Response to

P1028 – Infant Formula

FSANZ

Prepared by Dairy Australia

on behalf of the Australian Dairy Industry

Contact

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The Australian Dairy Industry

Dairy Australia welcomes the opportunity to present this submission in response to P1028 Infant Formula Review.

Dairy Australia is the dairy industry-owned service company, limited by guarantee, whose members are farmers and industry bodies, including the Australian Dairy Farmers, and the Australian Dairy Products Federation

Australian dairy is a $13 billion farm, manufacturing and export industry.

Australia's 6400 dairy farmers produce around 9.2 billion litres of milk a year.

The Australian dairy industry directly employs 43,000 Australians on farms and in factories, while more than 100,000 Australians are indirectly employed in related service industries.

Our industry has the potential to grow substantially over the next decade to meet growing domestic and international demand.

Realising this growth potential and expanding the industry's economic, social and environment benefits depends on a positive national and international operating environment.

Underpinning Dairy Australia's policy and regulatory, public health, nutrition science, and dietetic expertise is commitment to evidence based public health policy and food regulation. Our role is to provide expertise and evaluate, proposals in light of the most current relevant evidence, in the context of sound regulatory and policy development principles.

The dairy industry advocates core principles within which all regulatory requirements must operate. Regulation should be:

- Minimum but effective;
- Risk (science/evidence) based;
- Cost proportionate to benefit;
- Outcomes focussed;
- Proportionate to risk;
- Nationally consistent and enforceable; and should:
- Support innovation;
- Support and promote international and domestic trade; and
- Support competition.

The dairy industry has and continues to participate actively in the development and review of regulatory initiatives including FSANZ standards. The industry considers this is critical to responding to changing consumer needs, the continually evolving evidence base and supporting innovation, whilst ensuring health and safety is protected.

The dairy industry fully supports breast feeding as the best option for infants, however recognises that infants that cannot or are not breast fed must have access to safe and nutritionally suitable food.

Key points

Supporting Document 1: Definitions and Nutrient Composition

Conversion factors

- It has been identified that the primary limits on nutrient composition specified in Codex STAN 72-1981 on a per 100 kcal basis have not all been correctly converted to a per 100kJ basis in this Codex standard. These errors have led to some values being applied in Standard 2.9.1 intended to be aligned with Codex being incorrectly stated.

DEFINITIONS AND TERMINOLOGY

- Current product definitions should be retained.

PROTEIN

- Evidence does not support the need to change the current protein minimum and maximum. Any reduction in protein must be carefully considered to ensure infant health is not inadvertently put at risk. Evidence regarding a range of health outcomes, and the inter-relationship between all nutrients and ingredients collectively should be assessed for any formulas substantively outside current standards.
- Dairy Australia opposes a Nitrogen Conversion Factor of 6.25 for milk protein based infant formula and argues instead that an NCF of 6.38 is scientifically justified and in harmony with Codex.
- FSANZ should consider the Digestible Indispensable Amino Acid Score (DIAAS) method for measuring protein quality on the completion of validation work that would enable implementation.
- Requirements for amino acids should align with Codex STAN 72-1981.

FAT

- Dairy Australia opposes the proposal to lower the maximum amount of trans fatty acids (TFAs) to 3% total fatty acids as this is not aligned with Codex. FSANZ should note the definition of TFA in Codex does not align with that in the Food Standards Code in that the Codex definition excludes Conjugated Linoleic Acid (CLA). Importantly the Codex definition explicitly states that the limit is intended to facilitate the use of milk fat in infant formula.
- Dairy Australia does not support the introduction of a restriction specific to phospholipids.

CARBOHYDRATE

- Lactose should remain the predominant source of carbohydrate in infant formula.

VITAMINS, MINERALS AND ELECTROLYTES

- For nutrients, unless there are sound scientific or technological justifications that suggest a different approach would be more appropriate Dairy Australia advocates that the following principles apply:
    - Guideline Upper Limit (GUL) where no Nutrient Reference Value (NRV) Upper Limit (UL) set as no safety concerns; and
    - consistency with Codex where possible;
- Folate should be expressed in infant formula as folic acid, as current tests for folate are unreliable
- Dairy Australia supports a GUL for iodine because there is no established upper limit, no apparent safety concerns and significant variability in milk iodine content.

OTHER OPTIONAL SUBSTANCES

- Choline should be listed as a mandatory substance in infant formula with a minimum of 1.7 mg/100KJ, however the upper limit of 12mg/100KJ should be GUL.
- Dairy Australia is of the view and if an increased minimum is prescribed for L-carnitine content, the upper limit should be a GUL.
- Dairy Australia supports the FSANZ preliminary view to mandate inclusion of inositol in infant formula at the current minimum level 1.0 mg/100KJ. An upper limit of 9.5 mg/100KJ set as a GUL (in line with Codex STAN 72-1981) would be appropriate
- For nucleotides Dairy Australia is in agreement with the FSANZ preliminary view. However the combined total level must be determined. It is also important that the Code is clear that limits should only apply when nucleotides are added.

Supporting Document 2: Safety and Food Technology

STATEMENT OF PROTEIN SOURCE

- Dairy Australia does not support prescribing the placement/location of the protein source statement on infant formula labels.

NUTRITIVE SUBSTANCES AND NOVEL FOODS IN INFANT FORMULA

- Premarket assessment of nutritive substances and novel foods as they relate to infant formula should be included in the scope of P1024 rather than separately or as part of P1028.

CARRY-OVER PRINCIPLE FOR FOOD ADDITIVES AND INFANT FORMULA

- Dairy Australia strongly supports the continuation of the carry over principle for food additives to infant formula, in alignment with Codex.

Supporting Document 3: Provision of Information

PROVISION OF INFORMATION

- Dairy Australia sees that there is currently regulatory clarity provided by Nutrition, Health and Related Claims Standard 1.2.7 regarding ingredient and health claims for infant formula.
- Nutrition and ingredient information labelling regulation should be supportive of product differentiation.
- Dairy Australia suggests that an evidence (including consumer research) based and alignment with policy and regulatory principles assessment (including cost benefit analysis) be undertaken in regards to permissions for 'content claims' in infant formula, and this be used to inform development of the best regulatory options.
- Innovation cannot be supported if there is no way for caregivers and health professionals to differentiate between available formulas to recognise those that provide basic adequate nutrition from those that provide a lesser gap in nutrition and health outcomes against the bench mark of breast milk.
- Dairy Australia supports the continuation of voluntary declaration of macronutrient subgroups.
- Dairy Australia does not support the aligning names of ingredients with nutrient declarations in the nutrition information statement as the two requirements serve different purposes.
- Dairy Australia supports retaining the requirement that nutrition information be expressed per 100ml as made up. Voluntary inclusion of base units per 100g in alignment with Codex is also supported.
- Flexibility in communicating product reformulations should be preserved. Labelling is only one method for communicating with caregivers and health professionals.

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2 SUPPORTING DOCUMENT 1: DEFINITIONS AND NUTRIENT COMPOSITION

2.1 FSANZ PRELIMINARY VIEW

No.	Section of the SD	Question
Q1.1	All	For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

2.2 OVERARCHING ISSUES

2.2.1 CONVERSION FACTORS

It has been identified that the primary limits on nutrient composition specified in Codex STAN 72-1981 on a per 100 kcal basis have not all been correctly converted to a per 100kJ basis in this Codex standard. These errors have led to some values being applied in Standard 2.9.1 intended to be aligned with Codex being incorrectly stated. A number of the limits that require correction are documented in the relevant sections of this submission.

This issue was notified to CCNFSDU37 held in November 2015. These errors have led to some values being applied in Standard 2.9.1 (intended to be aligned with Codex) being incorrectly stated. The inconsistencies that result from these incorrect conversion calculations create barriers to trade.

The preference is for these technical corrections to be made as soon as possible rather than waiting for the changes from Proposal P1028 to be implemented.

2.3 DEFINITIONS AND TERMINOLOGY

Dairy Australia supports the FSANZ view to retain the current definitions

2.4 PROTEIN

2.4.1 CONTENT

Dairy Australia agrees with FSANZ that the evidence does not support a need to change the current protein minimum and maximum. Any reduction in protein must be carefully considered to ensure infant health is not inadvertently put at risk. Evidence regarding a range of health outcomes, and the interrelationship between all nutrients and ingredients collectively should be assessed for any formulas substantively outside current standards.

Further Protein and Evidence Considerations

Dairy Australia's review of the evidence is in general agreement with FSANZ. The current available evidence does not support a reduction in the current protein range. There insufficient evidence to support an association between the levels of protein for the current regulated range and increased risk of obesity. To reduce protein without consideration of the evidence regarding other factors may result in inadvertent adverse outcomes.

Many of the studies feeding formulas to infants with protein levels lower that the current Food Standards Code range are proprietary formulas. It is important to consider that the compositional details including specific ingredients that may play a role in outcomes are not declared. It is often not clear what the protein has been replaced with nor is it clear how the intervention formulas overcome the known availability and utilisation of amino acids etc. in formula compared to breast milk that has informed the current protein ranges set for infant formulas.

There may be differences in the presence or absence of particular ingredients comprising the formula for the control arm versus the intervention arm. Some of this information may be available through details associated with the registration of the trials in question, however this information is generally not included in the published papers. Conclusions tend to focus only on the protein difference, and other known confounders are not generally accounted for.

It is difficult when applying a standard that states a range for macro –nutrients to ensure that any significant reduction in one macronutrient will be replaced by other macronutrient specific types consistent with the composition of the propriety formulas that the evidence considers, when concurrently, there is a lack of evidence regarding the effect of replacing the reduction in protein with various types of carbohydrates and fats and health outcomes including risk of obesity when energy remains constant.

Current evidence gaps

In addition to the papers included in the FSANZ preliminary assessment, a recent systematic review published in the Journal of Nutrition found there is insufficient evidence to support a link between protein concentration in infant formula and risk of obesity later in life.[1] The review of 12 randomised controlled trials concluded protein concentration during the first year of life is not associated with linear growth, weight or weight gain. At this stage, the evidence is insufficient to support reducing protein concentration in infant formula, and given no nutrient has been been unequivocally associated with the development of obesity,[2] Dairy Australia supports maintaining current protein levels.

Additionally, as highlighted in the systematic review by Abrams *et al.* (2015)[3], lowering protein levels in formula should undergo a cost-benefit analysis and consider risks such as consumer mixing errors, ad-libitum vs restricting number of feeds, along with long-term growth and risk of obesity. It is therefore argued, that lowering the protein level may have the potential to compromise the nutrient intake of potentially at risk populations.

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[1] Patro-Golab B, Zalewski B, Kouwenhoven S, Karas J, Koletzko B, Bernard van Goudoever J et al. Protein concentration in milk formula, growth, and later risk of obesity: A systematic review. J Nutr. 2016;146(3):551-564.

[2] ESPGHAN Committee on Nutrition. Role of dietary factors and food habits in the development of childhood obesity: a commentary by the ESPGHAN Committee on Nutrition. J Pediat Gastroent Nutr. 2011;52:662-669.

[3] Abrams SA, Hawthorne KM, Pammi, M. Systematic review of controlled trials of lower protein or energy-containing infant formulas for use by healthy full-term infants. Adv Nutr. 2015;6(2):178-188.

There are concerns that the current paediatric studies investigating different formulas (low and high protein levels) and growth focus on limited endpoints related to growth and weight. The current body of evidence investigating the health impacts of lower protein formula, as reviewed by Abrams *et al.* (2015)[4] focuses mainly on weight, length, obesity risk and BMI and although these biomarkers are used as a proxy for healthy development, they do not adequately assess or provide coverage of important aspects of the developmental process. There is a lack of evidence of longer-term studies of the impacts of lower protein diets on assessing the full gamete of developmental endpoints including: developmental milestones, psychological, behavioural and physical sign of malnutrition (especially associated with protein energy malnutrition: hair, skin, face, glands, heart, liver, spleen, muscle and bone).

