF even though:

- Different formulas may have differing whey protein to casein ratios (Maubois & Lorient, 2016), and
- the source and processing of the whey protein ingredient used in the final formula may cause differences in caseino-glycomacro peptide, alpha-lactalbumin and beta-lactoglobulin levels (IDF Bulletin 482, 2016)[1].

31. The use of science based NCFs is important for economic, nutritional and sustainability reasons.

- The physical Working Group on endorsement of methods of analysis & sampling at the 37th session of CCMAS recognized that "*the [NCF] factors have severe economic aspects*."
- IDF Bulletin 482 (2016) draws attention to the fact that the determination of protein is important in terms of both nutrition and sustainability. "*There is growing interest in the complex relationship between nutrition and environmental sustainability … and this relationship is a significant feature of the United Nations Sustainable Development Goals* …"

32. Hence, within this context it is important that appropriate scientifically valid methods are used to determine the protein content of foods, including infant formula. While this impact is obvious for soy (where use of NCF= 6.25 would overestimate the protein content by 8-9% compared with the use of NCF=5.71), it may appear to those unfamiliar with the dairy industry to be less of an issue for milk based products where milk protein is underestimated by about 2% (6.25 vs 6.38). However, AU/NZ regulations cannot be looked upon in isolation in terms of their impact in the global scheme.

[1] The whey protein profile varies depending on whey processing. IDF Bulletin 482 shows that for a wide variety of processing conditions, and for various ratios of whey protein to casein, the NCFs for final infant formula product formulations is in the range 6.30 -6.50, with mean 6.39 and median 6.38.

In a global context 2% of dairy protein is the entire amount of dairy protein produced by the NZ dairy sector, affecting all the land, water and other resources and emissions used or created to produce that milk. Even when viewed only on a national basis for AU/NZ respectively, this 2% difference for milk based products cannot be ignored, especially because it would be an arbitrary, non-science based, change.

33. In summary, Fonterra supports NCF=6.38 for milk protein and NCF=5.71 for soy protein based formulas for scientific, nutritional, sustainability and economic reasons.

34. **Protein Quality:** *A recent FAO/WHO report recommended the Digestible Indispensable Amino Acid Score (DIAAS) as a protein quality calculation methodology. FSANZ considers that the amino acid composition of breast milk should still be the reference for determining an infant's amino acid requirements, a position that aligns with Codex.*

35. Fonterra agrees with the FSANZ preliminary conclusion that the amino acid (aa) breast milk reference pattern (with the suggested modifications as outlined by INC) should remain within the FSANZ Infant Formula Std 2.9.1 (S29-6) for the time being. Fonterra is of the view that implementation of DIAAS as a protein scoring system, with suitable age related targets as recommended by the FAO, will provide additional clarity to the formulation of IF, and ensure that proteins used in IF will deliver bioavailable amino acids to the infant. Thus Fonterra considers the aa reference pattern outlined in (S29-6) should be reassessed at such time as a supporting framework enabling full implementation of the DIAAS protein scoring system method has been completed.

36. The FAO has acknowledged the importance of using human milk as the scoring pattern for protein quality in infants for a number of years (FAO/WHO, 1991), and consider the consider the growth and metabolic state of a breast fed infant as the normative standard for this age. They also acknowledged that the digestibility and bioavailability of amino acids are important factors as not all dietary proteins are digested and utilized to the same extent (FAO/WHO, 1991). A number of regulatory agencies acknowledge this and require adjustment for the quality of the protein, either for IF, FoF or foods for special medial purposes (Lewis, 2012) and Codex had previously required quality evaluation for IF, in addition to meeting the breast milk amino acid pattern.

37. In 2013 a FAO Expert Consultation on dietary protein quality was held. The expert consultation provides an update and improvements to the Protein Digestibility Corrected Amino Acid Score (PDCAAS) method for measuring dietary protein quality, referred to as Digestible Indispensable Amino Acid Score (DIAAS). The key findings of the report that relate to the FSANZ infant formula review are that dietary amino acids should be treated as individual nutrients, and that for regulatory purposes two amino acid scoring patterns are recommended: birth to six months; and 6-36 months, and that if protein quality of FUF needs to be assessed then the most up-to-date method should be used. The DIAAS methodology maintains that the breast milk pattern is still the desired target for IF, however, it provides understanding of whether the protein provides available amino acids to meet the requirements of infants. The FAO Expert Working Group's report (2014) recommended the adoption of the DIAAS method by Codex, however also recognised that there is further work to be completed to ensure a supporting framework to enable full implementation of the DIAAS method.

38. Fonterra notes that PDCAAS (WHO/FAO 1991) is not suitable as a protein quality calculation methodology for use in IFFO. This is because it is based around the ability of a protein to

meet the nutritional requirements of a 2-5 year old child.

39. ***Amino acid content****: The minimum requirements for amino acids in infant formula are mainly based on 'typical' amino acid profiles of breast milk. Some differences exist between the minimum amount of some of the 11 required amino acids in Standard 2.9.1 and Codex STAN 72-1981.*

40. Fonterra agrees with the FSANZ proposal to align the minimum levels of isoleucine, leucine, lysine, threonine, tryptophan and valine with those in Codex STAN 72-1981. As outlined in detail by INC, we do not agree with the FSANZ preliminary position to retain the current expressions for the amino acids minimums for tyrosine, phenylalanine, methionine, and cysteine, and instead considers these should be amended to be consistent with Codex STAN 72-1981.

Fat

41. ***Trans-fatty acids****: FSANZ proposes lowering the maximum amount of trans fatty acids (TFAs) to 3% total fatty acids and thereby aligning with Codex. Codex states that the TFA limit of 3% is to allow for milk fats.*

42. **Fonterra Response**: does not support the proposal to lower the TFA content from 4% to 3% of TFAs. We support retention of a 4% limit in the context of different TFA definitions between FSANZ and Codex.

43. The FSANZ definition of TFAs differs from Codex. The Food Standards Code defines TFA as *All trans fatty acids*, whereas Codex defines TFA as *Only methylene-interrupted trans fatty acids* (CAC/GL 2-1985) i.e. the former encompasses CLA in the TFA count, and the latter does not. Hence the FSANZ proposal to align with Codex TFA limits on the 3% numerical value of 'TFA' does not align with the scope of fatty acids that are encompassed in this definition. Differences between the Food Standards Code and Codex definitions are currently accounted for by differing TFA limits in Codex and [Standard 2.9.1] of 3% and 4% of total TFA, respectively.

44. Fonterra notes that "*The acceptance of up to 3% of trans fatty acids* [in Codex] *is intended to allow for the use of milk fat in infant formulae*" (Codex STAN 72–1981). Milk fat serves as an important delivery medium for fat soluble vitamins, various fatty acids and factors beneficial to health. Breast milk contains TFA around 2-5% of fatty acids (Larqué et al 2001). Typical TFA values (measured as C18:1) in bovine milk fat, range from 1.29 to 7.31% of total fat (Precht et al, 2000, review of milk fat from >12 countries). No studies have linked intake of TFAs with adverse effects on growth or developmental outcomes in infants (EFSA, 2014). Both TFA and cis-9,trans-11-CLA are present in milk and therefore are contained in formula in which milk fat has been used as a fat source and are not of safety concern in the amounts which are naturally introduced to formula from milk fat (EFSA, 2014). It is important therefore that TFA levels are not unduly capped infant formula to also allow natural milk TFA levels, noting TFA is also present in breast milk and there are no issues with such levels.

45. Furthermore, the TFA content of cows' milk may vary with feed, season, breed (Kliem et al 2013; Mansson 2008), with up to 10% TFA of total fat reported under certain feeding regimes

(Briard-Bion et al 2008). Pasture-fed cows have higher CLA levels (Kelly et al 1998). CLA in New Zealand milk fat is typically 1.1 % (range 0.8-1.5) of total fat while the methylene interrupted TFA is typically 3.9% (MacGibbon and Taylor 2006). Thus it can be estimated CLA makes up about 22% of the Food Standards Code TFA definition. It follows that the Food Standards Code already aligns with the Codex STAN 72-1981 TFA maximum levels (because of the different definition) and thus to change to a 3% TFA cap would take this out of alignment (to a value of 2.3% Codex definition equivalent TFA).

46. Fonterra further note and support the New Zealand Codex opinion from 2004 which advocated for a higher TFA level in Codex STAN 72-1981 of 4% using the Codex TFA definition (CX/NFSDU 04/6-Add.1. Agenda Item 5b).

47. ***Phospholipids****: Standard 2.9.1 does not contain provisions that relate to phospholipids in infant formula while Codex STAN 72-1981 specifies a maximum permitted amount of phospholipids. FSANZ considers total phospholipids should be restricted but is uncertain about what that maximum should be noting that the evidence does not support alignment with the higher Codex maximum*.

48. **Fonterra Response**: does not support the introduction of a restriction specific to phospholipids. We note the absence of specific safety concerns or evidence of adverse effects in infants and the absence of market failure currently where no phospholipids limit has been specified, We thus consider that there is no strong scientific justification to set an upper phospholipid level in the Food Standards Code.

49. Phospholipids are integral structural components of biological membranes, a source of metabolites with various physiological functions and have key functions in signal transduction, neural development and cell functions. In milk and in the intestinal lumen, phospholipids contribute to solubilizing lipophilic compounds. Phospholipids are an important component of human milk (Koletzko et al 2001, Jensen 1996).

50. As FSANZ has outlined, the phospholipid content of human breast milk differs by stage of lactation (colostrum, transitional and mature milk) (Garcia 2011, 2012, Jensen 1995, 1996, Sala Villa 2005), between mothers (Mitoulas 2002) and fat content of the feed (i.e. foremilk and hindmilk; Mizuno et al., 2009).

51. Jensen (1995) summarises breast milk phospholipid values ranging from 0.06–2.0 g/L and more recent analysis also support a similar range. Breast milk phospholipid analysis reported by Giuffrida et al 2013 (using HPLC-ELSD detection) noted a wide range of levels at 129 to 384 mg/L from samples, however these were only collected at a single time point of 4 weeks post-partum, and it is known that there are large variations across lactation. Higher levels across the stage of lactation were reported by Sala Villa and colleagues (2005) using HPLC-ELSD detection and Garcia (2011, 2012) using TLC and NMR respectively, found a large range of 0.13 to 1.6g/L. This data highlights the importance of consideration of the full range and not just the mean.

52. In formulas there are two contributions to the phospholipid concentration;

- Lecithin added as a processing and dissolution aid, and
- Naturally occurring phospholipids from cow's milk ingredients

53. Lecithin, commonly from soy, may be added for reasons such as to instantize dry infant formula powders for easier dispersion in water, or to the oil blend during the manufacture of infant formula to stabilize the oil droplets during emulsification of the oil blend with the proteins. Soy and other vegetable lecithins are mostly composed of phosphatidylcholine (PC). Bovine phospholipids naturally present in milk and milk-derived ingredients are composed of sphingomyelin (SM), PC, phosphatidylethanolamine (PE), phosphatidylserine (PS) and phosphatidylinositol (PI) with a distribution similar to that of human milk (Jensen 1990, MacGibbon and Taylor 2006). The compositional profile of phospholipids naturally present in cow's milk are more similar breast milk than that of vegetable- and egg-derived phospholipid sources, and are found encased in the milk fat globule membrane (MFGM) (MacGibbon and Taylor 2006).

54. Expert bodies and both Codex and EU infant formula regulations define a maximum limit of 2g/L of phospholipids as safe and justified;

- Codex STAN 72-1981 maximum for phospholipids in infant formula is 300 mg /100kcal (72 mg /100kJ) which converts to approximately 1.5 g/100g powder or 2g/L of liquid made up formula

- EU Directive 2006/141/EC and (EU) Regulation 2016/127, define a maximum phospholipid limit of 2g/L for infant formula

- The EFSA (2014) and ESPGHAN Coordinated International Expert Group (2005) opinions on the composition of infant formula considered a maximum phospholipid concentration of 2g/L as appropriate, with the latter outlining consideration of the safety of this level with respect to triglyceride/phospholipids ratios obtained (Koletzko et al 2005).

- Phospholipids derived from egg yolk (including PC, PE, SM, PI in its profile) were Generally Recognised As Safe in the USA for use in term and pre-term formula at levels up to 2g/L (GRN 000411).