Other considerations include macronutrient balance. Dairy proteins are among the best quality alternatives when human milk is not an option. While present in differing concentrations to human milk, bioactive protein components are present in bovine milk including a-lactalbumin, lactoferrin, ostepontin and other bioactive proteins, from the milk fat globular membrane.[5] Changes in macronutrients could possibly dilute these components in the infant diet.

If protein content decreases, this would need to be balanced by increases in fat or carbohydrate and at this stage, there is a large gap in the evidence as to what the best replacement would be including which specific fats and carbohydrates. The focus of the current arguments around the impact of reducing the protein levels in formula on overweight and obesity appears to ignore other nutrients and dietary components. There is very scant published information and no systematic reviews looking at the impact of other nutrients within formulas on overweight and obesity, apart from adjusting protein. With any lowering of protein levels, there is the introduction of fats and/or carbohydrates which both provide energy sources to formula. The recommended selected macronutrient has received little attention and it is therefore proposed that a systematic review on the best replacement should be undertaken before making recommendations to lower protein in the absence of a clear evidence based better option.

Although, initial evidence may be suggestive that higher levels of fat (within guided levels) do not equate to increased overweight and obesity,[6] it is of concern that protein will potentially be replaced with glucose polymers. Dairy Australia believes that further work is need to understand what the preferred calorific replacement to protein should be before any consideration of protein reduction. There is currently a large evidence gap on what macronutrients would suitably replace protein in a proposed lower protein formulations for formula. There is not enough evidence to suggest that either greater contributions of fat or carbohydrate would provide an additional benefit and beyond that, it is even more unclear what types of fats or carbohydrates would be best suited for replacement to better counter the proposed early higher protein impact on weight gain.

Trial formulas that are substantively outside the current standard should be assessed for safety and suitability.

In the current context of evolving evidence regarding foods and health outcomes, to only consider a single macronutrient change in isolation, particularly for the sole source of nutrition for a vulnerable population involves inherent risk.

[4] Abrams SA, Hawthorne KM, Pammi, M. Systematic review of controlled trials of lower protein or energy-containing infant formulas for use by healthy full-term infants. Adv Nutr. 2015;6(2):178-188.
[5] Lonnerdal B. Infant formula and infant nutrition: bioactive proteins of human milk and implications for composition of infant formulas. Am J Clin Nutr. 2014;99(3):712S-717S.
[6] Michaelsen K, Greer F. Protein needs early in life and long-term health. Am J Clin Nutr. 2014;99(3):718S-722S.

Along with critiques of papers in the preliminary assessment, it should be noted as outlined above, that many published papers of studies aiming to link protein content to obesity do not disclose the full composition of infant formulas used in all arms. There may be compositional/ingredient differences other than protein and macronutrient differences between control and trial arms.

The specific low protein formulations used within the study trials, may well be safe and suitable, however this does not necessarily translate to a lowering of the protein range within the standard delivering safe and suitable infant formula. Any reduction in protein must be carefully considered to ensure population infant health is not inadvertently put at risk.

Evidence regarding a range of health outcomes, and the interrelationship between all nutrients and ingredients collectively, should be assessed for any formulas substantively outside current standards to ensure all products on the market are safe and suitable.

Assessment should ensure that the formulation delivers sufficient available/utilizable energy, protein/amino acids and other nutrients to safely meet infant requirements when fed to infants under various caregiver feeding regimes including restricted number/amount of daily formula feeds vs ad libitum.

2.4.2 CONSISTENCY WITH CODEX – PROTEIN CONVERSION CALCULATION

Protein levels are currently not 'identical' to those in Codex Standard 72-1981, from a manufacturing perspective. This inconsistency that results from incorrect conversion calculations creates a barrier to trade.

Technical amendments are required to the both the MINIMUM and MAXIMUM levels for protein to address an error in the conversion calculation. The MINIMUM protein level requires correction from 0.45 g/100 kJ to 0.43 g/100 kJ, consistent with 1.8 g/100 kcal which is the resultant value when using the FSANZ standard conversion factor of 4.18. Similarly, the MAXIMUM protein level requires correction from 0.7 g/100 kJ to 0.72 g/100 kJ consistent with 3.0g/100kcal when using the FSANZ standard conversion factor of 4.18.

Calculation of Protein Nitrogen Conversion Factors

Dairy Australia disagrees with FSANZ. **We recommend that scientific justification takes precedence over arbitrary considerations.**

Dairy Australia endorses 5.71 Nitrogen Conversion Factor (NCF) for soy proposed by FSANZ, but is opposed to the change proposed to the NCF of 6.25 for milk protein based infant formula on the basis of the following scientific and trade considerations.

In support of a science-based approach, the NCF=6.38 for milk protein products and NCF=5.71 for soy protein products have been well-established and documented in the scientific literature.[7,8] The proposed move to an arbitrary, non-science based NCF for milk based formula while applying a more scientific approach to the NCF applied for soy based formulas appears to be inconsistent.

[7] International Dairy Federation (2016). Bulletin of the IDF No. 482/2016. Evaluation of nitrogen conversion factors for dairy and soy. Available: http://www.fil-idf.org/Public/Publication.php?ID=41548.
[8] Maubois J, Lorient D. Dairy proteins and soy proteins in infant foods nitrogen-to-protein conversion factors. Dairy Sci Technol. 2015;96(1):15-25.

From a science perspective:

- IDF Bulletin 482 concludes that for milk protein products there is a lack of scientific justification for a NCF=6.25.

  For both dairy protein and soy protein, scientific publications based on experimental and/or theoretical analysis of NCFs consistently demonstrate that use of an NCF of 6.25 is incorrect and scientifically flawed.

- Similarly, Maubois & Lorient (2016)[9] conclude:

  Such a 6.25 value has absolutely no recognised scientific basis…, and especially for infant formulas, it is not appropriate for any used protein source: it overestimates by around 10% soy proteins and underestimates by 2% milk proteins. Only use of both specific conversion factors will give a true indication of the protein content.

  In contrast, there is considerable scientific evidence to justify a NCF=6.38 for milk protein products irrespective of the whey protein to casein ratio (Table 1) as well as of the source of whey used in final product formulations.[10]

  Calculation of NCF for milk based IF depending on the whey protein to casein ratio as reported by Maubois & Lorient 2016

Proportion in infant formula whey protein / casein	Nitrogen to protein conversion factor for infant formula
20/80	6.370
30/70	6.375
50/50	6.385
60/40	6.390

[9] Maubois J, Lorient D. Dairy proteins and soy proteins in infant foods nitrogen-to-protein conversion factors. Dairy Sci Technol. 2015;96(1):15-25.

[10] 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.

Trade and economic concerns: The practical importance of using science based NCFs has been widely recognized. To buy milk products on a protein conversion factor of 6.38 and to use these products as an ingredient with a protein conversion factor of 6.25 results in a 2%loss or devaluation – this does not make economic sense.

1. The nitrogen conversion factor of 6.38 was established by Codex for milk and milk products and is used globally for analysis s. If NCF=6.25 were to be applied to milk based ingredients used in infant formula products, then 2% of the protein is "deleted at the stroke of a pen", i.e. it is there, but it is considered not to be there. It is noted that the conversion factor of 6.38 is used for label declarations of protein content in Australian and New Zealand milk-based infant formula as per Standard 2.9.1.

2. The physical Working Group on endorsement of methods of analysis and sampling at the 37th session of CCMAS[11] recognized that "*the [NCF] factors have severe economic aspects*."

3. 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 …"*

4. Australian and New Zealand regulations cannot be looked upon in isolation in terms of their impact in the global scheme. In a global context 2% of dairy protein is the entire amount of dairy protein produced by the NZ dairy sector and all the land and other resources and emissions used or created to produce that milk.

Due to this significant impact, it is important that appropriate scientifically valid methods are used to determine the protein content of foods, including infant formula.

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

2.4.3 PROTEIN SOURCE

FSANZ proposes no change to protein requirements in relation to source

Dairy Australia agrees with FSANZ that the current approach to sources of protein is appropriate. Standard 2.9.1 does not specify the source of protein that can be used; the definition of an infant formula product requires that the product must be based on milk or other edible food constituents of animal or plant origin. We do not believe any amendments are required at this time.

2.4.4 PROTEIN QUALITY

Dairy Australia agrees 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. However **Dairy Australia notes that Protein Efficiency Ratio (PER) is out of date and does not reflect current science, as is based around the ability of a protein to meet the nutritional requirements of a 2-5 year old child. Ideally protein quality calculations should be consistent with the FAO Expert Working Group's report,** "Research approaches

[11] Codex Committee on Methods of Analysis and Sampling 37 (CCMAS37) Physical Working Group Report on endorsement of MAS http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-715-37%252FCRD%252Fma37_CRD2x.pdf.

and methods for evaluating the protein quality of human foods" (2014).[12] The DIAAS method should be considered further to be the protein quality calculation methodology. We recognise that this will require further development and availability of validation data to support the implementation of the DIAAS method.

Dairy Australia continues to emphasise the importance of linking protein content with protein quality.

We consider that safe minimum content of protein needs to ensure that the product achieves the required indispensable amino acid profile and with evidence of adequate "bioavailability", i.e. protein quality assessment.

For such a vulnerable population group for whom Infant Formula is a sole source of nutrition, protein content cannot be considered in isolation of protein quality. Ideally this should be done in consideration of new international recommendations.

There is some recognition of the view that while the factorial method has been used for the USDRIs (2005) and the FAO/WHO (2007)[13] safe intakes, it has recently been questioned. Using more sophisticated methods such as the Indispensable Amino Acid Oxidation methods which may give higher estimates of requirements.[14]

The assessment of protein quality in the current Infant Formula Standard was determined by Protein Efficiency Ratio (PER). The PER method is a bioassay in rats and is considered out of date and of limited value in evaluating the suitability of proteins for infant feeding. More recently, a Joint FAO/WHO Expert Consultation on Protein Quality Evaluation recommended the use of the Protein Digestibility Corrected Amino Acid Score (PDCAAS) to determine protein quality. The recommendations of the Joint FAO/WHO expert consultation (1989) informed the Codex Infant Formula Standard which is based on the amino acid content in breast milk as the reference protein.

More recently, in 2013 an FAO Expert Consultation on dietary protein quality was held. The expert consultation provides an update and improvements to the PDCAAS method for measuring dietary protein quality, referred to as Digestible Indispensable Amino Acid Score (DIAAS).[15] The key findings of the report of relevance, 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 needs to be assessed then the most up-to-date method should be used.

The DIAAS methodology maintain that the breast milk pattern is still the desired target for infant formula, however the DIAAS methodology provides understanding of whether the protein provides available amino acids to meet the requirements of infants.

It is noted that the FAO Expert Working Group's report, "Research approaches and methods for evaluating the protein quality of human foods" (2014) recommended the adoption of the DIAAS method by Codex. It is also recognised that there is further work to be completed to ensure a supporting framework to enable full implementation of the DIAAS method.

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[12] FAO. (2014). Research approaches and methods for evaluating the protein quality of human foods. Report of a FAO Expert Working Group 2 – 5 March 2014 Bangalore, India. Available: http://www.fao.org/3/a-i4325e.pdf

[13] FAO/WHO/UNU (2007).Protein and amino acid requirements in human nutrition Report of a joint FAO/WHO/UNU expert consultation (WHO Technical Report Series 935). Available: http://whqlibdoc.who.int/trs/who_trs_935_eng.pdf

[14] Elango R, Ball RO, Pencharz PB. Recent advances in determining protein and amino acid requirements in humans. Br J Nutr. 2012;108(Suppl 2):S22-30.

[15] FAO (2013). Dietary protein quality evaluation in human nutrition. Report of an FAO expert. FAO food and nutrition paper 92. Available: http://www.fao.org/ag/humannutrition/35978-02317b979a686a57aa4593304ffc17f06.pdf.

2.4.5 AMINO ACID CONTENT

FSANZ propose retaining min isoleucine, leucine, lysine, threonine, tryptophan and valine with Codex, maintain current expression of 2 sulphur amino acids and aromatic amino acids specifying min for Cys and Phe and summed values of SAA and AAA because the expression is clear and retain current minimums for SAA and AAA in standard 2.9.1

The minimum requirements for amino acids in infant formula are mainly based on 'typical' amino acid profiles of breast milk. Dairy Australia notes there are currently differences between the minimum amount of some of the 11 required amino acids in Standard 2.9.1 and Codex STAN 72-1981.

Dairy Australia is in general agreement with the FSANZ proposal to align the minimum levels of isoleucine, leucine, lysine, threonine, tryptophan and valine with those in Codex STAN 72-1981.

There is no general agreement with the FSANZ preliminary position to retain the current expressions for the amino acids minimums for tyrosine, phenylalanine, methionine, and cysteine. The quality of protein is considered important but compliance is not straightforward. This is due to the natural variability in amino acid content of milk ingredients and minimising the quantity of excess, naturally occurring amino acids whilst meeting the minimums.

We propose that the requirements for the amino acids tyrosine, phenylalanine, methionine, and cysteine are amended to be consistent with Codex STAN 72-1981. The Codex minimum amino acid requirements are based on more recent data for breast milk composition. Of note the average content of human milk is:

- 9 mg cysteine/100kJ;
- 6mg methionine/100kJ and
- a ratio of methionine : cysteine around 0.8[1].

Codex STAN 72-1981 allows either individual minimums of 9mg cysteine/100kJ and 6 mg/100kJ methionine or a combined total of 15 mg/100kJ provided the methionine : cysteine ratio is less than 2 (or in the case of that the ratio is between 2:1 and 3:1, the suitability of the formula has to be demonstrated by clinical testing). These levels are safe for infants subsequently consistency with Codex STAN 72-1981 can be achieved in at least one of two ways with the same outcome. The intention is to find a way of expressing the methionine/cysteine/cystine requirement that removes the need for a footnote as is currently used in Codex. We recognise that the expression of this provision in Standard 2.9.1 might be different and presents two examples for consideration, taking cysteine and methionine as the example.

For Example 1: The key concern is that where the specific levels for cysteine/cysteine and methionine are applied then the ratio and a total amount for cysteine/cysteine and methionine is NOT ALSO applied.

For this example, where the ratio of methionine:cysteine/cystine is less than 2:1 (or up to 3:1 where suitability of formula demonstrated by clinical evaluation) then a total of methionine AND cysteine/cystine can be used. This might be expressed as follows:

Example 1 (more closely reflects how requirements are specified in the Codex STAN 72-1981)

L-amino acid	Minimum amount per 100kJ
Cysteine & cystine	9mg
Methionine	6mg

OR, where methionine:cysteine & cystine ratio < 2:1 (or up to 3:1 where suitability of formula demonstrated by clinical evaluation) then

Cysteine, cystine & methionine	15mg

For Example 2: The key concern remains, that where a total of methionine AND cysteine/cysteine is mandated, then specific levels of methionine and cysteine/cysteine are NOT mandated unless the methionine:cysteine/cystine ratio is greater than 2:1 (or unless suitability of formula demonstrated by clinically evaluation). In this latter situation the specific ratios can be set as cysteine & cystine 9mg and methionine 6mg. This might be expressed as follows:

Example 2 (Codex requirements rearranged)

L-amino acid	Minimum amount per 100kJ
Cysteine, cystine & methionine	15mg

OR, where methionine:cysteine & cystine ratio >2:1 (unless suitability of formula demonstrated by clinically evaluation)

Cysteine & cystine	9mg
Methionine	6mg.

One interpretation of the current Standard 2.9.1 expression encourages a higher methionine amount and a higher methionine:cysteine ratio – where cysteine is at the minimum of 6 mg/100kJ, methionine would need to make up the balance (13mg/100ml) whether naturally occurring or fortified, leading to a ratio 2:17. This is due to the higher combined total required by Standard 2.9.1.

The Codex STAN 72-1981 expressions would encourage levels and a ratio more closely in line with breast milk. The preference is a minimum of 9 mg/100kJ of cysteine and 6 mg/100kJ of methionine leading to a ratio close to 0.67 or where the footnote is applied. This could be a cysteine amount of 6 mg /100kJ and a methionine amount of 9 or 12 mg/100kJ and a ratio of 1.5 or 2 respectively, both of which are closer to breast milk than the FSANZ expression.

Achieving a cysteine amount of 9mg/100kJ is not feasible using some milk proteins within the range of total protein permitted. Hence, the inclusion of a combined total together with a ratio is important to allow for the range of products currently available on the market.

The additional note regarding clinical evaluation of suitability for formulas with methionine to cysteine ratios between 2:1 and 3:1 is also important. This approach ensures regulations applied do not inadvertently lead to compliance issues for formulas developed with lower protein contents more closely aligned to protein levels in breast milk that have been clinically demonstrated as suitable to support infant growth and development.

In addition the current Standard 2.9.1 expression creates a barrier to trade with other international markets, examples of which will be provided by individual member companies as Commercial-in-Confidence information.

2.5 FAT

2.5.1 FAT CONTENT

FSANZ proposes retain same min for total fat and lower max to align with Codex

Dairy Australia supports retaining the minimum and lowering the maximum to align with Codex STAN 72-1981 as proposed by FSANZ.

Units of expression

Units of expression should be expressed in terms of absolute values per 100 kJ of energy.

2.5.2 SOURCE OF FAT

FSANZ seeking feedback re current approach re setting criteria for fat composition and restricting harmful fatty acids (tfa) similar to Codex.

As a general principal the use of dairy fats should not be excluded through setting limits that do not allow for the natural content and variation of specific fatty acids naturally occurring in cow's milk unless the balance of evidence supports setting limits for infant populations. While there are notable differences in terms of fatty acid composition and triacylglyceride structure, evidence suggests bovine milk fats are most similar to human fats[16].

2.5.3 RESTRICTION ON CERTAIN FATS:

2.5.3.1 MYRISTIC ACID (C14:0) AND LAURIC ACIDS

Maintaining the current arrangements of no restrictions for myristic and lauric acids is supported by Dairy Australia.

FSANZ considers it appropriate to maintain no restriction on the levels of myristic and lauric acids in Standard 2.9.1. This is in line with recent expert opinion but inconsistent with Codex. Dairy Australia agrees and notes

[16] Zou X, Huang J, Jin Q, Guo Z, Liu Y, Cheong L et al. Lipid composition analysis of milk fats from different mammalian species: potential for use as human milk fat substitutes. J Agric Food Chem. 2013;61(29):7070-7080.

not having a restriction aligns with the most recent expert opinions and also provides for flexibility for industry.

Myristic and lauric acids are present in human milk and the content of the levels of these fatty acids in infant formula are comparable. Typical levels of myristric and lauric acid in bovine milk fat are 15% of total fat, however levels can vary with feed and breed.[17] The typical levels of myristric and lauric acid in infant formula range from 8-18% of total fat, however infant formula with levels as low as 0.9% have been reported.[18]

2.5.3.2 TRANS FATTY ACIDS

Dairy Australia does not agree with FSANZ 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.**

A 3% limit is not aligned with Codex. Dairy Australia suggests the issue of what an appropriate limit may be to accommodate the use of milk fats in infant formula **requires further consideration regarding the differences in definitions between Codex and FSANZ for trans fatty acids.**

On closer scrutiny Dairy Australia suggest that the FSANZ proposal does not align with Codex when the differences in Trans Fatty Acid definitions are accounted for.

The FSANZ definition of TFAs differs from Codex:

1. The Food Standards Code defines TFA as *All trans fatty acids*, whereas
2. 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, as the Food Standards Code definition includes a higher amount.

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.

Codex states that the TFA limit of 3% is to allow for milk fats.

"*The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant formulae*" (CODEX STAN 72 – 1981)

Limits should be applied for the use of commercially hydrogenated oils to limit industrially produced trans-fat. To set an appropriate limit for naturally occurring trans fatty acids in milk fat, a balance is required between infant specific fat utilization and metabolism[19] and the recognition given to the variability of TFA levels in cow's milk as a key constituent of infant formula. We acknowledging that global reductions in trans-fatty acids are targeted at industrially produced trans-fatty acids consumption[20] and not naturally occurring trans-fat from

[17] MacGibbon A, Taylor M. (2006) Composition and Structure of Bovine Milk Lipids in *Advanced Dairy Chemistry Volume 2, Lipids, 3rd Ed*, (P.F. Fox and P.L.H. McSweeney, eds.) Springer, New York, pp 1-43.
[18] Zunin P, Boggia R, Turrini F, Leardi R. Total and "free" lipids in commercial infant formulas: Fatty acid composition and their stability to oxidation. Food Chem. 2015;173:332-338.
[19] Tinoco SM, Sichieri R, Moura AS, Santos F S, Carmo M. The importance of essential fatty acids and the effect of trans fatty acids in human milk on fetal and neonatal development. Cad Saude Publica. 2007:23(3):525-34.
[20] European Commission (2015). Report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population. Available: http://ec.europa.eu/food/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf

cow's milk. We are also aware that reductions in maternal intake of industrially produced trans fatty acids is reflected in a reduction in trans fatty acids in breast milk, as opposed to elimination[21,22].

The trans-fatty acid content of cow's milk may vary from 1.29 to 7.31 % of total fat,[23] with up to 10% trans-fatty acid of total fat reported under certain feeding regimes.[24]

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.[25] Typical TFA values (measured as C18:1) in bovine milk fat, range from 1.29 to 7.31% of total fat.[26]

The TFA content of cows' milk may vary with feed, season and breed,[27,28] with up to 10% TFA of total fat reported under certain feeding regimes.[29] Pasture-fed cows have higher CLA levels.[30]

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%.[31] Thus CLA makes up about 22% of the FSANZ 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 for the Food Standards Code would take it out of alignment (to a value of 2.3% Codex definition equivalent TFA).

Note also that the NZ Codex opinion from 2004 which advocated for a higher TFA level in the Codex IF Std of 4% using the Codex TFA definition (CX/NFSDU 04/6-Add.1. Agenda Item 5b).

[21] Ratnayake W, Swist E, Zoka R, Gagnon C, Lillycrop W, Pantazapoulos P. Mandatory trans fat labeling regulations and nationwide product reformulations to reduce trans fatty acid content in foods contributed to lowered concentrations of trans fat in Canadian women's breast milk samples collected in 2009-2011. Am J Clin Nutr. 2014;100(4):1036-1040.
[22] Friesen R, Innis SM.Trans fatty acids in human milk in Canada declined with the introduction of trans fat food labeling. J Nutr. 2006;136(10):2558-61.
[23] Precht D & Molkentin J. Trans unsaturated fatty acids in bovine milk fat and dairy products. Eur J Lipid Sci Technol. 2000;102:635-639.
[24] Briard-Bion V, Juaneda P, Richoux R, Guichard E, Lopez C. Trans-C18:1 isomers in cheeses enriched in unsaturated fatty acids and manufactured with different milk fat globule sizes. J Agric Food Chem., 2008;56(20):9374-82.
[25] Larqué E, Zamora S and Gil A. Dietary trans fatty acids in early life: a review. Early Hum Dev. 2001;65(Supp 2):S31-41.
[26] Precht D & Molkentin J. Trans unsaturated fatty acids in bovine milk fat and dairy products. Eur J Lipid Sci Technol. 2000;102:635-639.
[27] Kliem KE, Shingfield KJ, Livingstone KM, Givens DI. Seasonal variation in the fatty acid composition of milk available at retail in the United Kingdom and implications for dietary intake. Food Chem. 2003;141:274–281.
[28] Månsson H. Fatty acids in bovine milk fat. Food Nutr Res. 2008;52:10.3402/fnr.v52i0.1821.
[29] Briard-Bion V, Juaneda P, Richoux R, Guichard E, Lopez C.Trans-C18:1 isomers in cheeses enriched in unsaturated fatty acids and manufactured with different milk fat globule sizes. J Agric Food Chem. 2008;56(20):9374-82.
[30] Kelly ML, Kover ES, Bauman DE, van Amburgh ME, Muller D. Effect of intake of pasture on concentrations of conjugated linoleic acid in milk of lactating cows. J Dairy Sci. 1998;81(6):1630-1636.
[31] MacGibbon A, Taylor M. (2006) Composition and Structure of Bovine Milk Lipids in Advanced Dairy Chemistry Volume 2, Lipids, 3rd Ed, (P.F. Fox and P.L.H. McSweeney, eds.) Springer, New York, pp 1-43.