- In addition, the expert panel coordinated by the Early Nutrition Academy considered a higher maximum level of 3.5g/L phospholipids for older infants in Codex STAN 156-1987 was appropriate: "*For IF fed from birth, a maximum phospholipid concentration of 300 mg/100 kcal (equivalent to about 2 g/l) has been set following the precautionary approach. For older infants at the age of FUF feeding, there are few concerns regarding the provision of phospholipids with usual complementary feeds which provide considerable amounts of phospholipids. For example, infants will consume about 3.5 g phospholipids with one hen's egg. Research into the roles of phospholipids in human milk fat globules indicates potential benefits of adding certain phospholipids to FUF, in addition to solubilizing lipophilic compounds and acting as a source of long-chain polyunsaturated fatty acids. Therefore, a concentration of 550 mg/100 kcal (equivalent to about 3.5 g/l) is recommended as the guidance upper level.*" (Koletzko et al, 2012)

55. As outlined by FSANZ, the potential nutritional benefits of formula with phospholipid-containing MFGM from bovine milk and also of formula supplemented with egg or vegetable derived phospholipids on normal growth, immunity or developmental outcomes has been studied. These studies in both pre-term and term infants further support the safety of phospholipids in infant formula. For example; Carlson et al (1998) (n=119) supplemented pre-term infants with egg phospholipids at 3.96g total PL/L for 34 weeks and Tanaka et al, 2013 fed low birthweight infants

(n=12) 0.2g/L for 12 weeks with positive effects on immunity and no adverse effects. Studies by Billeaud et al. (2014), Timby et al. (2014a,b; 2015) also support the conclusion of safety of formula with phospholipids, with the latter trials showing a positive effect on neurodevelopment. Similarly, studies in older infants 6-12months (e.g. Zavaleta et al., 2011) also support this conclusion. We note that Fewtrell (2015) commentary on the Timby (2015) paper did not outline concerns on the safety of MFGM supplemented infant formula. A recent review of literature by Hernell and colleagues (2016) summarised the safety and efficacy effects of six MFGM supplementation trials in infants and children and clinical results suggested the MFGM-supplemented formulas were safe.

56. In summary, in the absence of specific safety concerns or any evidence of adverse effects in infants and the absence of market failure currently where no phospholipids limit has been specified, Fonterra considers that there is no strong justification to set an upper phospholipid level.

Q1.6 What amount of lecithin is used in infant formula for technological purposes?

57. **Fonterra Response**: Manufacturers may add lecithin for technological purposes including to instantize dry infant formula powders for easier dispersion in water, or adding to the oil blend during the manufacture of infant formula to stabilize the oil droplets during emulsification of the oil blend with the proteins.

Vitamins, minerals and electrolytes

58. **Approach to setting guidelines or maximum amounts***: In Standard 2.9.1 all nutrients have either a maximum amount or a recommended guideline maximum amount (GUL). Codex uses a similar approach, but Codex has GULs for 20 micronutrients compared to 14 in the Code. FSANZ is exploring whether the GULs should be formally incorporated into Standard 2.9.1.*

59. Fonterra strongly supports the continued use of non-binding GULs to serve as guidance for industry in designing formulations. Where there is a safety concern, maximums are mandated.

60. ***Vitamin A****: FSANZ is supporting expressing of vitamin A requirements in units of µg alone (rather than RE), as this clarifies that β-carotene should not contribute to the vitamin A content. The Code would then align with Codex and other international regulations in relation to the contribution of β-carotene to vitamin A content but will differ in relation to the vitamin A units*.

61. Fonterra agree with FSANZ's preliminary view to exclude beta-carotene from the calculation vitamin A due to uncertainties regarding the relative equivalence of beta-carotene to retinol in infants (Koletzko et al, 2005). It should be noted that currently the calculations for the contribution of β-carotene are difficult. The Food Standards Code currently prescribes β-carotene conversions factors to retinol equivalence as 12 µg/1µg of retinol equivalence for natural β-carotene and 6µg/1µg of retinol equivalence for synthetic β-carotene. Natural β-carotene is not well defined and the Food Standards Code also includes a note that 'Natural forms of provitamin A may have conversion factors that are not provided in this table. Current testing methods do not differentiate between

natural and synthetic β-carotene. We therefore support the FSANZ preliminary view to measure and declare Vitamin A as µg of retinol.

62. We consider permission to include β -carotene should be retained as a source of pro-vitamin A. This approach is aligned with both Codex Standard 72-1981, and CAC/GL10-1979. Carotenoids including β-carotene are naturally present in breast milk (Gossage et al, 2002; Lipkie et al, 2015; Mackey et al, 2013). β-carotene is an anti-oxidant (Matos et al, 2015) and technically can assist with the stability of the formulation by reducing the oxidation of lipids (Zou et al, 2012). The addition of carotenoid mixtures to formula has been demonstrated to be well tolerated and growth was similar with that of breast-fed infants (Mackey et al, 2013). β-carotene is also found naturally present at low levels in some of the ingredients used in infant formula including milk fat and vegetable oil.

63. ***Folate**: Neither Codex STAN 72-1981 nor Standard 2.9.1 currently use dietary folate equivalents (DFE) to express the folate content of infant formula. FSANZ's preliminary view is to retain units of µg of folate even though this differs from Codex STAN 72-1981. FSANZ is unsure whether allowing for natural folate but not adopting the DFE units would make any difference*.

64. Fonterra support alignment with Codex STAN 72-1981 for both folate nutrient levels, and the expression of folate as folic acid i.e. Fonterra do not support FSANZ's preliminary view to retain units of *µg of folate* and do not consider the use of DFE units appropriate.

Q1.9 Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.

65. Folic acid is the dominant form of folate in a fortified infant formula. Analytically, it is less challenging to quantify folic acid alone than to capture all folate forms natural and added (Arcot et al., 2005). Natural folate levels in milk vary, and some of this variation is due to analytical differences. Indyk (2011) compared total folate levels of skim milk and infant formula from four different folate analytical methods. Skim milk powder folate levels ranged from 13- 60 *µg* /100g depending on method. Similarly, four different infant formula folate contents were compared, infant formula with the lowest folate content ranged from n.d. – 99 and highest IF folate ranged from 116-160 *µg* /100g.

66. Fonterra note that implementation of a minimum folate requirement that also includes natural folate is dependent on the capability of the analytical method to capture both natural folate and added folic acid. Currently there are complexities in measuring both (Arcot et al, 2005).

67. While Fonterra consider that the natural folate forms and added folic acid should be reported separately, this is not currently practical given methodology complexities in measuring both, and furthermore availability of space on the label. We propose at this time that natural folate content is excluded, and folate is reported as folic acid, an approach aligned with Codex Stan 72- 1981.

Q1.10 If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied?

68. Fonterra does not support folate being expressed as dietary folate equivalents (DFE). This is because there is significant variability and uncertainty related to the exact bioavailability in infants of natural milk folate forms (Sanderson 2003, Suitor et al 2000, Ohrvik et al 2011). DFE factors were

established in adults and it is unknown whether folic acid in infant formula is more or less bioavailable than folates in human milk.

69. Furthermore, neither Codex nor the Food Standards Code uses DFE to express the folate content of infant formula. While the EU do use DFE to express folate content of infant formula, the EFSA (2014) report, which references the conclusions of the Scientific Opinion on Dietary References Values (DRV's) for folate report (EFSA 2014) shows however that there is limited evidence to *support the use DFE "evidence base for the figures used by IOM in the DFE definition is somewhat uncertain" and there is also conflicting evidence on the definition of DFE "validity of the dietary folate equivalency definition has not been confirmed in studies".*

70. ***Selenium****: Standard 2.9.1 and Codex STAN 72-1981 have very similar minimum selenium amounts (0.25µg/100kJ and 0.24µg/100kJ, respectively). Standard 2.9.1 prescribes a maximum of 1.19µg/100kJ whereas Codex lists a GUL of 2.2µg/100kJ. There are significant geographical variations in the selenium content of soil and food crops in many countries particularly New Zealand. P93 recommended a range of 0.42ug per 100kJ to 0.89ug/100kJ in infant formula.*

71. FSANZ's preliminary view is that increasing the minimum requirement for selenium in Standard 2.9.1 (to 0.48µg/100kJ) may be appropriate for the Australian and New Zealand context. This level is the same as the level recently updated by the US. However this would not align with Codex STAN 72-1981 and may require reformulation of some products. If the minimum requirement was raised and the Codex higher GUL also adopted, FSANZ notes that the range may remain similar.

Q1.14 Do you support raising the minimum and maximum amount of selenium required in infant formula?

72. **Fonterra Response**: Fonterra supports the INC conclusion that the current minimum for selenium is appropriate for Australia and New Zealand because manufacturers do not generally target the minimum but rather target a level higher than the minimum in order to be assured of compliance. The FSANZ label survey confirms this, particularly for New Zealand, which has the more serious selenium deficiency.

73. We further note that while it technically feasible to meet the increased minimum, and reduced manufacturing range when compared to Codex given the range will be similar to what currently exists in Standard 2.9.1, there are complexities around managing different requirements of a higher selenium minimum in ANZ when compared to Codex export markets. Alignment with the full Codex range allows us to better harmonise formulations between markets.

Q1.15 Do you support moving the maximum amount to a GUL?

74. **Fonterra Response**: Fonterra supports the proposal to move the maximum amount to a GUL and an increase of the GUL to align with Codex STAN 72-1981.

75. ***Iodine:*** *The minimum iodine amount in Standard 2.9.1 is 1.2µg/100kJ while Codex STAN 72 1981 is 2.5µg/100kJ which is more than double. Codex STAN 72-1981 lists a GUL of 14µg/100kJ while Standard 2.9.1 has a maximum of 10µg/100kJ. FSANZ concludes that a higher maximum of*

14µg/100kJ would be unlikely to adversely pose a risk to infant health. FSANZ's label survey showed that the range of iodine content was 2.10–5.92µg/100kJ. FSANZ's preliminary view is that alignment with the higher Codex minimum and maximum (GUL) amount for iodine may be appropriate for Australian and New Zealand infants.

Q1.16 Do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL?

76. **Fonterra Response**: Fonterra supports full alignment with the iodine range outlined in Codex Stan 72-1981 of 2.5-14µg/100kj, including that the upper limit as a GUL and not a maximum. Fonterra notes the technical difficulties encountered in consistently achieving the current Standard 2.9.1 iodine range of 1.2-10µg/100 kJ which is not aligned with Codex STAN 72-1981.

77. Nutritional reasons detailing our support for increased iodine levels aligned with Codex STAN 72-1981 are detailed in the INC submission, including that since 2010 ANZ pregnant and breastfeeding women supplementation programs have been introduced to mitigate risks associated with iodine deficiency in infants (NHMRC 2010). It is important formula fed babies also receive sufficient iodine through formula to enable achievement of the iodine AI in infancy.

78. Fonterra consider that consistent principles should be applied in determining whether a maximum or a GUL is appropriate for nutrients, noting maximum levels are generally set for nutrients that have documented adverse health effects and for which upper safety limits have been established. GUL's generally consider history of safe use and values derived on the basis of meeting nutritional requirements. In the case of iodine, Fonterra consider a GUL is more appropriate than a maximum given there is no UL established for iodine in infancy, and absence of any safety concern in the Codex STAN 72-1981 use of a GUL.

79. Pasture based feeding regimes require the use of feed supplements (e.g. mineral salts, licks) to deliver important trace elements for animal health and welfare, including iodine, an essential nutrient. The seasonal nature of our milk source, and differences in on farm practices and feed supplements results in variation in the nutrient content of milk, including iodine levels. Codex STAN 72-1981 mandates an appropriate range and GUL limit for iodine. We note the variability of iodine levels in milk was the reason that Standard 2.9.3 was amended in relation to iodine. Permitted forms of vitamins, minerals and electrolytes

80. Vitamin A: FSANZ's preliminary view is to retain the permitted forms of Vitamin A, providing alignment between the Code and Codex. Fonterra supports this view.

Q1.22 What is the justification to retain β-carotene as a provitamin A form?

81. **Fonterra Response**: Fonterra supports continued permission for β-carotene as a provitamin A form in infant formula aligned to Codex STAN 72-981. Although it has not been considered appropriate to take the contribution of β-carotene into account when estimating requirements of

Vitamin A owing to a lack of knowledge on the bioconversion, the limited data available in children would suggest that there may be some bioavailability.

Q1.23 What technical justification can you provide for the use of the nutrient forms listed in table 8.2 for use in infant formula?