2.5.3.3 PHOSPHOLIPIDS

Dairy Australia does not support the introduction of a restriction specific to 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.

Dairy Australia suggests that in the absence of specific safety concerns, evidence of adverse effects and absence of market failure in the absence of phospholipid limits, there is no clear justification to set an upper limit. From a risk based, cost benefit analysis, setting an upper limit will incur cost of compliance with no clear benefit.

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. Phospholipids are an important component of human milk. [32,33]

Phospholipids may be added as a source of long-chain polyunsaturated fatty acids"[34] and there are no known safety impacts at current levels.

> "*Phospholipids such as phosphatidyl choline have key functions in signal transduction affecting important cell functions. In milk and in the intestinal lumen phospholipids contribute to solubilizing lipophilic compounds. Phospholipids may also be added to infant formulae as a source of long-chain polyunsaturated fatty acid. A maximum concentration of 300 mg/100 kcal (equivalent to about 2 g/L) seems safe with respect to the potential range obtained of triglyceride/phospholipids ratios."*[35]

In infant formula there are two contributions to the phospholipid concentration;

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

Lecithin, commonly from soy, is added as a source of long-chain polyunsaturated fatty acids, to 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 or other vegetable lecithin are mostly composed of phosphatidylcholine. Bovine phospholipids naturally present in milk and milk ingredients, however are composed of sphingomyelin, PC, phosphatidylethanolamine, phosphatidylserine and phosphatidylinositol, similar to that of human milk.[36,37]

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[32] Koletzko B, Rodriguez-Palermo M, Demmelmair H, Fidler N, Jensen R, Sauerwald T. Physiological aspects of human milk lipids. Early Life Dev. 2001;65(Supp 2):S3-S18.
[33] Jensen RG. The lipids in human milk. Progress Lipid Res. 1996;35:53-92.
[34] Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group. Journal of Pediatric Gastroenterology and Nutrition. 2005;41(5):584-599.
[35] Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr. 2005;41(5):584-599.
[36] Jensen RG. Lipids of bovine and human milks: a comparison. J Dairy Sci. 1990;73(2):223-40.
[37] MacGibbon A, Taylor M (2006). Composition and Structure of Bovine Milk Lipids in Advanced Dairy Chemistry Volume 2, Lipids, 3rd Ed, (P.F. Fox and P.L.H. McSweeney, eds.) Springer, New York, pp 1-43.

Expert bodies have concluded that a maximum limit of 2g/L of phospholipids in infant formula is safe and justified;

- Current CODEX STAN 72-1981 maximum for phospholipids in infant formula is 72 mg /100kJ, 300 mg /100kcal which converts to approximately 1.5 g/100g powder or 2g/L of liquid made up formula (or 2000mg/L)

- 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 (2015). 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[38]

- In addition, in a recent review led by an expert panel coordinated by the Early Nutrition Academy[39] considered a higher recommendation for a phospholipids maximum of 3.5g/L for older infants in Codex STAN 156-1987 as 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.*"

Furthermore,

- The JECFA lecithin Acceptable Daily Intake was previously established as 'not limited for adult lecithin intake (FAO 1973)

- Phospholipid ingredients derived from egg yolk were Generally Recognised As Safe for use in term and per-term formula at levels up to 2g/L (GRN 000411).

If a limit on phospholipids must be specified, then alignment with Codex Standard and recent EU/ESPGHAN/ EFSA expert opinion in that a phospholipids limit of 2g/L would be the preferred option.

[38] Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN Coordinated International Expert Group. J Pediatr Gastroenterol Nutr. 2005;41(5):584-599.

[39] Koletzko B, Bhutta Z, Cai W, Cruchet S, Guindi M, Fuchs G et al. Compositional requirements of follow-up formula for use in Infancy: Recommendations of an international expert group coordinated by the Early Nutrition Academy. Ann Nutr Metab. 2013;62(1):44-54.

2.6 CARBOHYDRATE

Definitions and calculations relevant to carbohydrate

FSANZ proposes current definitions and calculations appropriate

2.6.1 INTRODUCTION OF MAXIMUM AND MINIMUM LEVEL

FSANZ proposes retain current not specifying maximum and minimum, as amount will be balance between fat and protein content to make up energy.

Dairy Australia agrees with the FSANZ proposal to retain the current approach by not specifying a minimum and maximum amount for carbohydrate for the same reasons identified as FSANZ.

The Dairy Australia position is to align with Codex STAN 72-1981.

Introduction of maximum and minimum level – FSANZ states that Standard 2.9.1 does not directly specify a minimum or maximum level of carbohydrate for infant formula as it is indirectly controlled by the provisions for protein, fat and energy content. Codex STAN 72-1981 lists a carbohydrate range of 2.2–3.3 g/100 kJ. FSANZ considers it appropriate to retain the current approach by not specifying a minimum and maximum amount for carbohydrate, noting this is in effect aligned with the Codex range.

2.6.2 CARBOHYDRATE SOURCE

FSANZ propose maintain current provisions with no mandatory restrictions on source due to lack of evidence.

Dairy Australia acknowledges the paucity of evidence in regards to carbohydrate source and health outcomes in infants <1 year of age and as such, **considers maintaining the current approach in Standard 2.9.1 reasonable**.

Carbohydrate evidence

While there are currently no specific safety concerns in regards to source of carbohydrate, lactose accounts for most of the dietary carbohydrate in human breast milk.[40] Accordingly Dairy Australia supports the use of lactose as the principal source of carbohydrate in infant formula.

When considering carbohydrate source it important to bear in mind that exposure to other significant sources of carbohydrate, other than lactose, may have nutritional implications. For example, well established is that taste preferences develop early in life, particularly in relation to carbohydrate, which may then influence food choices and potentially contribute to obesity.[41]

Like breast milk, the major source of carbohydrate in cow's milk is lactose[42] and similarly, this should remain as the predominant source of carbohydrate in infant formula, especially in light of its role in facilitating

[40] Stephen A, Alles M, de Graaf C, Fleith M, Hadjilucas E, Isaacs E et al. The role and requirements of digestible dietary carbohydrates in infants and toddlers. Eur J Clin Nutr. 2012;66(7):765-779.
[41] Mennella J. Ontogeny of taste preferences: basic biology and implications for health. Am J Clin Nutr. 2014;99(3):704S-711S.
[42] Stephen A, Alles M, de Graaf C, Fleith M, Hadjilucas E, Isaacs E et al. The role and requirements of digestible dietary carbohydrates in infants and toddlers. European Journal of Clinical Nutrition. 2012;66(7):765-779.

absorption of calcium.[43] Recent evidence has suggested additional benefits of lactose, where a typical infant formula containing lactose as the principal source of carbohydrate is unlikely to have negative effects on blood glucose levels or insulinaemic responses, and consequent developmental or programming effects.[44] It has been suggested that the effects of other carbohydrate types (for example, maltodextrins, corn syrup solids and sucrose) warrant further study, given infant formula can vary widely in carbohydrate composition and GI values.[45]

2.7 ENERGY

Energy Content

Dairy Australia supports FSANZ's proposal to reduce the maximum energy amount to align with that in Codex STAN 72-1981. This is supported by expert opinion.[46]

"The IEG proposes an energy density of infant formulae in the range of 60–70 kcal/100 ml, which is appropriate to support physiological rates of weight gain in healthy infants."[47]

And;

"3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy." (Codex STAN 72-1981)

Calculation of energy density

Dairy Australia supports FSANZ's proposal to maintain the application of energy factors for calculating the energy density of infant formula. The Food Standards Code's energy factors should continue to apply to infant formula including both energy factors for available and unavailable carbohydrate.

[43] Abrams SA, Griffin IJ, Davila PM. Calcium and zinc absorption from lactose-containing and lactose-free infant formulas. Am J Clin Nutr. 2002 Aug;76(2):442-6.
[44] Wright C, Atkinson F, Ramalingam N, Buyken A, Brand-Miller J. Effects of human milk and formula on postprandial glycaemia and insulinaemia. Eur J Clin Nutr. 2015;69(8):939-943.
[45] Wright CJ, Atkinson FS, Brand-Miller JC. Glycaemic and Insulinaemic responses to commercially available infant formulas. Australas Med J. 2010;3:865–876.
[46] Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN Coordinated International Expert Group. J Pediatr Gastroenterol Nutr. 2005;41(5):584-599.
[47] Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN Coordinated International Expert Group. J Pediatr Gastroenterol Nutr. 2005;41(5):584-599.

2.8 VITAMINS, MINERALS AND ELECTROLYTES

2.8.1 APPROACHES TO SETTING GUIDELINES OR MAXIMUM AMOUNTS

FSANZ propose to retain some MAX and move others to GUL to align with Codex. Folate, phosphorous and selenium require further information.

Unless there are sound scientific or technological justifications that suggest a different approach would be more appropriate Dairy Australia advocates that the following principles apply:

- **GUL where no NRV upper limit set as no safety concerns; and**
- **consistency with Codex where possible;**

Dairy Australia notes that, it does not make economic sense for a manufacturer to add more than required. A balance is required between technological and manufacturing constraints, known variability, ensuring end of shelf life content, a history of apparent safe use in infant formulas and the scientific justification to determine where an absolute maximum or a guideline upper limit is the most appropriate.[48]

2.9 OTHER OPTIONAL SUBSTANCES

2.9.1 CHOLINE

Dairy Australia agrees with FSANZ's preliminary view is that choline should be listed as a mandatory substance in infant formula with a minimum of 1.7 mg/100 kJ., **however are of the view that the upper limit of 12mg.100kj should be a GUL.**

2.9.2 L-CARNITINE

Dairy Australia is in agreement with FSANZ's view that L-carnitine should be mandatory and that a minimum content (conversion corrected) that is increased to 1.2 mg/100kcal (0.287 mg/100kJ) is appropriate. **However, there are significant concerns with the proposed maximum of 0.8 mg/100kJ,** particularly in combination with the proposed increased minimum. Subsequently it is recommended that no maximum be set for L-carnitine in infant formula at this time, that **a GUL would more appropriate**, and must account for the natural variation in L-carnitine content of milk.

2.9.3 INOSITOL

Dairy Australia supports the FSANZ preliminary view to mandate inclusion of inositol in infant formula at the current minimum level 1.0 mg/100 kJ. This would align with Codex STAN 72-1981.

An upper limit of 9.5 mg/100 kJ being set as a GUL in line with Codex STAN 72-1981 would be the most appropriate.

[48] MacLean Jr W. C. et al. Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. J Food Compost Anal. 2010;23:44-53.

2.9.4 NUCLEOTIDES

In regards to nucleotides, retention of combined totals in principle, **Dairy Australia is in agreement with the FSANZ preliminary view. However the combined total level needs to be determined. It is also important that the Code is clear on the limits applying only when nucleotides are added**

The key issue with drafting for the maximum amount is to ensure that the maximum applies only when nucleotides are added.

2.10 DEFINITIONS

Q1.2	2.2	Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula? (1) "satisfies by itself the nutritional requirements of infants less than 6 months of age" (2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding " (3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age (4) no change

The definitions in the revised Code, and set out below are adequate and Dairy Australia supports FSANZ view that these definitions be retained.

2.10.1 DEFINITION OF INFANT FORMULA PRODUCT

Dairy Australia is in agreement with FSANZ that the definition outlined below is sufficiently clear and does not require further amendments.

Food Standards Code revised definition:

*"**infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.".*

2.10.2 DEFINITION OF INFANT FORMULA

FSANZ reports apparent confusion around the age range of the infant formula and the follow-on formula product categories. Alternative definitions have been proposed by stakeholders for consideration with the view to provide clarity.