82. As a manufacturer of formula for both the NZ market and internationally, for reasons of alignment to Codex and therefore flexibility for manufacture, avoidance of barriers to trade and innovation, Fonterra considers that all the forms of nutrients permitted in Codex STAN 72-1981 as outlined by Nutrient Compounds from the Advisory Lists of Codex CAC/GL 10-1979 should be permitted for nutritional use in Infant formula, on the basis that they are safe for infants. Fonterra is unaware of any safety concerns or rationale that would support removal of these current listed nutrient forms.

Other Optional Substances

83. **Choline**: *Standard 2.9.1 permits choline as an optional substance in infant formula, whereas Codex STAN 72-1981 prescribes the mandatory addition of choline. Both standards specify the same minimum amount, but different maximum amounts. Also Codex STAN 72-1981 lists the maximum as a GUL*

Q1.24 Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.

84. **Fonterra Response**: FSANZ's preliminary view is that choline should be listed as a mandatory substance in infant formula with a mandatory range of 1.7 -12 mg/100kJ.

85. Fonterra are supportive of the approach to mandate the requirement for choline in infant formula recognizing this is an essential nutrient. However, we consider full alignment with Codex should be sought and that the maximum level proposed of 12mg/100kJ should be a GUL i.e. 1.7 to 12mg/100kJ (GUL).

86. Nutritional and technical reasons for support of the Codex GUL are outlined by INC, including the absence of market failure with Codex GUL levels and absence of UL for choline. The relevance of the review by Tang and Hazen (2014) which suggests a potential role of choline, in the presence of certain gut microbiota, to development of a metabolite mechanistically linked to CVD risk is questioned given there are no studies in infants and young children that show choline could have an adverse effect.

87. ***L-carnitine****: L-carnitine is considered an indispensable nutrient for newborn infants because of a short term, insufficient synthesising capacity. L-carnitine is naturally present in breast milk, cows' milk and goats' milk. FSANZ is proposing to mandate L-carnitine with limits of 0.3-0.8mg/100kJ whether added or not.*

Q1.27 Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.

88. **Fonterra Response***:* FSANZ's preliminary view is that L-carnitine should be listed as a mandatory substance in infant formula with a mandatory range of 0.3-0.8mg/100kJ. Fonterra agrees that L-carnitine should be mandatory in infant formula and, however, we have significant concerns regarding the proposed maximum of 0.8mg/100kJ for both nutritional and technical reasons and are of the position that further consideration should be given to full alignment with Codex Stan 72-1981 requirements for this nutrient which do not set a maximum level (similarly to the EU 127/2016).

89. INC explain in detail the nutrition and technical rationale as to why industry strongly do not support the setting of a maximum of 0.8mg/100kJ. The INC note neither the Scientific Committee for Food (SCF) (2003) nor EFSA (2014) opinions considered a maximum, and note the reference to Koeth et al (2013) review which identifies a potential role of L-carnitine, in presence of certain gut microbiota, to a CVD risk factor, however there is no evidence to suggest this effect in infants and children. We further note that natural levels of L-Carnitine in milk. Thus in the absence of a UL we consider it would be appropriate to maintain consistency and set no maximum level for this nutrient.

90. ***Inositol****: FSANZ states that inositol is considered to be conditionally essential for infants mainly because they may lack the developmental maturity for endogenous synthesis. Inositol is one of the phospholipids found in breast milk. It is present in human tissues predominantly as myo-inositol in free or phosphorylated forms endogenously synthesised from glucose.*

91. FSANZ also states that Standard 2.9.1 and Codex STAN 72-1981 permit the same range 1.0-9.5mg/100kJ, although Codex lists inositol as a mandatory inclusion with a GUL. Many infant formulas contain this substance and no adverse effects in infants consuming these formulas have been reported.

Q1.30 Do you support inclusion of a mandatory minimum requirement for inositol in infant formula?

92. ***Fonterra Response****:* We support the FSANZ preliminary view to mandate inositol in infant formula at the current minimum level 0.96mg/100kJ. This conditionally essential nutrient for infants and would then align with Codex STAN 72-1981. We support the proposed upper level of 9.5mg/100kJ however consider this should be a GUL in line with Codex STAN 72-1981.

Q1.31 Do you support listing the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex?

93. Fonterra support listing the permitted form as myo-inositol. Inositol is found naturally in milk including milk whey protein ingredients and is seasonally variable (Indyk HE et al, 2016). In addition Lecithin also contains bound inositol. Free and total myo-inositol in seasonal milk were within the ranges of 2.3 to 4.5 mg/100 g and 5.3 to 8.7 mg/ 100 g, respectively (Indyk HE et al, 2016).

94. Codex GL 10–1979 lists myo-inositol (previously referred to as meso-inositol) as the only permitted form of the inositols. Myo-inositol in milk can be found as free or bound myo-inositol. Codex does not outline what forms are to be measured as myo-inositol (i.e. free, or free plus that bound both as phosphatidylinositol and inositol phosphates). While current global methods may vary in what forms are measured, it is common to measure total myo-inositol (free + bound) in infant formula.

Safety & Food Technology

95. **Measuring scoop**: Fonterra strongly disagrees with the standardisation of measuring scoops for the reasons FSANZ has identified. As identified by FSANZ, mandating a standard scoop size would require all products in the market to have the very similar energy, nutrient and powder density. These vary between formulas as a result of the use of different ingredients and different composition within the requirements. Mandating the scoop size would create significant technical challenges and would limit the formulation composition. This would not only create increased costs but could also limit the formulations available. It should also be noted that mandating the scoop size is also not aligned with Codex or other international practice.

96. Fonterra supports the ongoing use of the statement on labels advising that only the scoop enclosed should be used when preparing the product in accordance to Standard 2.9.1-19 (3) however, we oppose the exact wording of this statement being mandated as there is no evidence that there is any issues with current statements being used on labels.

Nutritive substances and novel foods in infant formula products

97. Fonterra supports Standard 2.9.1 being included within the scope of Proposal P1024 going forward, as recommended by the Infant Nutrition Council (INC).

98. Fonterra submits that pre-market assessment of nutritive substances and novel foods for infant formula ingredients is most appropriately and effectively considered as part of the P1024 review, for the following reasons:

- Identical issues with the current system: The Fonterra and INC submissions on Proposal P1024 both described how the issues and problems identified in that Proposal that apply to the general food supply are the same as the issues and problems for the regulatory regime as it applies to infant formula products, particularly in relation to definitional issues.

- Consistency across the entire Food Code: The current nutritive substances and novel foods regime applies to all foods, including those carved out of P1024. Fonterra supports continuing to apply a consistent regime across the entire food code, to avoid creating regulatory gaps where certain foods are covered under a different system for approvals.

- Efficiency in process: FSANZ has proposed excluding Standard 2.9.1 from P1024, but the current review (P1028) only covers infant formula products (ages 0-6 months). We note that FSANZ does not currently have a plan to address any subsequent regulatory changes for follow-on formula or infant formula products for special dietary use (which are often very closely tied together with infant formula), leaving a regulatory gap.

99. As Fonterra considers infant formula (along with other products covered by Standard 2.9.1) should be included within the scope of P1024, our submission on P1024 included comments relevant to infant formula. For completeness, we have provided comments in response to the relevant questions in this submission, but request that FSANZ also consider our additional

comments on nutritive substances and novel foods from our P1024 submission (attached **Appendix I**).

100. Further, should FSANZ decline to consider Standard 2.9.1 within the scope of P1024, we note it is crucial that any regime developed specifically for infant formula aligns with the regime for general foods. FSANZ should also develop a plan for addressing necessary regulatory changes for follow-on formula and infant formula products for special dietary use (as well as other standards excluded from P1024) as promptly as possible.

Q2.15 Should all or only certain substances proposed for use in infant formula require pre-market assessment?

101. Fonterra submits that pre-market assessment of nutritive substances and novel foods for infant formula ingredients is most appropriately and effectively considered as part of the P1024 review, for the following reasons:

- Identical issues with the current system: The Fonterra and INC submissions on Proposal P1024 both described how the issues and problems identified in that Proposal that apply to the general food supply are the same as the issues and problems for the regulatory regime as it applies to infant formula products, particularly in relation to definitional issues.
- Consistency across the entire Food Code: The current nutritive substances and novel foods regime applies to all foods, including those carved out of P1024. Fonterra supports continuing to apply a consistent regime across the entire food code, to avoid creating regulatory gaps where certain foods are covered under a different system for approvals.
- Efficiency in process: FSANZ has proposed excluding Standard 2.9.1 from P1024, but the current review (P1028) only covers infant formula products (ages 0-6 months). We note that FSANZ does not currently have a plan to address any subsequent regulatory changes for follow-on formula or infant formula products for special dietary use (which are often very closely tied together with infant formula), leaving a regulatory gap.

102. Fonterra's submission on the P1024 proposal includes detailed comments that are relevant for infant formula as well as the general food supply. For ease of reference, we repeat these comments here. Additional detail on our key points is provided in our submission on P1024 (Appendix I).

103. Fonterra supports the proposal of the Infant Nutrition Council (INC) that, with appropriate differentiation, the framework proposed in P1024 as Option 3 (although it requires further development as noted subsequently in this submission) should be applied to Standard 2.9.1, including infant formula.

104. Fonterra notes that under the framework proposed as option 3, all substances for use in infant formula would undergo a pre-market assessment, but that not all pre-market assessments need to be undertaken by FSANZ. The Eligible Food Criteria pathway and Pre-Market Self-Assessment with Notification pathway in the proposed P1024 framework also constitute pre-market

safety assessments. Fonterra submits that this would meet the relevant Ministerial Policy Guidelines on the Regulation of Infant Formula Products[2].

105. The specific differentiation required would address the vulnerability of the target population who are consuming infant formula and the unique role of infant formula as the sole source of nutrition for infants 0 to around 6 months where breastfeeding is not undertaken.

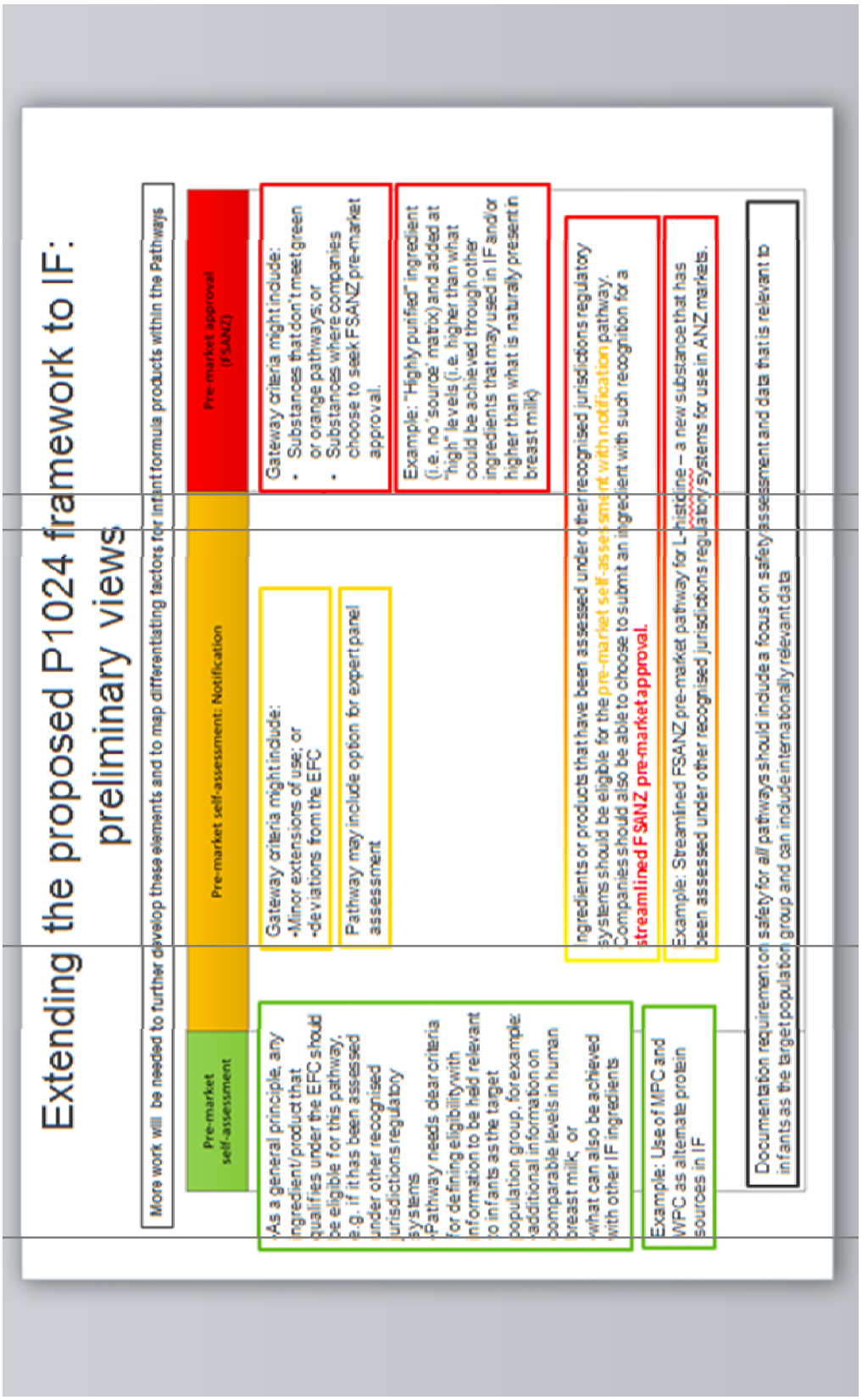
106. Fonterra proposes that these differentiating criteria should include:

1. Across all pathways (i.e. general principles for all infant formula ingredients):
    a. The documentation requirement on safety for *all* pathways should include a focus on safety assessment and data that is relevant to infants as the target population group and can include internationally relevant data
2. Pre-market self-assessment (Eligible Food Criteria (EFC) pathway)
    a. As a general principle, any ingredient/product that qualifies under the EFC should be eligible for this pathway, e.g. if it has been assessed under other recognised jurisdictions
    b. Pathway needs clear criteria for defining eligibility with information to be held relevant to infants as the target population group, for example:
        i. additional information on comparable levels in human breast milk; or
        ii. what can also be achieved with other IF ingredients
3. Pre-market self-assessment with notification
    a. Pathway criteria should include minor extensions of use and/or deviations from the EFC
    b. May include a requirement for an expert panel assessment to provide review of the safety assessment
4. Pre-market approval via FSANZ
    a. Pathway criteria should include:
        i. Substances that don't meet criteria for the pre-market self-assessment pathways (Eligible Food Criteria pathway or pre-market self assessment with notification)
        ii. Substances where companies choose to seek FSANZ pre-market approval.

These points are also provided in the attached diagram (**Figure 1**).

[2] Ministerial Policy Guideline, Regulation of Infant Formula Products, Specific Policy Principle (i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that:
i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or
ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source has a different form/structure, or is produced using a substantially different technique or technology.

Figure 1: Proposal for Extension of Proposed P1024 Framework to Infant Formula. Preliminary Views.



107. Fonterra proposes the elements above to facilitate a meaningful discussion on the application of the P1024 Option 3 framework to infant formula ingredients. We note that more work will be needed on these elements and to map differentiating factors for infant formula products within the Pathways.

108. The framework should also recognise assessment of an ingredient or product in another reputable jurisdiction. Specifically:

- As a general principle, any ingredient or product that qualifies under the Eligible Food Criteria should be eligible for the Eligible Food Criteria pathway, including if it has been assessed under other recognised jurisdictions regulatory systems.
- Ingredients or products that have been assessed under other recognised jurisdiction's regulatory systems should be eligible for the pre-market self-assessment with notification pathway.
- However, considering issues such as protection of intellectual property, companies should also be able to choose the FSANZ pre-market approval pathway, even if the ingredient/product is eligible for the pre-market self-assessment with notification pathway.
- To support such a choice, the framework should include a streamlined facility for the FSANZ Pre-Market Approval Pathway for substances that have already been assessed in other jurisdictions.

109. Fonterra has also identified areas of the proposed Option 3 framework where we see significant challenges with its application to dairy ingredients, including infant formula ingredients. Our support for Option 3 is predicated on these concerns being adequately addressed for both general foods and infant formula ingredients. These concerns are discussed in detail in our submission on P1024, and are also summarised below.

110. FSANZ has focused on concentration of components as a key indicator of safety risk, and has designed a framework that identifies concentrated foods and ingredients as requiring additional safety assessment. The dairy industry, however, has a long history of fractionating and concentrating milk to produce foods and ingredients with safe use including in infant formula (e.g. milk protein concentrates). This history of safe should be recognised by the regime to support efficient allocation of regulatory resources and avoid unnecessary regulatory burden.

111. Addition of dairy components to a food (including infant formula) at a concentration higher than that achievable from whole milk does not automatically create a health risk. The focus should be on whether the finished product will significantly alter the total dietary intake of nutrients.

112. The appropriate basis for comparison in a safety assessment, therefore, is what can be delivered to a final product through typical dairy ingredients (including Milk Protein Concentrate (MPC), Whey Protein Concentrate (WPC), cream powders, sweet whey powder, etc). This provides the ability to account for different addition rates of ingredients, with comparison against components in the final product, instead of forcing a focus solely on comparison between ingredients. For example, WPC can be used at a lower addition rate as an alternative to whey powder as a protein source.

113. The effectiveness of the proposed regime is contingent on being able to compare concentration of nutrients in a finished product against an appropriate basis. In order for the proposed regime to provide an appropriate level of risk-based regulatory oversight, it is not sufficient from a dairy perspective to have whole milk as the only point of comparison for assessing

concentration of components. It appears this is not FSANZ intent, and that the Proposal envisages "simply processed" commodities being used as a point of comparison as well. Fonterra supports this concept, although we note that further work is required to ensure the Eligible Food Criteria deliver on this intent (see comments below).

114. Innovation of infant formula products generally emerges from the efforts of manufacturers to mimic breast milk as closely as possible. The appropriate point of comparison for concentration for IF ingredients, therefore, is not fluid milk (or the source commodity), but should include:

- breast milk; and
- other ingredients currently used in infant formula products

115. Specifically, Fonterra seeks recognition that FSANZ pre-market approval should not be required for concentrated dairy ingredients that deliver key components at level that could feasibly be achieved either through addition of other dairy ingredients at higher addition rates. This is important for dairy ingredients where (for example) lactose content may be reduced to enable formulation flexibility, but chemical components are still the same and still inherently safe.

116. Further to the concerns noted above, evaluation of the proposed Eligible Food Criteria (EFC) against examples of common dairy ingredients demonstrates that the Criteria do not provide clarity or allow an objective assessment of the "eligibility" of dairy ingredients. The EFC as proposed are not able to identify the boundary between a simply processed commodity, an extract or a substance.

117. EFC2 provides a list of eligible commodities and list of processing techniques that will result in eligible "simply" processed commodities. Dairy ingredients are almost all produced using the criteria listed as "Processing Techniques that would be likely to meet criterion 2" (P1024 SD3 table 3, p8). This means under EFC2 as currently drafted, it is not possible to objectively evaluate when a product ceases to be "simply processed", and is considered an extract or a substance. As EFC2 is also used as the basis to determine whether an extract or a substance is eligible under EFC3 or EFC4, this lack of clarity undermines the entire EFC regime.

For example:

- **dried sweet whey** is classified as "simply processed" in the Lactoferrin example in P1024 Supporting Document 3 (p23). Dried sweet whey is processed using: physical fractionation (separation of cream and skim milk; separation of curd and whey), thermal processing, mixing, enzymatic processing, filtration, evaporation and drying.
- **Permeate** is provided as an example of a "substance" (P1024 SD3, p14, paragraph 3). Permeate is processed using two or three processing steps (physical fractionation, thermal processing and filtration)
- It is not possible to deduce why permeate (which undergoes fewer processing steps than the "simply processed" dried sweet whey) would be a "substance" rather than "minimally processed"

We have provided additional examples along these lines in our submission on P1024.

Fonterra also identified a range of more specific concerns with the Eligible Food Criteria, including:

- The proposed exclusion of enzymatic processing from the list of eligible food processes under EFC2;
- The need for an expanded approach to identifying eligible microorganisms; and
- Recognition that the proposed regime is fundamentally a series of positive lists (for eligible microorganisms, commodities and food classes, processes and potentially enzymes) and thus a pragmatic approach for amending these lists is required.

118. Fonterra has requested FSANZ re-consider the Eligible Food Criteria in light of these concerns, and has also requested additional targeted consultation with the dairy industry before drafting commences on a revised proposal to address these weaknesses.

119. Regarding the Pre-market self-assessment with notification pathway, Fonterra has noted that the ability to protect intellectual property (IP) will be critical for this pathway to have utility for industry. We proposed an alternative approach, similar to the self-determined US GRAS system:

- Company X develops the dossier to use as the basis for determination;
- The dossier is subject to an expert panel review;
- Company X holds the dossier and expert panel review in house; and
- The dossier can be requested by food authorities if required.

Q2.16 What would be the cost and trade implications of your preferred position?

120. Fonterra notes that shifting consideration of pre-market safety assessment for infant formula ingredients under the scope of P1024 (i.e. alignment under the general foods regime, with differentiating factors for infant formula) will provide clarity and consistency across the regulatory regime. Such clarity and consistency is good regulatory practice, and supports trade (both imports and exports) of infant formula and infant formula ingredients.

121. Alignment between the infant formula and general foods regimes also provides a simpler regulatory environment for companies, reducing complexity and transaction costs.

122. In our submission on P1024, Fonterra encouraged FSANZ to consider whether the proposed changes have any implications for New Zealand and Australian exports of dairy products.

Q2.17 If only certain substances for use in infant formula should require pre-market assessment, where should the 'line' be drawn for the substances that do require pre-market assessment and those that do not? What is your rationale?

123. Fonterra notes that our answer to question 2.15 addresses these points, in particular the paragraphs on the differentiating criteria for applying Option 3 to infant formula. We also refer FSANZ to Table 1, which proposes key criteria and examples for each pathway in a graphical format.

Q2.18 If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

124. Fonterra notes that our answer to question 2.15 addresses these points. We also refer FSANZ to Table 1, which proposes key criteria and examples for each pathway in a graphical format.

Contaminants

125. In relation to contaminants, Fonterra supports FSANZ's views in relation to acrylonitrile, tin, vinyl chloride, arsenic and lead but considers that further consideration is needed in relation to aluminium, as detailed below.

*126. **Aluminium**: FSANZ considers it is appropriate to retain an ML for aluminium and is proposing to set an ML of 0.05 mg/100 mL to apply to all infant formula.*

127. Fonterra's preference is to align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex Stan 193-1995), noting also that EU does not list aluminium as a contaminant metal in infant formula (nor any foods) (Commission Regulation (EC) No 1881/2006), and nor does the US.

128. We consider that any new contaminant limit should be based upon risk. Whilst UK researchers have recently questioned the levels of aluminium in infant formula (BMC Pediatrics, 2013, 13:162), those researchers did not take into account the fact that aluminium had been re-evaluated by JECFA in 2012, and the Provisional Tolerable Weekly Intake (PTWI) for aluminium was revised upwards to 2 mg/kg-bodyweight (JECFA 2012).

129. Additionally, expressing a limit in units of 'mg/100 mL' does not make use of the convenient prefixes provided for by the Système International d'unités (SI) which would have been either 'mg/L' or 'mg/kg'.

130. ***Lead***: The Code includes an ML for lead of 0.02mg/kg in infant formula (Schedule 19, S19-4).

131. Fonterra is supportive of lowering of the limit for lead in infant formula to equal that described by Codex in Standard 193-95 (2015 update). However, our preference is for the limit to be expressed on a dry powder basis, rather than on an 'as consumed' basis, because the vast majority of infant formula traded in Australia and New Zealand (as well as sold at retail outlets) is in the powdered form, rather than as a ready-to-consume format.

132. Codex has previously applied a 7-fold concentration factor between powdered- and ready-to-consume infant formula (REP11/CF & REP12/CF). Therefore, the limit for lead in powdered infant formula should be increased from the 0.01 mg/kg in ready-to-consume formula by 7-fold to 0.07 mg/kg.

Food Additives

133. Aligning food additive permissions in the Food Standards Code with Codex: FSANZ notes that if the Food Standards Code (FSC or *Code*) was to be aligned with Codex, then a range of amendments to the Code would be needed, such as additional permissions, changes to maximum permitted levels (MPLs), and revision of some nomenclature and INS numbers

134. **Acidity regulators**: FSANZ has identified 12 food additives that are listed in Codex STAN 72-1981 as acidity regulators: sodium dihydrogen phosphate (INS 339i), disodium hydrogen phosphate (INS 339ii), trisodium phosphate (INS 339iii), potassium dihydrogen phosphate (INS 340i), dipotassium hydrogen phosphate (INS 340ii), tripotassium phosphate (INS 340iii), sodium carbonate (INS 500i), sodium hydrogen carbonate (INS 500ii), potassium carbonate (INS 501i), potassium hydrogen carbonate (INS 501ii), sodium hydroxide (INS 524), and potassium hydroxide (INS 525).