Dairy Australia supports retaining the current Food Standards Code definition as outlined below.

The current definition is:

*"**infant formula** means an infant formula product that:*

(a) is represented as a breast-milk substitute for infants; and

(b) satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months."

Dairy Australia considers that while there is an overlap between the 0-12 month range for infant formula and the 6-12 month follow-on formula range, changing the age range is unlikely to deliver a clear benefit.

Under the current standard there is a high degree of consistency between 6-12 month follow-on formula and infant formula. Composition varies only in a few key areas.

Should the situation change in light of future reviews of follow-on composition in Standard 2.9.1, any significant changes as an outcome would prompt a reconsideration of this issue.

The use of infant formula to 12 months is justified in a minority of cases, and should not be unavailable for these specific instances. For most infants, at around 6 months, a follow-on formula compositionally is more reflective of developmental needs, for example Iron requirements. Infant formula for 0-12 months does not preclude follow-on formula use for older infants 6-12 months depending on individual infant's needs. We believe the current standard reflects this.

The nutrient requirements of infants change as they develop. Breast milk composition changes dramatically over time and is no longer suitable as a sole source of nutrition by around 6 months of age. For those infants that cannot be breastfed or are not breastfed and subsequently are not accessing a food source that constantly changes to meet developmental needs, retaining the availability of follow-on products with a nutrient composition more closely aligned with the nutrient requirements of older infants from 6-12 months than infant formula is considered a reasonable solution.

2.11 SOY PROTEIN MINIMUM

Q1.3	3.1	Do you support a higher minimum of 0.5 g/100 kJ for infant formula based on isolated soy protein? Please provide your rationale?

On the basis that the Nitrogen conversion factor for soy (as outlined above in Q1.1) should be updated to reflect current evidence from 6.25 to 5.71, and the resulting need to increase the minimum level by 10%, the same limits as in Codex should be aligned with the requirements specified in Standard 2.9.1.

The current minimum (and maximum) for protein in infant formula, based on isolated soy protein, is the same for all product sources. The minimum is therefore 0.45 g/100 kJ (which must be corrected to 0.43 g/100 kJ, consistent with 1.8 g/100 kcal).

As FSANZ notes, there are no indications we are aware of, that soy-based formulas formulated under either the Codex Standard 72-1981 or Standard 2.9.1 are unable to meet nutritional needs to support normal growth and development. The provisions in Standard 2.9.1 have been in place for many years without evidence of issues related to protein source levels. However any change to Nitrogen conversion factors must be accounted for.

2.12 FATS

Q1.5	4.5	What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale

As a general principal the use of dairy fats should not be excluded through setting limits that do not allow for the natural content and variation of specific fatty acids naturally occurring in cow's milk unless the balance of evidence clearly supports setting limits for infant populations.

Lipid sources used in infant formula need to be carefully considered in order to optimise the health of the infant and in particular, research has shown the use of dairy fat is an important consideration when attempting to replicate certain structural properties of human breast milk and maximise health outcomes for infants. While there are notable differences in terms of fatty acid composition and triacylglyceride structure, evidence suggests bovine milk fats are most similar to human fats.[49,50] Human milk contains a number of bioactive compounds, including cerebrosides, glycerophospholipids, gangliosides and sphingolipids and similarly, bovine fats in infant formula also serve as an important delivery vehicle of these unique compounds[51]. This is in contrast to non-mammalian sources of lipids, which do not contain many of these components and are regarded as less complex.

The addition of bovine fat-derived ingredients to infant formula has been associated with positive physiological outcomes. In regards to neurological development, evidence has suggested that compounds

[49] Zou X, Huang J, Jin Q, Guo Z, Liu Y, Cheong L et al. Lipid composition analysis of milk fats from different mammalian species: Potential for use as human milk fat substitutes. J Agric Food Chem. 2013;61(29):7070-7080.
[50] MacGibbon AKH and Taylor MW (2006) Composition and structure of bovine milk lipids in Advanced Dairy Chemistry Volume 2, Lipids, 3rd Ed, (P.F. Fox and P.L.H. McSweeney, eds.) Springer, New York, pp 1-43
[51] Delplanque B, Gibson R, Koletzko B, Lapillonne A, Strandvik B. Lipid quality in infant nutrition: Current knowledhe and future opportunities. J Pediatr Gastroenterol Nutr. 2015;61(1):8-17.

beyond DHA found not only in breast milk, but also bovine milk are important to cognitive development. For example, in a small study, Gurnida *et al*. (2012) showed that consumption of infant formula supplemented with bovine milk-derived gangliosides increased serum gangliosides over infants who consumed unsupplemented formula.[52] In this study, measures of cognitive development (hand-eye co-ordination and IQ) were significantly higher than in infants consuming unsupplemented formula and importantly, were not significantly different from those of breast fed infants.

Other dairy fat-derived compounds may also have specific advantages to the development of the infant. In a randomised controlled trial, Timby *et al*. (2014) found a direct effect of milk-fat globule membrane (MFGM) enriched infant formula on the cognitive development of infants,[53] with similar findings reported by others.[54] While these findings are positive, there is a need for sufficiently powered, high quality randomised controlled trials further assessing the safety and efficacy of MFGM derived from dairy fats in infants.

The blend of fat sources in infant formula translates into compositional differences, including differences in proportions and structure of fatty acids, and consequent influences on physiological outcomes in infants. For example, palmitic acid is mainly esterified in *sn*-2 position of triglycerides in breast milk and dairy fat, but not in vegetable oils. Recent work suggests this structural difference to be of significant benefit to the infant, where those who consumed a sn-2 palmitate enriched (synthetically produced) formula, resulted in improvement in comfort outcomes, including softer stools.[55] While there are benefits in mimicking the properties of mammalian fat sources, a recent review article by Borlieu *et al*. (2015) proposed that the addition of cow's milk to a vegetable oil blend (as opposed to mimicking properties) may further optimise lipid quality of infant formula and achieve similar digestive outcomes to those in breast fed infants.[56]

As identified by Delplanque *et al*. (2015) significant research opportunities exist in this space.[57] There is a need to further assess the effects of various sources of fats in infant formula, particularly dairy fats. As earlier stated, evidence shows bovine milk fats are most similar to human fats and the current body of work suggests health benefits of dairy fats, or dairy fat derived ingredients to infants that are similar to that of breast fed infants. However, much is still unknown, including potential interactions of macronutrients and other bioactive components. Taken together, this should further support and stimulate innovation in regards to fat source and optimising infant nutrition.

[52] Gurnida D, Rowan A, Idjradinata P, Muchtadi D, Sekarwana N. Association of complex lipids containing gangliosides with cognitive development of 6-month-old infants. Early Hum Dev. 2012;88(8):595-601.
[53] Timby N, Domellof E, Hernell O, Lonnerdal B, Domellof M. Neurodevelopment, nutrition, and growth until 12 mo of age in infants fed a low-energy, low-protein formula supplemented with bovine milk fat globule membranes: a randomized controlled trial. Am J Clin Nutr. 2014;99(4):860-868.
[54] Billeaud, Puccio G, Saliba E, Guillois B, Vaysse C, Pecquet S et al. Safety and tolerance evaluation of milk fat globule membrane-enriched infant formulas: A randomized controlled multicenter non-inferiority trial in healthy term infants. Clin Med Insights Pediatr. 2014;8:51-60.
[55] Yao M, Lien E, Capeding M, Fitzgerald M, Ramanujam K, Yuhas R et al. Effects of term infant formulas containing high sn-2 palmitate with and without oligofructose on stool composition, stool characteristics, and bifidogenicity. J Pediatr Gastroenterol Nutr. 2014;59(4):440-448.
[56] Bourlieu C, Bouzerzour K, Ferret-Bernard S, Bourgot C, Chever S, Ménard O et al. Infant formula interface and fat source impact on neonatal digestion and gut microbiota. Eur J Lipid Sci Technol. 2015;117(10):1500-1512.
[57] Delplanque B, Gibson R, Koletzko B, Lapillonne A, Strandvik B. Lipid quality in infant nutrition: Current knowledhe and future opportunities. J Pediatr Gastroenterol Nutr. 2015;61(1):8-17.

For infants that cannot be breast fed, we understand that formulated products will never be able to replicate breast milk or the benefits breast milk delivers to both mother and child. However it is still important that policies, regulations and standards are supportive of innovation, research and ongoing development of infant formula ingredients (including fats) that collectively deliver improved health outcomes that lessen the gap between formula-fed infants and the benchmark of breast fed infants.

2.13 CARBOHYDRATE

Q1.8	5.3	What issues, if any, do you have with the current approach to regulation of the source of carbohydrate in infant formula? Please provide your rationale.

Dairy Australia acknowledges the paucity of evidence in regards to **carbohydrate source** and health outcomes in infants <1 year of age and as such, **agrees maintaining the current approach in Standard 2.9.1 is a reasonable approach.**

2.13.1 CARBOHYDRATE IN BREAST AND BOVINE MILK

Like breast milk, the major source of carbohydrate in cow's milk is lactose.[58] Similarly, lactose should remain as the predominant source of carbohydrate in infant formula. Especially in light of its role in facilitating absorption of calcium.[59] Recent evidence has suggested additional benefits of lactose, where a typical infant formula containing lactose as the principal source of carbohydrate is unlikely to have negative effects on blood glucose levels or insulinaemic responses, and consequent developmental or programming effects.[60] It has been suggested that the effects of other carbohydrate types (for example, maltodextrins, corn syrup solids and sucrose) warrant further study, given infant formula can vary widely in carbohydrate composition and GI values[61].

As with protein and lipids, carbohydrate composition of breast milk is also complex, and contains bioactive factors, including oligosaccharides. Human milk oligosaccharides act as prebiotics by supporting growth of beneficial bacteria in the colon[62] and attempts to replicate these benefits is currently an active area of research. Oligosaccharides are also present in bovine milk, although in comparison to human milk, are present in much lower concentrations. Their structure is however considered similar to those of human breast milk, although simpler in structure.[63] Research has demonstrated that this structural similarity may also lead to similar protective effects of human breast milk, however exact characterisation and quantification of bovine milk oligosaccharides is challenging due to lack of precise analytical techniques.[64] Given the complexities of bovine milk carbohydrates and compositional similarities with breast milk, this represents a worthy area for

[58] Stephen A, Alles M, de Graaf C, Fleith M, Hadjilucas E, Isaacs E et al. The role and requirements of digestible dietary carbohydrates in infants and toddlers. Eur J Clin Nutr. 2012;66(7):765-779.
[59] Abrams SA, Griffin IJ, Davila PM. Calcium and zinc absorption from lactose-containing and lactose-free infant formulas. Am J Clin Nutr. 2002;76(2):442-6.
[60] Wright C, Atkinson F, Ramalingam N, Buyken A, Brand-Miller J. Effects of human milk and formula on postprandial glycaemia and insulinaemia. Eur J Clin Nutr. 2015;69(8):939-943.
[61] Wright CJ, Atkinson FS, Brand-Miller JC. Glycaemic and insulinaemic responses to commercially available infant formulas. Australas Med J. 2010;3:865–876.
[62] Vandenplas Y, Zakharova I, Dmitrieva Y. Oligosaccharides in infant formula: more evidence to validate the role of prebiotics. Br J Nutr. 2015;113(09):1339-1344.
[63] Zivkovic ABarile D. Bovine Milk as a Source of functional oligosaccharides for improving human health. Adv Nutr. 2011;2(3):284-289
[64] Gopal P Gill H. Oligosaccharides and glycoconjugates in bovine milk and colostrum. Br J Nutr. 2000;84(S1).

future research and innovation. Further developments may maximise the health benefits of dairy sourced carbohydrates in infant formula, especially in light of a lack of evidence for other carbohydrate sources. As with the other nutrients, much is still unknown, especially in regards to potential interactions of components and health outcomes in infants.