135. Fonterra considers that these 12 substances could be used as either food additives (technological purpose of acidity regulators)as in other countries as well as processing aids or as permitted forms of minerals in the manufacture of foods including infant formula as currently permitted by Standard 2.9.1. All are approved for use by Codex and therefore technological justification and safety assessments have been completed. Fonterra strongly concurs with INC that their continued inclusion is justified from both a trade harmonisation perspective and support of innovation.

136. **Starch sodium octenyl succinate**: FSANZ consider an extension of use outside of the future work of this Proposal.

137. As outlined by INC, although this is not within the scope of Proposal P1028 the inclusion of Octenyl succinic acid (OSA)–modified starch (starch sodium octenyl succinate) (INS 1450) for infant formula products for special dietary use based on a protein substitute is supported (Schedule 15, Class 13.1.3) as per the agreement at CCNFSDU 36 (November 2014) and confirmed by CAC38 (July 2015). JECFA79 concluded that the consumption of OSA-modified starch in infant formula or formula for special medical purposes intended for infants is not of concern at concentrations up to 20 g/l. Furthermore, we additionally note the use of starch sodium ocetnyl succinate as a permitted nutrient carrier in nutrient carriers that may be used in infant formula CAC/ GL 10-1979.

138. **Carry-over principle for *food additives and infant formula:*** *FSANZ states there has been confusion about how the carry-over principle in the Code operates for infant formula. For clarity, and to be consistent with the Codex approach, FSANZ proposes that the carry-over principle for food additives should not apply to infant formula.*

139. Fonterra considers that Codex does allow for carry-over of certain food-additives into infant formula and therefore believes the food additive carry-over principle with provisions [as outlined by Codex] should continue to apply to infant formula. Fonterra supports permissions for all food additives and nutrient carriers included in Codex STAN 72-1981 Section 4 Food, the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children CAC/ GL 10-1979, which may be present in infant formula products as a result of carry-over from raw material or direct addition and consider appropriate provisions should continue to allow for these ANZ Infant Formula products.

140. Trade barriers may exist where additives are permitted to be carried over from raw ingredients under Codex, but not permitted for use in infant formula products in the Food Standards Code.

Q2.32 Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.

141. **Fonterra Response**: See above. In summary, Fonterra notes there has been no evidence of any food safety or market issue with the FSANZ status quo which allows for carry-over of additives into infant formula, our preference is to retain this approach. However, if FSANZ proceed with the change as proposed, Fonterra supports the continuation of the carry-over principle for food

additives to infant formula as is applied by Codex STAN 72-1981. To further restrict any food additive permissions for carry-over, and not adopt the full list of Codex infant formula additive permissions, would create significant trade barriers and not be technologically feasible.

142. Regarding **Processing Aides**, Fonterra is supportive of FSANZ regulation of processing aids and their stance not to consider any changes under this Proposal.

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Annex I: Fonterra P1024 Submission

Fonterra Co-operative Group Limited Submission on:

FSANZ Call for Submissions – Proposal P1024

Revision of the Regulation of Nutritive Substances and Novel Foods

24 March 2016

Executive Summary

168. Fonterra welcomes the opportunity to comment on the Proposal to investigate the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code. We agree that there is ambiguity under the current regulatory regime for nutritive substances, and support a review that would remove this ambiguity.

169. Fonterra supports several aspects of the proposal including adopting a risk-based approach, the intention to align with international approaches and introduction of a pathway for pre-market self-assessment.

170. There are, however, areas of the regime where we see significant challenges in applying the proposed regime to dairy ingredients.

171. FSANZ has focused on concentration of components as a key indicator of safety risk, and has designed a framework that identifies concentrated foods and ingredients as requiring additional safety assessment. The dairy industry, however, has a long history of fractionating and concentrating milk to produce foods and ingredients with safe use (e.g. cheese, milk powders and milk protein concentrates). This history of safe should be recognised by the regime to support efficient allocation of regulatory resources and avoid unnecessary regulatory burden.

172. Addition of dairy components to a food at a concentration higher than that achievable from whole milk does not automatically create a health risk. A more appropriate basis for comparison in a safety assessment is what can be delivered to a final product through typical dairy ingredients (including Milk Protein Concentrate (MPC), Whey Protein Concentrate (WPC), cream powders, sweet whey powder, etc). This then enables a meaningful comparison for addition rate of concentrated dairy ingredients and components delivered to a final product to other dairy ingredients that could alternately be used.

173. Further to the concerns noted above, evaluation of the proposed Eligible Food Criteria against examples of common dairy ingredients demonstrates that the Criteria do not provide clarity or allow an objective assessment of the “eligibility” of dairy ingredients. Under Eligible Food Criterion 2 (EFC2) it is not possible to objectively evaluate whether a product is “simply processed”, or should be considered as an extract or a substance. It is also not possible to determine which ingredients or products can be used as the basis for comparison for Eligible Food Criterion 3 or 4.

174. Fonterra has also identified a range of more specific concerns with the Eligible Food Criteria, including:

a. The proposed exclusion of enzymatic processing from the list of eligible food processes under EFC2;
b. The need for an expanded approach to identifying eligible microorganisms; and
c. Recognition that the proposed regime is fundamentally a series of positive lists (for eligible microorganisms, commodities and food classes, processes and potentially enzymes) and thus a pragmatic approach for amending these lists is required.

175. Fonterra requests FSANZ re-consider the Eligible Food Criteria in light of these concerns. Fonterra requests additional targeted consultation with the dairy industry before drafting commences on a revised proposal to address these weaknesses.

176. As noted above, Fonterra is supportive of introducing a pathway for pre-market self assessment by industry, although the ability to protect intellectual property (IP) will be critical for this pathway to have utility for industry. We propose an alternative approach, similar to the self-determined US GRAS system:

a. Company X develops the dossier to use as the basis for determination;
b. The dossier is subject to an independent expert review;
c. Company X holds the dossier and independent expert review in house; and
d. The dossier can be requested by food authorities if required.

177. We also consider ingredients destined for infant formula should included in the scope of this review, and that the proposed regime, with some modifications outlined subsequently in our submission, should be applied to these products.

178. Fonterra notes that consistency in implementation and enforcement across jurisdictions will be critical for this regime. The introduction of the Eligible Food Criteria and pre-market self-assessment with notification pathways, in particular, will require consistency of implementation across jurisdictions to avoid creating significant business risk for companies.

179. Finally, Fonterra encourages FSANZ to consider whether the proposed changes have any implications for New Zealand and Australian exports of dairy products, in particular clarification of the relationship between the proposed regime and existing New Zealand and Australian approaches for addressing conflicts between domestic and export market regulatory regimes.

180. Fonterra welcomes the opportunity to work with FSANZ to address these concerns.

Fonterra Co-operative Group Limited

181. 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.

182. Fonterra is 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.

183. 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 and Western Star. Fonterra also operates a dedicated sales channel for the foodservice industry which services restaurants, cafes, hotels and QSR operations.

184. 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, New Zealand and Melbourne, Australia, 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. Fonterra 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

185. Fonterra welcomes the opportunity to comment on the Proposal to investigate the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (the Code). The key objective with respect to this proposed Standard is to achieve the correct balance between the role of food Standards in protecting the integrity of the food supply, and also supporting industry innovation.

186. Fonterra supports development of a regulatory regime for novel foods and ingredients that conforms to the following principles:

a. Promotes food safety and consumer confidence in the food supply;
b. Provides for appropriate regulatory interventions based on risk
c. Provides regulatory certainty while supporting innovation
d. Allows companies to protect intellectual property
e. Provides a credible system that can be leveraged internationally
f. Recognises safety approvals of reputable overseas jurisdictions
g. Recognises the long, safe history of use of dairy products and dairy ingredients
h. Recognises that not all concentration or extraction steps create risk (i.e. create imbalance in total daily intake of nutrients)
i. Focuses on safety, not efficacy (which is covered under a different regulatory regime)

187. We agree with FSANZ's view that the current regulatory regime for nutritive substances creates uncertainty for both enforcement agencies and industry. We welcome consideration of a new regime that removes this ambiguity while also aligning with the principles set out above.

188. With this in mind, Fonterra is supportive of several elements of the Proposal:

a. Recognition that there are varying levels of risk arising from **new** products, and that a graduated risk management approach is appropriate to manage those risks;

b. Recognition that is it appropriate to use existing products and ingredients with a history of safe use as a point of comparison for safety assessments;

c. Intent to align with international approaches; and

d. Introduction of a pathway for pre-market self-assessment as an alternative to FSANZ pre-market assessment.

189. We support a proportionate approach that allows for a 'step up' in regulatory requirements commensurate with risk and promise which allows for simplified assessments and streamlined decision making.

190. There are several points in the proposals, however, that we find concerning and that require further clarity/development in order for the proposed alternative regime to be considered viable for further development. These issues are identified below, along with our recommendations for addressing these concerns.

191. Inclusion of Infant Formula Products

192. The Proposal explicitly excludes Infant Formula Products (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Food for Special Medical Purpose (Standard 2.9.5) from this review. Fonterra notes that reviewing the current regulatory regime for nutritive substances and novel foods without consideration of these products will not support development of a regime that can be applied across the entire Food Code. We consider his particularly important when Infant Formula Products and products manufactured as Formulated Meal Replacement and Formulated Supplementary Foods (Standard 2.9.3) are often very closely tied togehter. The current nutritive substances and novel foods regime applies to all foods including those carved out of this proposal. It is not clear how the regulatory gap would be handled in a situation where some foods are covered under a different system for approvals. In addition, we note that a regulatory regime for nutritive substances has particular applicability to products under these standards: the term 'nutritive substances' is used in 6 standards in the Food Standards Code (outside the structure and definitions). All but one standard (Standard 1.3.2 Vitamins and Minerals) are in Part 2.9 including Standard 2.9.1. Consideration of the future regulation of nutritive substances cannot effectively be conducted if most of the standards that apply the term are excluded from the scope of Proposal P1024.

193. Fonterra will therefore include the issues raised in this consultation from the perspective of Standard 2.9.1, in order to provide comprehensive assessment of the proposed regime, and to ensure consistency of approach across the Food Standards Code.

194. As discussed in more detail later in our answers to specific questions, Fonterra supports the proposal of the Infant Nutrition Council (INC) that, with appropriate differentiation, the framework

proposed in Option 3 (although it requires further development as noted subsequently in this submission) should be applied to Standard 2.9.1.

195. **Recognition of the long history of safe consumption of dairy products and ingredients.**

196. We understand FSANZ is intending to identify substances that when concentrated and added to food can create health risks. It is important that FSANZ recognise that concentration itself is not necessarily risky – the focus should be on whether the finished product will significantly alter total dietary intake of nutrients. For example, many dairy foods and ingredients with a long history of safe consumption are produced through fractionating and concentrating various milk components, including cheese, milk powders and milk protein concentrates. Addition of dairy components to a food at a concentration higher than that achievable from whole milk does not automatically create a health risk.

197. A regulatory regime that does not appropriately reflect this history of safe consumption by requiring pre-market safety assessments of dairy ingredients with low health risk, will not provide for efficient allocation of regulatory resources and would add unnecessary regulatory burden to the dairy industry. For example, as we will discuss further below, this regime as drafted would have required a full pre-market assessment for whey protein concentrate and milk protein concentrates which we do not consider justified.

198. Proposed system should account for different addition rates of ingredients

199. As noted above, the focus of safety assessments in this context should be on whether the finished product will significantly alter total dietary intake of nutrients. The basis for comparison should be what can be delivered to a final product through ingredients. This provides the ability to account for different **addition rates** of ingredients (with comparison in final product) instead of forcing a focus solely on comparison between ingredients.

200. Specifically, Fonterra seeks confirmation from FSANZ that pre-market assessment should not be required for concentrated dairy ingredients that deliver key components at level that could feasibly be achieved either through addition of other dairy ingredients at higher addition rates, or using different processing steps as an alternative to the intended product. For example:

a. 1 gram of a new dairy ingredient could deliver the same key components as 10 grams of an existing dairy ingredient;
b. High (10%) protein beverage: could be produced by processing milk through ultrafiltration to increase level of protein to ~20g per 200mL serve, or using addition of milk protein concentrate (MPC) to skim milk to achieve the same protein level.

201. Fonterra has provided separately examples of demonstrating how ingredients with different concentrations of key components can be used at different addition rates to achieve the same effect.

202. Recognition that pre-market assessment should not be required for concentrated dairy ingredients that deliver key components at level that could feasibly be achieved through addition of other dairy ingredients albeit at higher addition rates is important for dairy ingredients where (for example) lactose content may be reduced to enable formulation flexibility, but chemical components

are still the same and still inherently safe. We note that this is a very different concept from Eligible Food Criterion 4 (EFC4) which only allows for addition to within the natural variation of a food

203. Ability to use appropriate food products and ingredients for comparison of concentration

204. As identified in the discussion above, the effectiveness of the proposed regime is contingent on being able to compare concentration of nutrients in a finished product against an appropriate basis. In order for the proposed regime to provide an appropriate level of risk-based regulatory oversight, it is not sufficient from a dairy perspective to have whole milk as the only point of comparison for assessing concentration of components. It appears this is not FSANZ intent, and that the Proposal envisages "simply processed" commodities being used as a point of comparison as well. Fonterra supports this concept, although we note that further work is required to ensure the Eligible Food Criteria deliver on this intent. This lack of clarity from the Eligible Food Criteria is discussed further below, however, we thought it would be helpful to provide FSANZ with additional examples to support further consideration of appropriate bases for comparison.

205. For example:

a. 10g of MPC delivers the same protein as 286 g of whole milk. When a new ingredient is manufactured, it may be more appropriate to compare this new ingredient to what could be achieved through addition of MPC or other dairy ingredients to the final product, rather than fluid milk;
b. The example of addition of lactoferrin to yogurt in SD3 (table A3) is also relevant here. We support FSANZ intent that, when assessing whether lactoferrin added up to a certain level in yogurt is eligible under the Eligible Food Criteria, the comparison should be to what could be achieved using sweet whey powder in the final product, rather than fluid milk.

206. The examples Fonterra has provided separately demonstrating the range of dairy ingredients that can be used, for example, to provide protein in finished products are also relevant here.

207. Of specific concern for infant formula manufacture is that innovation of infant formula products generally emerges from the efforts of manufacturers to mimic breast milk as closely as possible. Therefore, for infant formula the appropriate point of comparison for concentration is not necessarily always the source commodity but could be breast milk. From this perspective, a differentiation of the Eligible Food Criteria for infant formula could be that an ingredient, when added to infant formula, may be compared to breast milk rather than necessarily the source commodity or substance.

208. Proposed Eligible Food Criteria lack clarity and certainty for dairy ingredients

209. Fonterra notes that the move to replace the current definition-based approach to determining products that require a pre-market safety assessment with the Eligible Food Criteria is intended to provide a system that is clear, objective and enforceable. In order to achieve this objective, it is important that we do not simply replace these ambiguous definitions with criteria that are equally ambiguous.

210. Detailed analysis of the proposed Eligible Food Criteria identifies that the Criteria, as currently proposed, do not provide clarity or allow an objective assessment of whether particular dairy ingredients require a pre-market assessment.

211. EFC2 provides a list of eligible commodities and list of processing techniques that will result in eligible "simply" processed commodities. Eligible commodities and simply processed commodities under EFC2 are also used as reference points to determine whether extracts and substances are considered eligible under Eligible Food Criteria 3 (EFC3) or EFC4. Evaluation of a range of current dairy products and ingredients demonstrates that the Criteria are not able to adequately identify the boundary between a simply processed commodity, an extract or a substance.

212. Dairy products are almost all produced using the criteria listed as "Processing Techniques that would be likely to meet criterion 2" (SD3 table 3, p8). This means under EFC2 as currently drafted, it is not possible to objectively evaluate when a product ceases to be "simply processed", and is considered an extract or a substance. It is also not clear what ingredients or products can be used as the basis for comparison for EFC3 or EFC4.

213. For example, in the lactoferrin example in Supporting Document 3 (SD3) p23, dried sweet whey is classified as "simply processed". It will have undergone: physical fractionation (separation of cream and skim milk; separation of curd and whey), thermal processing, mixing, enzymatic processing, filtration, evaporation and drying. It is not possible to deduce, from these criteria, why dried sweet whey is considered "simply processed" but lactoferrin (which has gone through similar processes but with additional physical fractionation and filtration steps) is not.

214. As another example, FSANZ refers to addition of permeate to milk to standardise nutrient levels due to seasonal variation (SD3, p14, paragraph 3) as an apparent example of a "substance" being added back to a source food. Permeate, however, will have only gone through two or three processing steps (physical fractionation, thermal processing and filtration) and thus, on the basis of the example noted above, it is not clear why it would be considered a "substance" rather than "minimally processed".

215. Other examples of dairy commodities that could be used as the basis for comparing concentration of dairy components for new dairy ingredients where it will be difficult to differentiate between simply processed, extract and substance under the criteria include:

a. Whole Milk Powder (WMP), which will have gone through the following processing steps: physical separation, thermal processing, mixing, crystallisation (where lactose added), evaporation and drying.
b. Whey Protein Concentrate (WPC), which will have undergone the following processing steps: physical fractionation, thermal processing, filtration (separating out milk permeate; retaining whey protein and fat; filtering out lactose and minerals), evaporation, drying.

216. The proposed structure for the Eligible Food Criteria, where EFC3 and EFC4 are assessed relative to the eligible commodities and simply processed commodities in EFC2, means that the criteria set as a whole lack clarity, objectivity and regulatory certainty in relation to dairy products.

217. We note that revising EFC2 to introduce a limit on the number of processing steps, or revising EFC3 or EFC4 to allow a fixed number of "extractions" will not resolve this problem. The

number of processing steps does not relate in any meaningful way to the safety risk associated with a food product. In addition, there is no clearly accepted meaning of what constitutes "extraction" as opposed to other processing steps such as filtration or evaporation.

218. Given the long history of safe use of dairy ingredients, our view is that an appropriately risk-based system would provide for the ability to use dairy ingredients that are currently on the market as the point of comparison for concentration. As noted above (paragraphs 31-40), comparison must also focus on an ingredient's use in a finished product, and therefore addition rate, rather than simply direct comparison between two ingredients.

219. We request FSANZ re-consider these criteria in light of the points raised above. Fonterra requests additional engagement with FSANZ, in the form of targeted consultation with the New Zealand and Australian dairy industries before drafting commences on the revised proposal, to address these weaknesses.

220. Exclusion of enzymatic processing from EFC2

221. Fonterra notes that FSANZ has proposed specifically excluding enzymatic processing from the list of eligible processes under EFC2. A blanket exclusion of enzymatic processing does not recognise the long history of safe use of certain enzymes/enzymatic processes (e.g. using rennet to separate milk into curds and whey) and is inconsistent with the approach used in Eligible Food Criteria 1 (EFC1) for microorganisms. It does not make sense that a product would automatically be ineligible under the Eligible Food Criteria if an enzyme is added directly, but the same product made using a microorganism to produce that enzyme would be eligible.

222. We note that, had this regime been in place, all whey protein ingredients would have required FSANZ pre-market assessment – including the sweet whey powder used in FSANZ own lactoferrin example (SD3, p 23). This suggests the current Proposal is not providing an appropriate risk-based framework.

223. We note that the Code already permits the use of enzymes as processing aids[3] to produce safe ingredients so excluding enzymatic processing from scope of Eligible Foods is a substantial reduction in existing permissions.

224. Fonterra requests that FSANZ revise the Proposal to include processing with enzymes with a long history of safe use under the Eligible Food Criteria. We refer to the positive list of enzymes used as processing aids in the Code[4]. This approach should be broadened by:

a. Adopting the same approach used by Codex of allowing use of "safe and suitable" enzymes e.g. Codex General standard for cheese (CODEX STAN 283-1978); and

b. Recognition of lists of approved enzymes in other jurisdictions. We note that the EU is in the process of developing a list of permitted enzymes, and that France includes a list of permitted enzymes in their list of processing aids[5]

[3] *Australia New Zealand Food Standards Code,* Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4
[4] *Australia New Zealand Food Standards Code,* Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4
[5] http://www.economie.gouv.fr/dgccrf/publications/juridiques/panorama-des-textes/Auxiliaires-technologiques

225. Expand approach to identifying eligible microorganisms under EFC1

226. We are concerned at the prospect of FSANZ basing the list of eligible microorganisms solely on the EFSA QPS list. We have reviewed the EFSA QPS list and several commonly used starters are absent from the list. This would result in a significant amount of the cheese manufactured in Australia and NZ potentially needing pre-market assessment, which is presumably not FSANZ's intention. Examples of missing microorganisms include:

a. Staphylococcus (most white mould and other specialty cheeses, salami and other)
    i. S. carnosus
    ii. S. xylosis
b. Penicillium (white mould cheese)
c. Geotricum (white mould cheese)
d. Macrococcus
e. Streptococcus salivarius
f. Micrococcus
g. Enterococcus (lots of salami and other foods)

227. We suggest that this criterion should be amended to allow for the use of microorganisms that meet a set of criteria where presence on the EFSA QPS list is only one way that eligibility could be established. These criteria could include:

a. Presence on similar lists published by other reputable Food Safety Authorities
b. Recognition in lists published by reputable scientific journals as having a long history of safe use, e.g. Journal of Food Microbiology's "Food fermentations: Microorganisms with technological beneficial use"[6]

228. Another alternative would be to adopt the Codex approach of allowing the use of "harmless" microorganisms in the General Cheese Standard (General standard for cheese (CODEX STAN 283-1978).

229. Pre-market self assessment through notification

230. As noted above, Fonterra is supportive of introduction of a pathway for pre-market self assessment by industry. This is a key element of introducing a graduated risk-management system that is proportionate with risk. The design of this pathway, however, will be crucial in determining the utility of this option for industry. Two key elements are the gateway criteria and the ability to protect intellectual property (IP).

231. Fonterra notes that FSANZ intends to develop appropriate gateway criteria if the draft framework is progressed. We look forward to working with FSANZ as these criteria are developed. As a preliminary position, Fonterra supports the gateway criteria proposed in the FSANZ presentation from the workshops for call for submissions:

a. International precedents;
b. Minor variations from eligible food criteria; and
c. Extensions of use.

232. The proposed requirement for dossiers to be made public is problematic. Publication of the full dossier would result in release of proprietary information, with no provision for companies to protect their IP. FSANZ suggests that the release of proprietary information can be managed by

[6] Bourdichon, F., et al., Food fermentations: Microorganisms with technological beneficial use, Int. J. Food Microbiol. (2012), doi:10.1016/j.ijfoodmicro.2011.12.030

timing the release of the dossier to coincide with the introduction of the product on the market. In our view this is inadequate to balance the release of all IP, which can take decades to develop and may relate to multiple products, including products not yet on the market.

233. We propose an alternative approach, similar to the US self-determined GRAS system, that would provide an appropriate balance of regulatory oversight and protection of IP. Our proposed alternative approach includes an independent expert assessment to add objectivity of assessment of safety:

a. Company X develops the dossier to use as the basis for determination;
b. The dossier is subject to an independent expert review;
c. Company X holds the dossier and independent expert review on file in house; and
d. The dossier can be requested by food authorities if required.

234. If FSANZ decide to proceed with requiring the dossier to be published on the website, then it should be acceptable for a summary or extract only to be made public, to prevent the release of all IP related to the ingredient/food.

235. Fonterra would also like to note that it is important that all three pathways (Eligible Food Criteria pathway, pre-market self-assessment with notification and pre-market approval by FSANZ) are carefully shaped to ensure they support appropriately calibrated regulatory interventions. For example, the existence of an industry self-assessment through notification pathway should not be used as rationale for progressing a regime with inadequate Eligible Food Criteria.

236. **Consistency of implementation and enforcement**

237. In order to provide the clarity, objectivity and regulatory certainty envisioned under this Proposal, consistency of implementation and enforcement across jurisdictions will be crucial. Fonterra understands that some jurisdictions have yet to establish regimes for implementing and enforcing the recently amended Health Claims regime, and note that this increases risk of inconsistency across how products will be treated in different jurisdictions.

238. Consistency between enforcement agencies in interpreting the Eligible Food Criteria and the gateway criteria for the pre-market self-assessment will be crucial under the proposed regime. For example, if a company determines a product meets the Eligible Food Criteria and markets that product across multiple jurisdictions, it should not be possible for one enforcement agency to object to this determination if another enforcement agency has already evaluated this determination and found it to be consistent with the Criteria.