It important to bear in mind that exposure to other significant sources of carbohydrate, other than lactose, may have nutritional implications. For example, well established is that taste preferences develop early in life, particularly in relation to carbohydrate, which may then influence food choices and potentially contribute to obesity.[65]

For infants that cannot be breast fed, we understand that formulated products will never be able to replicate breast milk and subsequently the benefits breast milk delivers to both mother and child. However it is still important that policies, regulations and standards are supportive of innovation, research and ongoing development of infant formula ingredients (including carbohydrate sources) that collectively deliver improved health outcomes that lessen the gap between formula-fed infants and the benchmark of breast fed infants.

2.14 FOLATE

Q1.9	7.2.1	Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.

Dairy Australia does not agree with FSANZ's preliminary view for folate expression.

We support the expression of folate content of infant formula as folic acid. This is aligned with the approach Codex has taken and is reflective of the fact that folic acid is the dominant form of folate in a fortified infant formula.

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. However, of note, neither Codex nor the Food Standards Code (including Standard 2.9.1) use dietary folate equivalents (DFE) to express the folate content of infant formula.

Even though the bioavailability of naturally occurring folate is difficult to determine, ideally the sum of naturally occurring folate and folic acid should be used. Expression as Dietary Folate Equivalents (DFE) is not appropriate at this time. There is significant variability and uncertainty related to the exact bioavailability in infants of natural milk folate forms.[66,67,68] 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. Subsequently, DFE should not be used to express folate content of infant formula.

[65] Mennella J. Ontogeny of taste preferences: basic biology and implications for health. Am J Clin Nutr. 2014;99(3):704S-711S.
[66] Sanderson P, McNulty H, Mastroiacovo P, McDowell I, Melse-Boonstra A, Finglas P et al. Folate bioavailability: UK Food Standards Agency workshop report. Br J Nutr. 2003;90(02):473.
[67] Suitor C, Bailey L. Dietary folate equivalents. J Am Diet Assoc. 2000;100(1):88-94.
[68] Ohrvik V, Witthoft C. Human folate bioavailability. Nutrients. 2011;3(12):475-490.

Test methodologies for folate versus folic acid are very difficult. While testing for total folic acid and folate remains the most appropriate approach, it is less challenging to quantify folic acid alone than to capture all folate forms, natural and added.[69]

There are differences between Codex (folic acid µg) and Standard 2.9.1 (folate µg) for how the minimum requirement of folate is expressed in infant formula. Standard 2.9.1 is expressed as folate (µg) which captures both naturally occurring folate and added folic acid in the amount of folate present in the infant formula.

Implementation of a minimum requirement that includes naturally occurring 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.[70]

MacLean *et al.* (2010)[71] mentions that up to 40% of the folate in the finished infant formula comes from the ingredients used to produce the infant formula and folic acid is added due to the losses of natural folates infant formula during manufacture and shelf life. Despite these losses, natural folates will still be present in the final product at varying amounts.

It would be ideal to measure both folic acid and naturally occurring folate. However, unfortunately the current tests for folate are not reliable. Further issues arise due to some of the naturally occurring folate potentially lost in manufacturing. Therefore it should be permissible to measure folic acid only.

Q1.10	7.2.1	If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied? Please provide a rationale in support of your view.

Dairy Australia does not support the application of folate being expressed as Dietary Folate Equivalents (DFE). Neither Codex nor the Food Standards Code uses DFE to express the folate content of infant formula. 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.

Except for the EU, there appear to be no other jurisdictions that use DFE to express the folate content of infant formula. It is also important to consider that the use of DFE by the EU does not appear to be support by a clear evidence base.

The *EFSA Scientific Opinion Paper on the essential composition of infant and follow-on formulae* (2014) references the 2014 *Scientific Opinion on Dietary References Values (DRV's) for* folate as the reason for moving to DFE's for infant formula. The 2014 DRV paper concludes the following for DFE:

> "The Panel notes that the DFE has been designed to take account of the fact that food folate has a lower bioavailability than folic acid added to foods or consumed as a supplement, although the evidence base for the figures used by IOM [Institute of Medicine, US] in the DFE definition is somewhat uncertain" (page 14)
>
> "The Panel also notes that the validity of the dietary folate equivalency definition has not been confirmed in studies" (page 14)

[69] Arcot J, Shrestha A. Folate: methods of analysis. Trends Food Sci Technol. 2005;16(6-7):253-266.
[70] Arcot J, Shrestha A. Folate: methods of analysis. Trends Food Sci Technol. 2005;16(6-7):253-266.
[71] MacLean W, Van Dael P, Clemens R, Davies J, Underwood E, O'Risky L, Rooney D, Schrijver J. Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. J Food Compost Anal. 2010;23(1):44–53.

"The Panel considers that two of three long-term investigations using whole diets indicate that the bioavailability of food folate relative to folic acid may be higher than previously assumed. However, the Panel also considers that results for folate bioavailability in these studies vary and that there is wide variation in estimates. "(page 14)

"The Panel considers that the difference in bioavailability between food folate and folic acid needs to be accounted for. In the absence of better data, the Panel agrees with the previous definition of the DFE" (page 14-15)

"The Panel suggests that studies to clarify the bioavailability of folic acid and natural food folates should be undertaken to improve the underlying database for the definition of the DFE" (page 38)

Though the EU does apply DFE, this does not seem to be supported by a sound evidence base. Based on the EFSA conclusions in this document it shows that there is limited evidence to support the use DFE and there is also conflicting evidence on the definition of DFE

2.15 IODINE

Q1.16	7.3.3.4	For Iodine, do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL? Please provide your rationale.

The iodine content in milk is highly variable.[72,73] As FSANZ outlined in their assessment, this was the reason that Standard 2.9.3 was amended in relation to iodine. **Similarly Dairy Australia supports a GUL for iodine**.

The minimum iodine amount in Standard 2.9.1 is 1.2 µg/100 kJ while Codex STAN 72-1981 is 2.5 µg/100 kJ which is more than double. Codex STAN 72-1981 lists a GUL of 14 µg/100 kJ while Standard 2.9.1 has a maximum of 10 µg/100 kJ. FSANZ concludes that a higher maximum of 14 µg/100 kJ would be unlikely to adversely pose a risk to infant health. FSANZ's label survey showed that the range of iodine content was 2.10–5.92 µg/100 kJ. 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.

Increased iodine levels in infant formula with values of 2.5-14ug/100kj aligned with Codex STAN 72-1981. A GUL is more appropriate than a maximum, given there is no UL established for iodine in infancy, and an absence of demonstrated safety concern.

Iodine plays a critical role in brain development. Since September 2009, iodised salt has been added to bread in Australia and New Zealand to address the re-emergence of iodine deficiency and widespread insufficiency. Since 2010, iodine supplementation of 150µg iodine/day has been recommended by the NHMRC and the New Zealand Ministry of Health for pregnant and breast feeding women to mitigate the risks associated with iodine deficiency in infants (NHMRC 2010).[74]

[72] Flachowsky G et al. Influencing factors on iodine content of cow milk. Eur J Nutr. 2014;53(2):351-65.
[73] MacLean Jr W C et al. Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised Codex infant formula standard. J Food Comp and Anal. 2010;23:44-53.
[74] National Health and Medical Research Council. (2010) Iodine Supplementation for Pregnant and Breastfeeding Women: Public statement, January 2010. Available: http://www.nhmrc.gov.au/guidelines-publications/new45

In light of the FSANZ comments that a proportion of younger infants would not achieve the iodine AI at the current minimum formula iodine levels, it is important this level is increased to align with the higher Codex minimum formula level to support achievement of the AI in infancy. It is important to recognise that an AI is the average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate. It is difficult to determine in this age group what would be the optimal level for most infants, and this may be higher than the AI.

We note that the Australian and New Zealand NRVs recommend an AI of iodine for infants of 90µg/day from 0-6 months old.[75] The EU iodine AI for infants is lower but significantly higher minimum iodine levels are mandated in the EU Infant Formula Standard Regulation 2016/127 at 3.6µg/100kj*.

The *EU AI for infants at 70µg/day was calculated simply on iodine breast milk levels. This approach is not appropriate in Australia and New Zealand where there is risk of insufficiently low iodine content of breast milk without maternal supplementation. As with other breastmilk nutrients, comparison with breast milk content is further confounded by the relationship between breast milk iodine concentration, breast milk volume produced and maternal fluid intake. Questions also arise as to how reliably the Iodine supply to the breast fed infant can be evaluated by urinary iodine concentration.[76]

2.16 CHOLINE

Q1.24	9.1	Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.

Dairy Australia agrees with FSANZ's preliminary view that choline should be listed as a mandatory substance in infant formula with a minimum of 1.7 mg/100 kJ., however are of the view that the upper limit of 12mg.100kj should be a GUL.

From a nutritional perspective, Choline is now classed as an essential nutrient in the Australia and New Zealand Nutrient Reference Values; with only AI's determined for infants.

The NHMRC & New Zealand Ministry of Health Nutrient Reference Values for Australia and New Zealand Choline recommendations for infants explain:

'The AI for 0-6 months was calculated by multiplying the average intake of breast milk (0.78 L/day) by the average concentration of choline in breast milk, and rounding. Breast milk from well-nourished mothers contains an average of 160 mg/L of choline delivered as choline, phosphocholine, glycerophosphocholine, phosphatidylcholine and sphingomyelin (Holmes-McNary et al 1996, Zeisel et al 1986). Infant formulas derived from soy or bovine milk contained significantly less phosphocholine than human milk. (Holmes-McNary et al 1996). The AI was thus set at 125 mg/day (160 mg/L x 0.78 L/day and rounded), or 18 mg/kg for the reference weight of 7 kg at this age.

[75] National Health and Medical Research Council (2014). Iodine. Available: https://www.nrv.gov.au/nutrients/iodine

[76] Andersen S, Møller M, Laurberg P. Iodine concentrations in milk and in urine during breastfeeding are differently affected by maternal fluid intake. Thyroid. 2014;24(4):764-772.

Although the free choline moiety is adequately provided by infant formulas and bovine milk, re-evaluation of the concentration of other choline esters, in particular glycerophosphocholine and phosphocholine, may be warranted.'

From a regulatory perspective, 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. Codex STAN 72-1981 lists the maximum as a GUL:

"f) Other Substances

Choline

Unit	Minimum	Maximum	GUL
mg/100 kcal	7	--	50
mg/100 kJ	1.7	--	12 "

Choline is an essential nutrient and an increased maximum is supported on the basis that, only at mid-point levels of the new range are AIs met. However the upper level is proposed as a maximum rather than a GUL based on a recent review publication by Tang and Hazen (2014)[77] which identifies a potential role of choline in CVD in the presence of certain gut microbiota. The new evidence has not been demonstrated in infants or children. The only source of choline for this age group would be breast milk or infant formula thus it is important that sufficient is provided, whilst allowing for natural variation and manufacturing capability. Our preliminary view would be the relevance of the new evidence to infants has not been determined hence it would be more appropriate to maintain consistency that in the absence of a UL, a GUL should be set.

Q1.25	9.1	What is the technological justification can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?

As noted above, FSANZ recognises that choline is an essential nutrient. While the forms choline citrate and/or choline hydrogen tartrate may be rarely used, they may be in the future and contribute to the provision of an essential nutrient. **The forms are demonstrated as safe** and Standard 2.9.1 should therefore include the forms: choline citrate and/or choline hydrogen tartrate.

[77] Tang W, Hazen S. The contributory role of gut microbiota in cardiovascular disease. J Clin Invest. 2014;124(10):4204-4211.

2.17 L-CARNITINE

Q1.27	9.2	Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.

Dairy Australia is in agreement with FSANZ's view that L-carnitine should be mandatory and that a minimum content (conversion corrected) that is increased to 1.2 mg/100kcal (0.287 mg/100kJ) is appropriate. However, there are significant concerns with the proposed maximum of 0.8 mg/100kJ, particularly in combination with the proposed increased minimum. **Subsequently it is recommended that no maximum be set** for L-carnitine in infant formula at this time, that **a GUL would more appropriate, and must account for the natural variation in L-carnitine content of milk.**

The proposed maximum is problematic, being too low to take into consideration the variable contribution of naturally occurring L-carnitine from cows' or goats' milk (especially the latter), the manufacturing issues nor the analytical measurement. A barrier to trade would emerge with the proposed maximum being out of step with trading partners.