239. We also note that in a situation where an application is made for FSANZ pre-market assessment for an ingredient that is not-novel or nutritive as it is an ‘eligible food’ FSANZ should not conduct the assessment. Instead, FSANZ should provide a reference letter that the ingredient is recognised as an ‘eligible food’. This approach would avoid a situation where the Eligible Food Criteria regime is potentially undermined by a FSANZ pre-market assessment. It would also support international trade by facilitating access to other markets that may question an ingredient’s approval status.

240. **Trade considerations**

241. Fonterra encourages FSANZ to consider whether the proposed changes have any implications for New Zealand and Australian exports of dairy products.

242. In Australia the current default under the Export Control (Milk and Milk Products) Orders 2005 is that: “Milk and milk products for export as food and their ingredients must not contain…a food additive, processing aid, vitamin, mineral, added nutrient, other matter or substance in contravention of the applicable requirements of the Food Standards Code”. There is an exemption where the importing country authority specifies an alternative requirement for the food additive, processing aid, vitamin, mineral, added nutrient, other matter or substance.

243. Where importing country regulations are silent, there is currently scope to export products that are not expressly permitted in the Code. We seek confirmation from FSANZ that this will continue under the proposed approach.

244. NZ legislation is similar with the requirement to seek an exemption (called a “60B exemption”) where an exported food does not meet the local regulatory requirements.

245. Whilst the requirement to seek exemptions does not change with the proposed alternative approach, the relationship between these two regime should be clarified as potential inconsistency creates significant business risks.

246. For example, Ingredient X is used in a product sold locally by Company A. Company A considers that, under the proposed regime, the product meets the Eligible Food Criteria. Company B decides to use ingredient X in an export product and determines that the ingredient does not meet the Eligible Food Criteria. As Company B is not planning to sell Ingredient X in Australia or NZ, Company B seeks and obtains a 60B exemption. This should not be considered to infer that ingredient X requires a pre-market safety assessment.

247. **Recognition of requirement for safety data**

248. For all criteria, including the approaches to microorganisms and enzymes, it is important to recognize the requirement that even for Eligible Foods, companies still have to undertake a safety assessment. If there is no available information on the ingredient, microorganism or enzyme to meet the requirements for microbiological, toxicological and nutritional safety as set out in Supporting Document 2 (SD2), a pre-market safety assessment will be required. The Eligible Food Criteria should be drafted with this requirement in mind. These criteria do not need to capture and eliminate every conceivable risk by themselves, but should work in concert with the requirement for safety data.

249. Moreover, recognising that a number of food and food ingredients have a long history of export from Australia and New Zealand, or that similar products may be consumed in other countries, toxicological data requirements (e.g. history of safe consumption), should also be able to be established on the basis of comparable global consumption.

250. **Pragmatic approach for amending lists**

251. The legal framework for approval of novel foods and ingredients should support pragmatic solutions – including being relatively easy to amend if required. Although FSANZ describes this as

a criteria-based approach, it is fundamentally based on a set of positive lists, including lists for microorganisms, eligible commodities and food classes, eligible processes and, as noted above, potentially enzymes. From a principle position, positive lists are not best practice in regulatory regimes, as despite good intentions and comprehensive consultation, accidental omissions will occur. It is also inevitable that lists become outdated over time. Given the fundamental role these lists play in the Proposal, it is critically important that there is a pragmatic process for expanding these lists once they are incorporated in the Code.

252. This is particularly important for omission of items that apply across an entire industry or group of industries, where an application by one company to amend the code via FSANZ pre-market approval is not appropriate

253. We request the FSANZ ensures there is a pragmatic process, with a timeline that is measured in weeks rather than months or years, for amending these lists before this regime is codified in the Code.

254. **Lack of key definitions**

255. The consultation documents do not provide definitions for key terms such as “extract”, “substances”, “natural range” and “pharmacological effect”. It is difficult to assess the impact of the proposed regime in the absence of these definitions. Further, we note that comprehensive definitions of these terms may be difficult to develop, and the development of a regime that relies on these terms may not provide any improvement over the current regime, where the absence of definitions for terms such as “nutritional purpose”, “normally consumed” have contributed to the uncertainty around the current regime.

256. We have provided further detail on specific “Questions for Submitters” in the Appendix.

257. If there are any queries relating to this submission, please contact Fiona Hutchinson, Senior Regulatory Manager – Advocacy (fiona.hutchinson@fonterra.com)

Yours faithfully

Greg McCullough
Group Director Food Safety Quality and Regulatory

Appendix: Responses to selected questions from FSANZ consultation documents

Refer section 3.3

How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

Fonterra agrees that there is ambiguity in relation to the definition of nutritive substances, as identified by the New South Wales Supreme Court in their decision in 2009. The lack of clarity resulting from this definition means that for food companies like Fonterra there is no regulatory certainty over whether a pre-market safety assessment is required for a particular ingredient or product. The lack of clarity also creates a risk of differing positions between enforcement agencies on whether a particular product requires a pre-market safety assessment. There is also the possibility of companies having different positions on whether a pre-market safety assessment is required, which could result in one company seeking pre-market approval for a product that another company has determined does not require a pre-market approval, creating an uneven playing field among industry participants. This lack of regulatory certainty creates risks for businesses that may stifle innovation.

Fonterra supports a robust regulatory system which ensures food safety and consumer confidence in the food supply. We note the comments from food enforcement agencies on the difficulties associated with removing products that pose a threat to consumer safety under the current regime, and support a review that will consider options for addressing these difficulties.

As it noted in paragraphs 24-27 above, Fonterra does not support excluding Infant Formula Products (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Food for Special Medical Purpose (Standard 2.9.5) from this review. Further, we note that the term 'nutritive substances', outside the structure and definitions of the Food Standards Code, is used in 6 standards in the Food Standards Code. All but one standard (Standard 1.3.2 Vitamins and Minerals) are in Part 2.9 including Standard 2.9.1. Consideration of the future regulation of nutritive substances cannot effectively be conducted if most of the standards that apply the term are excluded from the scope of Proposal P1024. Finally, we note that FSANZ does not currently have a plan to address any subsequent regulatory changes in these standards, except for infant formula.

Fonterra will therefore include the issues raised in this consultation from the perspective of Standard 2.9.1, in order to provide comprehensive assessment of the proposed regime, and to ensure consistency of approach across the Food Standards Code.

Refer section 4.2.1
Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.

Fonterra supports retaining a pathway for pre-market safety assessment by FSANZ for high risk foods. A requirement for pre-market safety assessment that is appropriately targeted to foods or ingredients with a high potential for risk for consumer safety is an important element of a regulatory regime that supports consumer confidence and will be considered robust internationally.

Fonterra also supports retaining the option of seeking exclusivity for ingredients that receive a pre-market approval by FSANZ.

Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.

The problems with the status quo identified in the Proposal focus on legal clarity, uncertainty and enforcement issues.

Fonterra notes that the current system does not provide any recognition of pre-market assessments conducted by reputable agencies overseas. This requires duplication, cost and time to repeat or amend work already conducted expertly elsewhere. A revised regime should include appropriate recognition of assessments conducted by reputable agencies overseas.

For some products, such as infant formula products, there is also the issue of limiting the population base for safety assessments to Australia and New Zealand. Fonterra supports INC's recommendation that infants are considered reasonably homogeneous worldwide and as a result, the population for infant formula products should be expanded to reflect the global community of infants 0-12 months.

Refer section 4.2.2
Do you support amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code? If so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2.

Fonterra does not believe that it is possible to amend the definition of "used as a nutritive substance" to address the limitations that have been identified in the current approach.

Refer section 4.2.3.1
Are the EFC appropriate for identifying foods that do not need regulatory approval?

Fonterra had identified significant challenges in applying the proposed EFC to dairy ingredients and dairy products. These concerns are set out in detail in paragraphs 28-61 and 80-86 and include:

- Lack of recognition that concentration of components is not inherently risky. Concentration must be assessed relative to total dietary intake of components (rather than particular "source foods") to adequately assess risk. For this reason, the proposed regime risks failing to recognise the long history of safe consumption of dairy products and ingredients, which is necessary to provide appropriate targeting of regulatory resources to high-risk foods and ingredients.
- Eligible Food Criteria should recognise that pre-market assessment should not be required for concentrated dairy ingredients that deliver key components at level that could feasibly be achieved through addition of other dairy ingredients (albeit at higher addition rates) or alternative processing steps.
- Addition of dairy components to a food at a concentration higher than that achievable from whole milk does not automatically create a health risk. A more appropriate basis for comparison in a safety assessment is what can be delivered to a final product through typical dairy ingredients (including Milk Protein Concentrate (MPC), Whey Protein Concentrate (WPC), cream powders and sweet whey powder).
- It is not possible to determine with any certainty which dairy ingredients will be considered eligible under the "simply processed" element of EFC2.
- The proposed structure for the Eligible Food Criteria, where EFC3 and EFC4 are assessed relative to the eligible commodities and simply processed commodities in EFC2 means that the criteria set as a whole lack clarity, objectivity and regulatory certainty in relation to dairy products.
- The Eligible Food Criteria should also recognise breast milk as the appropriate benchmark for comparison for ingredients in infant formula, rather than the source commodity necessarily.
- The blanket exclusion of enzymatic processing fails to appropriately recognise the use of enzymes with a long history of safe use (such as adding rennet to milk to separate curds and whey) under the Eligible Food Criteria. These criteria should be amended to to include processing with enzymes with a long history of safe use under the Eligible Food Criteria.
- The proposed approach to determining microorganisms that will be included in the Code under EFC1 is too narrow, and will result in several common starter cultures being excluded from the list. This criterion should be amended to allow for the use of microorganisms that meet a set of criteria where presence on the EFSA QPS list is only one way that eligibility could be established.

In addition to the points raised above, Fonterra notes the following detailed comments:

- The processing terms used in the consultation document (SD3, Table 3) are very general. We assume companies will be able to develop their own lists of what constitutes these processes, e.g. ion exchange resin (to produce Whey Protein Isolate/high-fat whey/demineralised whey powder) is a filtration step.
- The consultation documents do not provide definitions for key terms such as "extract", "substances", "natural range" and "pharmacological effect". It is difficult to assess the impact of the proposed regime in the absence of these definitions.

- Further, we note that comprehensive definitions of these terms may be difficult to develop, and the development of a regime that relies on these terms may not provide any improvement over the current regime, where the absence of definitions for terms such as "nutritional purpose", "normally consumed" have contributed to the uncertainty around the current regime.
- FSANZ notes that it may be necessary to provide an additional definition of "natural range" as used in EFC3, to avoid the use of "outlier" sources that do not reflect food sources that are commonly consumed (SD3, p 14). We note that there is very wide range of seasonal and breed-based variability in the composition of bovine milk, and highlight the critical importance of adequately reflecting this variability in this regime.
- NZFSA's discussion relating to this criterion in the discussion documents (including SD3) only discusses the situation where the total level of naturally occurring and added components in the target food is no higher than that present as if the *source food* were added to the target food. This criterion, however, also provides for *products described in criterion 2* (e.g. minimally processed commodities) to be used as the basis for comparison. We note that this adds additional complexity to issues such as "natural range" and "naturally occurring" and that this should therefore be reflected in any future discussions on this criterion.
- NZFSA notes that there is a continuum between extracts and substances, queries whether the distinction between extracts and substances should be maintained, and the more appropriate baseline. Given the challenges associated with fitting dairy products adequately into to proposed framework, Fonterra's preference is to have the widest possible choice of products to use as a comparison. As a preliminary position, we consider that the approach laid out in EFC3 would be the more appropriate to use than that in EFC4, although we note that the inadequacy of the Eligible Food Criteria as currently drafted makes it impossible to offer a final view.

We request FSANZ re-consider these criteria in light of the points raised above. Fonterra requests additional engagement with FSANZ, in the form of targeted consultation with the New Zealand and Australian dairy industries before drafting commences on the revised proposal, to address these weaknesses.

Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.

Fonterra is not aware of any foods that may meet the EFC that should be subject to pre-market assessment.

Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.

As noted above, Fonterra does not support a blanket exclusion for enzymatic processing in EFC2. This issue is discussed in full in paragraphs 53-57. We note that the Code already permits the use

of enzymes as processing aids[7] to produce safe ingredients so excluding enzymatic processing from the scope of Eligible Foods is a substantial reduction in existing permissions. Fonterra requests that FSANZ revise the Proposal to include processing with enzymes with a long history of safe use under the Eligible Food Criteria. We refer to the positive list of enzymes used a processing aids in the Code[8]. This approach should be broadened by:

a. Adopting the same approach used by Codex of allowing use of "safe and suitable" enzymes (e.g. Codex General standard for cheese (CODEX STAN 283-1978).

b. Recognition of lists of approved enzymes in other jurisdictions. We note that the EU is in the process of developing a list of permitted enzymes, and that France includes a list of permitted enzymes in their list of processing aids[9]

Fonterra also notes that the proposed approach to microorganisms under EFC1 would result in several common starter organisms being considered ineligible. This issue is discussed in more detail in paragraphs 58-61. Fonterra suggests that this criterion should be amended to allow for the use of microorganisms that meet a set of criteria where presence on the EFSA QPS list is only one way that eligibility could be established. These criteria could include:

c. Presence on similar lists published by other reputable Food Safety Authorities
d. Recognition in lists published by reputable scientific journals as having a long history of safe use, e.g. Journal of Food Microbiology's "Food fermentations: Microorganisms with technological beneficial use"[10]

Another alternative would be to adopt the Codex approach of allowing the use of "harmless" microorganisms in the General Cheese Standard (General standard for cheese (CODEX STAN 283-1978).

Finally, Fonterra also refers to the discussion under the question "Are the EFC appropriate for identifying foods that do not need regulatory approval? " and in paragraphs 28-61 that highlight challenges with the EFC as currently proposed. If these concerns are not addressed, then it is possible that the EFC may not capture a wide range of dairy ingredients and products that have a low food safety risk and should be considered eligible for the EFC pathway.

What type of information do you think should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this information would support safety.

Fonterra supports comments from the Infant Nutrition Council (INC) that a differentiating aspect of the Framework for infant formula products could be a requirement that all safety assessment dossiers should include a focus on data that is relevant to infants as the target population group, e.g. breast milk levels, history of safe use of other ingredients from the same source commodity,

[7] *Australia New Zealand Food Standards Code*, Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4

[8] *Australia New Zealand Food Standards Code*, Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4

[9] http://www.economie.gouv.fr/dgccrf/publications/juridiques/panorama-des-textes/Auxiliaires-technologiques

[10] Bourdichon, F., et al., Food fermentations: Microorganisms with technological beneficial use, Int. J. Food Microbiol. (2012), doi:10.1016/j.ijfoodmicro.2011.12.030

use of existing ingredients in infant formula formulated to current Standard 2.9.1 regulatory minimums and maximums.

Fonterra notes that this regime presents complications for its application to ingredient manufacturing as distinct from finished goods manufacturing. There is an interdependence between ingredient supplier and finished goods manufacturers in relation to the dossier and determination of eligibility. The final decision on level of use of an ingredient is made by the finished goods manufacturer, yet much of the proposed regime for assessing the need for a pre-market approval is based on the level of use of the ingredient in a final product. There may also be issues of intellectual property and interpretation of requirements from international suppliers.

Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?

The proposed exclusions to the EFC are based on products having an impact on weight or satiety. Fonterra notes that these exclusions are not intended to capture "weight loss" foods that qualify to carry diet or low energy or similar claims (SD3, p18). These exclusions, however, also need to carefully crafted to avoid capturing normal food-health relationships for foods that do not carry diet/low energy or similar claims. For example, proteins (including dairy proteins) are have an impact on satiety and may be promoted for weight management. This type of food-health relationship should not be used as the basis to exclude ingredients from the Eligible Foods Criteria Pathway.

Fonterra notes that the definition of "pharmacological properties" will be critical in determining whether we can support this exclusion. We support the comments of the NZ Food and Grocery Council in relation to this question, including noting that:

- If 'pharmacological properties' are intended to mean 'therapeutic properties' then NZFGC suggests that the only foods that would be affected are those that are within the scope of Standard 2.9.5 since all other uses of substances are for processing or dietary purposes.
- It is also the case that 'pharmacological properties' is in part defined by the context and the sector involved. Most vitamins and minerals might be considered to have 'pharmacological properties' but in the context of the general food supply, they are micronutrients for growth.
- Fonterra could envisage support for the pre-market safety assessment of substances with pharmacological properties so long as 'pharmacological property' and all other terms used to describe characteristics were clearly defined. We note that FSANZ has recognised this as a particular issue (SD3) and that "there does not appear to be an internationally recognised consistent definition of 'pharmacological' in the literature"
- We agree that a term such as 'biologically active substance' is too broad.

Refer section 4.2.3.3
Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?

Fonterra considers that the investigation of an alternative approach to regulating nutritive substance in the Code is a viable option. The current regime does not provide clarity or regulatory certainty, and it is difficult to see how the current definitions could be amended to provide the necessary clarity. Therefore, Fonterra supports investigation of an alternative approach to regulating nutritive substances in the Code.

In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? What aspects of the draft framework do you think are viable or not viable? Please provide supporting statements for your view.

Please note that although the summary of questions refers submitters to section 4.2.3.3. (Data and Dossier Requirements) only, Fonterra has interpreted this question to refer to Option 3 as a whole (i.e. Section 4.2.3: Option 3: Develop an alternative framework).

Fonterra supports further consideration of option 3 as set out in p17 of the Call For Submissions Consultation Document as a viable option.

Fonterra supports INC's comments that the framework proposed as Option 3 for general foods also being applied to infant formula products, with potential consideration of some differential elements specific to the target population. A proportionate approach to risk is a more efficient approach to managing the market entry of new food substances and, with appropriate differentiation, the framework proposed in Option 3 should therefore be applied to Standard 2.9.1.

Fonterra supports INC's proposal that the differentiation for infant formula products and ingredients is in relation to the prerequisite requirements for the Eligible Foods Pathway and the Pre-Market Assessment by Notification Pathway and the content of the data and dossier requirements for both. This would need to be designed to address the vulnerability of the target population who are consuming infant formula and the unique role of infant formula as the sole source of nutrition for infants 0-6 months where breastfeeding is not undertaken.

Fonterra supports INC's conclusion that the relevant Policy principles the Policy Guideline on the Regulation of Infant Formula Products encompass an interpretation that does not exclude the application of the Option 3 Framework including eligible food criteria and industry pre-market self-assessment.

Fonterra has also identified aspects of the proposed pre-market self-assessment pathway that require further consideration. These issues are discussed in detail in paragraphs 62-68 and cover:

- The need for suitably designed gateway criteria
- Revision of the proposal to require publication of the full dossier, to allow companies to protect their intellectual property.

Although Fonterra supports further consideration of option 3 as set out in p17 of the Call For Submissions Consultation Document as a viable option, we have identified a number of areas where improvements are required in the proposed framework in order for this approach to be considered viable. These relate to the Eligible Food Criteria in particular (as noted in our General Comments (paragraphs 28-61 and 80-86 and answers to questions on section 4.2.3.1) as well as the above comments on the self-assessment pathway. If these concerns cannot be adequately addressed, then Fonterra does not consider option 3 to be viable and will support maintenance of the status quo.

Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?

As a preliminary position, Fonterra supports foods and ingredients that meet the following criteria are being suitable for industry self-assessment:

- Products that have been subject to pre market assessment by overseas reputable or recognised authorities could be suitable for industry self assessment such as Codex (through member contributions and assessments by other international agencies such as JECFA), EU and USFDA (GRAS substances).
- Extensions of use
- Minor deviations from the EFC

As is noted in paragraph 68, Fonterra would also like to note that it is important that all three pathways (Eligible Food Criteria pathway, pre-market self-assessment with notification and pre-market approval by FSANZ) are carefully shaped to ensure they support appropriately risk-based regulatory interventions. For example, the existence of an industry self-assessment through notification pathway should not be used as rationale for progressing a regime with inadequate Eligible Food Criteria.

Please provide details of how a self-assessment pathway may or may not provide benefits to industry.

An appropriately calibrated pre-market self-assessment pathway would also for is a central element of an appropriately calibrated risk-management regime. Such a pathway would allow for lower-risk products that do not fit within the EFC but have sufficient information available to allow industry to establish that a product is safe for consumption to be assessed under an alternative regime to FSANZ pre-market assessment. Fonterra supports FSANZ comments that such as regime may provide greater control over time for market for new foods. We also note that the introduction of such a regime will allow regulatory attention be focussed on higher risk foods, allowing for more efficient allocation of regulatory resources.

As noted above and in paragraphs 62-68 the self-assessment pathway will need to be appropriately calibrated in order to deliver these benefits. Development of suitable gateway criteria and revising

the proposed approach to publicly releasing commercially sensitive details will be necessary for this pathway to offer any benefit to industry.

Would notification and publication of dossiers provide enough regulatory oversight and consumer confidence in relation to the safety of new foods? Please support your answer with detail of why you believe this is the case.

Fonterra does not support publication of the dossier under a pre-market self-assessment pathway. Complete comments on this issue are provided in paragraphs 65-67. Fonterra does not consider that publication of the dossiers is the best approach to provide regulatory oversight and consumer confidence in the industry self-assessment pathway. We propose an alternative approach, similar to the US self-determined GRAS system, which would provide an appropriate balance of regulatory oversight and protection of IP:

- Company X develops the dossier to use as the basis for determination;
- The dossier is subject to an independent expert review;
- Company X holds the dossier and independent expert review on file in house; and
- The dossier can be requested by food authorities if required.

Refer section 6.2

Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.

Fonterra supports retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ. We note that the FSANZ pre-market approval process may require the release of commercially sensitive information including IP, and that the ability to seek exclusive permission is a partial mitigation against the potential losses associated with such a release. We note that similar exclusivity provisions are provided in overseas regimes, such as the EU novel foods regime.

Fonterra notes that the provision of exclusivity may require further consideration in relation to a situation where FSANZ receives a request for pre-market approval with exclusivity for two identical (or near identical) products at the same time.

Can you identify any issues that may arise if exclusive permissions are available for FSANZ approved foods, but not available for industry self-assessed foods? Would the self-assessment process for non-eligible foods provide a trade-off against the lack of an exclusive permission for self-assessed foods (section 4.2.3)?

Fonterra refers to our comments above and in paragraphs 65-67 on the requirement for industry to be able to protect IP through either making the dossier available to regulatory agencies only, or being required to release only a summary of the dossier. In this situation, the self-assessment

pathway provides a suitable trade-off against the lack of an exclusive permission for self-assessed foods.

If FSANZ proceeds with requiring public release of the entire dossier per the current proposal, then Fonterra considers that the self-assessment process does not provide an adequate trade-off against the lack of an exclusive permission for self-assessed foods. For this reason, Fonterra strongly recommends the approach set out in paragraph 66, which provides a more appropriate balance between protection of IP and regulatory oversight of the self-assessment pathway.

Refer section 7.1

Do you support a cut-off date? Please provide reasons for your view.

Fonterra supports a cut-off date if products under Standards 2.9.1, 2.9.2 and 2.9.5 are included under the same regulatory regime. We note that a cut-off date has been used in the EU and US. If Standards 2.9.1, 2.9.2, and 2.9.5 are brought under the same regulatory regime at the same time, there could be a significant gap arising from differing regulatory regimes would result in considerable uncertainty over how these products are to be treated.

Do you see a need for grandfathering provisions? Please provide reasons for your view.

Fonterra supports grandfathering provisions to remove doubt about substances currently in the market, particularly those currently defined as 'nutritive substances'.

Do you see a need for a stock in trade provision? Please provide reasons for your view.

Fonterra considers the usual 12 month stock-in-trade provision is appropriate.

Refer section 7.2.3

Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development of any future standard is likely to take and will therefore be clearly signposted before changes are made to the Code.

Fonterra notes that a transition period of 12 months is would be considered more appropriate for a regulatory regime of this level of significant. We recognise, however, that regulators are seeking to address the problems with the current regime as soon as possible. In light of this, Fonterra notes that a short transition period (such as 6 months) would require extensive guidance to be in place before the commencement of the transition period.

There should also be recognition that special treatment may be required for products that were already in the process of application preparation since the investment in application preparation is a significant cost in its own right (outside the application fees and charges arrangements).

Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?

Given the possibility of a short (6 month) transition period for this regime, Fonterra notes that it will be important for FSANZ to work with a wide range of peak bodies to ensure industry is familiar with the requirements and guidance for the new provisions. Fonterra suggests this could include the

Dairy Australia, the Dairy Companies Association of New Zealand, the Infant Nutrition Council and the Food and Grocery Council's of Australia and New Zealand.

In addition to peak bodies, FSANZ should also be prepared to work directly with companies that have been in the process of preparing applications in the lead up to, and during, the transition process as these companies are at greatest risk of experiencing confusion, delays and additional costs over the transition period.