The potential extension of this proposed maximum of L-carnitine to follow-on formula is of further concern. Though, follow-on formula is out of scope of Proposal P1028, there is currently no distinction between infant formula and follow-on formula requirements for L-carnitine. Again the proposed maximum would present as a great concern to follow-on formula due to the same issues with the naturally occurring levels of L-carnitine in milk.

L-carnitine is considered an indispensable nutrient for new-born infants because of a short term insufficient synthesising capacity. In studies investigating L-carnitine concentrations in milk from different species, mean total carnitine concentrations have been reported to be in the range 0.9-1.6 mg/100 kcal in human milk. [78,79,80] Expert recommendations for a minimum are in line with the upper range at 1.2 mg/100 kcal.[81,82] On this basis Dairy Australia supports FSANZ view that L-carnitine should be mandatory and that a minimum content (conversion corrected) of 0.29mg/100 kJ (1.2 mg/100 kcal) is appropriate.

[78] Sandor A, Pecsuvac K, Kerner J, Alkonyi I. On carnitine content of the human breast milk. Pediatr Res. 1982;16(2):89-91.
[79] Penn D, Dolderer M, Schmidt-Sommerfeld E. Carnitine concentrations in the milk of different species and infant formulas. Neonatology. 1987;52(2):70-79.
[80] Ferreira I. Quantification of non-protein nitrogen components of infant formulae and follow-up milks: comparison with cows' and human milk. Br J Nutr. 2003;90(01):127.
[81] Life Services Research Office (LSRO), American Societies for Nutritional Sciences. Assessment of nutrient requirements for infant formulas. J Nutr. 1998;128(11S):2059S-2294S.
[82] Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN Coordinated International Expert Group. J Pediatr Gastroenterol Nutr. 2005;41(5):584-599.

In studies investigating L-carnitine concentrations in milk from different species, mean total carnitine concentrations have been reported to be in the range:

- 0.9-1.6 mg/100 kcal in human milk [83,84,85]
- 4.1-6.7 mg/100 kcal in cows' milk [86,87,88] and
- 3.2-4.4 mg/100 kcal in goats' milk [89,90]

Expert recommendations for a minimum are in line with the upper range at 1.2 mg/100kcal. [91,92]

There are concerns with the proposed maximum of 0.8 mg/100 kJ. We are aware that the basis of setting the maximum at 0.8 mg/100kJ dates back to LSRO 1998 which gave a recommended range as observed in breast milk. This range was increased (0.21 – 0.8 mg/100kJ) to accommodate the typical contribution found in cows' milk infant formula at that time. Neither the SCF Opinion (2003)[93] nor the EFSA Opinion (2014)[94] considered the maximum. In the absence of indications of any untoward effects of higher L-carnitine intakes in infants, the ESPGHAN[95] concluded that no maximum level needed to be set. Codex STAN 72-1981 does not set a maximum nor does the EU. The NRVs for Australia and New Zealand also do not refer to a UL.

[83] Sandor A, Pecsuvac K, Kerner J, Alkonyi I. On carnitine content of the human breast milk. Pediatr Res. 1982;16(2):89-91.
[84] Penn D, Dolderer M, Schmidt-Sommerfeld E. Carnitine concentrations in the milk of different species and infant formulas. Neonatology. 1987;52(2):70-79.
[85] Ferreira I. Quantification of non-protein nitrogen components of infant formulae and follow-up milks: comparison with cows' and human milk. Br J Nutr. 2003;90(01):127.
[86] Sandor A, Pecsuvac K, Kerner J, Alkonyi I. On carnitine content of the human breast milk. Pediatr Res. 1982;16(2):89-91.
[87] Penn D, Dolderer M, Schmidt-Sommerfeld E. Carnitine concentrations in the milk of different species and infant formulas. Neonatology. 1987;52(2):70-79.
[88] Ferreira I. Quantification of non-protein nitrogen components of infant formulae and follow-up milks: comparison with cows' and human milk. Br J Nutr. 2003;90(01):127.
[89] Sandor A, Pecsuvac K, Kerner J, Alkonyi I. On carnitine content of the human breast milk. Pediatr Res. 1982;16(2):89-91.
[90] Penn D, Dolderer M, Schmidt-Sommerfeld E. Carnitine concentrations in the milk of different species and infant formulas. Neonatology. 1987;52(2):70-79.
[91] Life Services Research Office (LSRO), American Societies for Nutritional Sciences. Assessment of nutrient requirements for infant formulas. J Nutr. 1998;128(11S):2059S-2294S.
[92] Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN Coordinated International Expert Group. J Pediatr Gastroenterol Nutr. 2005;41(5):584-599.
[93] Scientific Committee on Food (2003). Report of the Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae. (SCF/CS/NUT/IF/65 Final. 2003). Brussels: European Commission.
[94] EFSA. Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal.2014;12(7):3760.
[95]Koletzko B, Baker S, Cleghorn G, Neto U, Gopalan S, Hernell O et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN Coordinated International Expert Group. J Pediatr Gastroenterol Nutr. 2005;41(5):584-599.

FSANZ has indicated the need for a maximum upper level based on a single, recent review publication by Koeth *et al.* (2013)[96] which identifies a potential role of L-carnitine in CVD in the presence of certain gut microbiota. The new evidence has not been demonstrated in infants or children where the only source of L-carnitine for this age group would be breast milk or infant formula. It is important that sufficient L-carnitine is provided, however consideration must be given for natural variation in ingredients and manufacturing capability.

The revised tolerance does not take into consideration the variable contribution of L-carnitine from cow or goat milk. Wollard, Indyk, Wollard (1999)[97] analysed the L-carnitine in a range of infant formula products. The survey indicated a range of values from 6.9-30.1 mg/100g. Assuming an example reconstitution ratio of 13.0g of powder/100ml formula and an energy value of 280 kJ/100ml the upper figure of the range would be equivalent to 1.4 mg L-carnitine /100 kJ.

Our preliminary view would be that the relevance to infants of the new data presented by Koeth *et al.* (2013)[98] is not known and basing an upper limit on one paper would not generally be appropriate. We suggest that this in an area that requires further research. It would be more appropriate to maintain consistency that in the absence of a UL, no maximum should be set, and a GUL should be applied.

Q1.28 What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?

The nutritional justification for L-carnitine has been confirmed. Both L-carnitine hydrochloride and L-carnitine tartrate are safe to use as evidenced by their **inclusion in Codex STAN 72-1981**. While the forms L-carnitine hydrochloride and L-carnitine tartrate may be rarely used, they may be in the future and contribute to the provision of an essential nutrient. The forms are safe and Standard 2.9.1 should therefore include the forms: L-carnitine hydrochloride and L-carnitine tartrate.

Q1.29 If you have provided a technological justification for these forms what evidence to demonstrate safety can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?

As noted above, nutritional justification for L-carnitine has been confirmed and both L-carnitine hydrochloride and L-carnitine tartrate are safe to use as evidenced by **their inclusion in Codex STAN 72-1981**.

[96] Koeth R, Wang Z, Levison B, Buffa J, Org E, Sheehy B et al. Intestinal microbiota metabolism of l-carnitine, a nutrient in red meat, promotes atherosclerosis. Nat Med. 2013;19(5):576-585.
[97] Woollard D, Indyk H, Woollard G. Carnitine in milk: a survey of content, distribution and temporal variation. Food Chem. 1999;66(1):121-127.
[98] Koeth R, Wang Z, Levison B, Buffa J, Org E, Sheehy B et al. Intestinal microbiota metabolism of l-carnitine, a nutrient in red meat, promotes atherosclerosis. Nat Med. 2013;19(5):576-585.

2.18 INOSITOL

Q1.30	9.3	Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.

Dairy Australia supports the FSANZ preliminary view to mandate inclusion of inositol in infant formula at the current minimum level 1.0 mg/100 kJ.

It is agreed as 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.

FSANZ also states that Standard 2.9.1 and Codex STAN 72-1981 permit the same range 1.0-9.5 mg/100 kJ, 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.

Q1.31	9.3	Do you supporting listing the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex?

As above, this would align a conditionally essential nutrient for infants and would align with Codex STAN 72-1981.

An upper limit of 9.5 mg/100 kJ being set as a GUL in line with Codex STAN 72-1981 would be the most appropriate.

2.19 NUCLEOTIDES

Q1.32	9.4	Are there any issues with the clarity of the drafting for the maximum amount of nucleotides in the revised Code?

In regards to Nucleotides, **retention of combined totals in principle is supported in agreement with the FSANZ preliminary view. However the combined total level needs to be determined**. It is also important that the Code is clear on the limits applying only when nucleotides are added.

The key issue with FSC **drafting for the maximum amount**, is to **ensure that the maximum applies only when nucleotides are added.**

Standard 2.9.1 permits the optional addition of five specific nucleotides to infant formula, and outlines a minimum and maximum for each of the permitted nucleotides. It also states that “infant formula product must contain no more than 3.8 mg/100 kJ of nucleotide 5’-monophosphates”. Codex STAN 72-1981 permits the addition of nucleotides at the discretion of national authorities. Dairy Australia notes that Codex does not prescribe a maximum or minimum for nucleotides.

The continued inclusion of nucleotides as optional ingredients is supported. It is considered that the revised Code is clear that for each nucleotide added, then the individual maximum is the total of that nucleotide, including any naturally-occurring amount. It is recognised that other aspects, such as labelling, may not be clear.

Australia and New Zealand are currently out of step globally, by setting a minimum for nucleotides. No minimums are set by the US, Canada or the EU. We note also that there are no minimum or maximum set in 21 CFR 107 Infant Formula or in the Canadian FDR Infant Formula. While a minimum might have been based on the need to be above the innate level, this does not seem to be sufficient justification for mandating a minimum.

3 SUPPORTING DOCUMENT 2: SAFETY AND FOOD TECHNOLOGY

3.1 FSANZ PRELIMINARY VIEW SAFETY AND FOOD TECHNOLOGY

No.	Section of the SD	Question
Q2.1	All	For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

3.1.1 OTHER SAFE PREPARATION AND STORAGE ISSUES

3.1.1.1 MEASURING SCOOP

FSANZ seeking evidence that benefits outweigh costs for change is required

Dairy Australia supports the continued use of the statement that only the enclosed scoop in the can should be used for preparing the powdered infant formula contained in the can. There is **no evidence that we are aware of**, that any extension of the statement **would deliver benefits that outweigh costs**. As such an extension is not supported.

Standardisation of measuring scoops would raise unintended issues for the reasons FSANZ has identified, most particularly because infant formula powder bulk density varies across brands and ranges for a number of reasons including processing technology, composition and other physical attributes.

3.1.2 WARNING ADVISORY AND OTHER STATEMENTS

Legibility requirements for warning statements

Neither FSANZ nor Dairy Australia has identified any evidence, to indicate that the current requirements for infant formula requirements are inadequate.

Dairy Australia supports maintaining the current legibility requirements for infant formula.

3.1.3 STATEMENT OF PROTEIN SOURCE

Dairy Australia supports maintaining the current requirements regarding labelling statements of the specific source, or sources, of protein in the product, on the basis we are not aware of any evidence of issues with current labelling practices and the influence on ability to make informed choice regarding protein source.

3.1.4 CO-LOCATION OF PROTEIN SOURCE STATEMENT WITH THE NAME OF THE FOOD

Dairy Australia suggests maintaining the current mandatory statement about protein source and for it to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula') is more than adequate.

We are not aware of any evidence there is an issue with current requirements, subsequently it would be unlikely that a requirement for consistent placement would deliver benefits that outweigh the costs.

Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. All prescribed label changes require a packaging change which involves revised artwork and cost. Subsequently Dairy Australia does not support mandated changes in the absence of clear evidence that the benefits outweigh the costs.

3.1.5 WARNING STATEMENT ABOUT FOLLOWING INSTRUCTIONS EXACTLY

Dairy Australia fully supports the current requirements prescribing the wording in regards to following the instructions exactly to ensure the correct preparation of the powdered, concentrated, or 'ready-to-drink' formula.

3.1.6 WARNING STATEMENT THAT 'BREAST IS BEST'

Dairy Australia fully supports current requirement that the infant formula label contain the prescribed warning statement: 'Breast milk is best for babies' and 'Before you decide to use this product, consult your doctor or health worker for advice'.

Dairy Australia recognises that:

- Breast feeding is by far the best way to feed infants, and believes this is an important message to reinforce.
- Consultation with doctors and health workers enables appropriate medical advice on risks and considerations for the specific infant and infant/caregiver circumstances regarding the decision to either partially or completely use infant formula instead of breast feeding. Subsequently messages should encourage caregivers to seek appropriately qualified medical/health advice.

3.1.7 STATEMENT THAT INFANT FORMULA PRODUCT MAY BE USED FROM BIRTH

Dairy Australia supports the current requirement for a statement indicating that infant formula may be used from birth. When an infant does not receive breast milk, the only suitable and safe alternative is an infant formula that has been formulated to meet safety and nutritional suitability requirements consistent with current evidence.

3.1.8 STATEMENT ABOUT AGE TO OFFER FOODS IN ADDITION TO FORMULA

The current requirement for a statement on infant formula labels indicating that infants over the age of around 6 months should be offered foods in addition to the infant formula **is consistent with current Australian and New Zealand infant feeding guidance. On this basis Dairy Australia supports the current requirements.**

3.2 NUTRITIVE SUBSTANCES AND NOVEL FOODS IN INFANT FORMULA

With respect to the appropriate regulatory mechanism for considering the pre-market assessment of substances for use in infant formula, Dairy Australia would strongly encourage that Standard 2.9.1 be included in the scope of P1024. We do not support the need for having a different approach for infant formula products than any other food type.

In our response to P1024, Dairy Australia commented that "In principle, Dairy Australia is supportive of option 3 (introducing a risk-based regime with industry self-assessment pathways)". As noted in our earlier comments, however, there are elements of the Proposal that require further work before full support can be given.

3.3 CARRY-OVER PRINCIPLE FOR FOOD ADDITIVES AND INFANT FORMULA

Dairy Australia strongly supports the continuation of the carry-over principle for food additives to infant formula as has been the interpretation generally applied to date. To do otherwise would place all infant formula supplies for Australia and New Zealand in jeopardy and create significant trade barriers.

3.4 PROTEIN SOURCE INFORMATION

Q2.5	5.4	What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice?

Dairy Australia supports maintaining the requirement that the infant formula label contain a statement of the specific source, or sources, of protein in the product. This is important information to help consumers make an informed choice, however we are not aware of any evidence of issues with current labelling practices and the influence on ability to make informed choice regarding protein source.

Protein quality and quantity are regulated in the Food Standards Code for health and safety reasons. Subsequently **mandating a list of permitted protein sources for declaration on the label is not required, and therefore not supported.**

Q2.6	5.4	What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?
Q2.7	5.4	If so, should there be a requirement to prescribe the position of the statement of protein source on the label e.g. on the front of the package?

Dairy Australia suggests maintaining the mandatory statement about protein source and for it to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula') is more than adequate**. Dairy Australia does not support prescribing the position of the statement of protein source** on the label in the absence of strong evidence that the position of such a statement is a major concern for caregivers.

We are not aware of any evidence there is an issue with current requirements, subsequently it would be unlikely that a requirement for consistent placement would deliver benefits that outweigh the costs.

This does not point to a need to prescribing where the prescribed name (and by association, the protein source statement) should be located on the label.

3.5 TRADE AND COST IMPLICATIONS OF MANDATED ADVICE

Q2.8	5.4	What are the cost and trade implications of prescribing the position of the statement of protein source ion the label?

Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. **All prescribed label changes require a packaging change which involves revised artwork and cost.**

In terms of trade impacts, **such a requirement would be inconsistent with other jurisdictions and would effectively present as a non-technical barrier to trade**. This would decrease the likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply of product to a vulnerable population group. Product labels are not the only means of communicating information to consumers, and consideration should be given to other options ahead of mandating labelling requirements for information that is not deemed to convey vital food safety information.

Infant formula is most often packaged in high value printed metal cans which are only made by a very limited number of suppliers in Australia. Label changes involve a significant lead time to prepare new artwork, and then coordinate with supplier production schedules in order to have new packaging available for use.

Q2.13	5.9	What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?

Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. **All prescribed label changes require a packaging change which involves revised artwork and cost.**

In terms of trade impacts, **such a requirement would be inconsistent with other jurisdictions and would effectively present as a non-technical barrier to trade**. This would decrease the likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply of product to a vulnerable population group. Product labels are not the only means of communicating information to consumers, and consideration should be given to other options ahead of mandating labelling requirements for information that is not deemed to convey vital food safety information.

Infant formula is most often packaged in high value printed metal cans which are only made by a very limited number of suppliers in Australia. Label changes involve a significant lead time to prepare new artwork, and then coordinate with supplier production schedules in order to have new packaging available for use.

3.6 SUBSTANCES REQUIRING PREMARKET ASSESSMENT

Q2.14	6	Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

With respect to the appropriate regulatory mechanism for considering the pre-market assessment of substances for use in infant formula, **Dairy Australia would strongly encourage that Standard 2.9.1 be included in the scope of P1024. We do not support the need for having a different approach for infant formula products than any other food type.**

In our response to P1024, Dairy Australia commented that "In principle, Dairy Australia is supportive of option 3 (introducing a risk-based regime with industry self-assessment pathways)". As noted in our earlier comments, however, there are elements of the Proposal that require further work before full support can be given.

Success in realising benefits over cost will depend on whether new regulations can be revised to provide:

- clarity regarding conformance with the Eligible Foods pathway,
- Suitable gateway criteria for each level
- protection of IP under the industry self-assessment pathway,
- clarity over the evidence required to support these assessments, and
- scope of recognition of other jurisdiction assessments/decisions

The supporting documentation of P1024 discusses issues around the existing regulatory context covering nutritive substances and novel foods for the general food supply, which apply equally to the situation for products being considered in P1028. It will be important as for other targeted food groups that assessment pathways for substances for use in infant formula products give the necessary consideration to the specifics as they pertain to the particular target population who will consume the products.

A consistent approach to the regulation of new substances for all foods, including infant formula, will allow for greater clarity for manufacturers and therefore encourage innovation within a common structure. This consistent approach should be structured so as to take into consideration the specific needs of infant formula, breast milk as the benchmark and other foods with specific consumer targets.

Dairy Australia therefore encourages that future work on Proposal P1028 not include consideration of nutritive substances and novel foods and that this work transfer, and come within an amended scope of Proposal P1024.

As commented earlier, and in the Dairy Australia submission to P1024, a reworked version of Option 3 should apply to Standard 2.9.1 and as such would provide support to all substances for use in infant formula being required to undergo pre-market consideration, some of which would also require a pre-market assessment.

In considering P1024 and P1028 in parallel, Dairy Australia is of the view that, all substances for use in infant formula require pre-market assessment but not all pre-market assessments need to be undertaken by FSANZ. Dairy Australia notes that The Eligible Food Criteria pathway and Pre-Market Self-Assessment with notification pathway in the proposed P1024 framework also constitute pre-market safety assessments.

Consistent with the Dairy Australia P1024 submission, of note for consideration by FSANZ:

- This position is consistent with the Ministerial Policy Guidelines, which require pre-market assessments for all IF ingredients.
- The basis for comparisons should be with existing dairy ingredients that may also be used in infant formula, not just milk.
- The proposed system should account for different addition rates of ingredients: 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 with a long history of consumption.
- The 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.

Q2.15	6	What would be the cost and trade implications of your preferred position?

Dairy Australia considers, this, would in many areas be a continuation of current arrangements (e.g. in relation to novel foods which would continue to require pre market assessment) but would also address the problems and issues identified by FSANZ in Proposal P1024. This approach would close gaps but would do so at more reasonable costs.

Dairy Australia's preferred position is to support a framework where costs are proportional to benefits and risks, subsequently supporting innovation. Costs in proportion to benefit and risk, are difficult to quantify. This is due to the broad continuum of associated costs of developing ingredients and the broad spectrum of level of risk associated with bringing novelty to market.

In the Dairy Australia submission to P1024 some indicative costs associated with putting a novel food/substance through a premarket assessment were described:

"Launching a Novel Food is a very expensive exercise and is not easy to achieve, no matter whether it is a paid application or not. Benefits must significantly outweigh costs of development and bringing a product to market.

Examples, but not limited to, expenses related to pre-market assessment can include.

- *Literature searches and preparation of submission - $50,000*
- *Trials to support safety and suitability – a minimum of $100,000 each. (It is also becoming more difficult and therefore more expensive to find someone who is prepared to carry out the trials). Complex trials have been quoted at upwards of $1mill.*
- *Application to FSANZ $25,000 - $150,000*

Cost and trade implications can be minimised where a framework recognises/translates the assessments/decisions of other jurisdictions, including Asian jurisdictions such as Japan.

- Recognition of assessments undertaken overseas would address costs and trade implications to the greatest extent possible while still meeting Australia and New Zealand's legal and sovereignty concerns. It is therefore strongly encouraged that consideration be given to existing assessments where there are available and relevant to the Australia and New Zealand context.

A risk based stepped approach that includes a 'self-assessment pathway' for lower risk novelty, particularly those derived from foods/ingredients already with long term consumption. This again is supportive of minimising cost and trade implications, whilst still ensuring safety in keeping with Australia and New Zealand's standards

The approach being proposed in P1028 for infant formula would essentially require the same pathway that currently exists as a minimum, with the addition of information specific to the targeted consumer group. The costs are potentially prohibitive unless a clear market benefit is identified. However this is made more difficult to capitalise on, given restrictions of promotion which apply to products in this category.

Q2.16	6	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?

As per our response Question Q2.15 above. As described in Proposal P1024, **Dairy Australia proposed that, with appropriate differentiation, the framework described for Option3 (although it required further development) should be applied to Standard 2.9.1**. Dairy Australia therefore supports all substances for use in infant formula requiring pre-market consideration but not all requiring pre-market assessment undertaken by FSANZ

Q2.17	6	If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

This would be best addressed **through inclusion of substances for use in infant formula in P1024**, where by any definitions or characterisations are developed to apply with consistent risk based principles across all novel foods/ingredients including those for use in infant formula.

3.7 CARRY-OVER PRINCIPLE FOR FOOD ADDITIVES AND INFANT FORMULA

Q2.31	8.3	Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.

Dairy Australia strongly supports the continuation of the application of carry-over principle for food additives to infant formula. To date this has been the interpretation applied. To not continue to do so, would place infant formula supplies for Australia and New Zealand in jeopardy whilst creating significant trade barriers**.**

We recognise that FSANZ sees there has been confusion about how the carry-over principle in the Code operates for infant formula. With the objective of clarity, and consistency with the Codex approach, FSANZ proposes that the carry-over principle for food additives should not apply to infant formula. However the following points should be considered

- Codex STAN 72-1981 Section 4 Food Additives outlines food additives as listed in this Section, or in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* CAC/ GL 10-1979, may be present in infant formula products, as a result of carry-over from raw material or ingredient.

- This indicates that Codex does allow for carry-over of food additives into infant formula and on this basis the food additive carry-over principle should continue to apply to infant formula in the FSANZ standard (the status quo)

- This position is also consistent with alignment with Codex in relation to permitted carry-over additives as noted in our 2012 submission on this issue, that is, permission for all food additives outlined in Codex STAN 72-1981 Section 4, as well as CAC/GL 10-1979, that may be intentionally added or carried over into infant formula are supported.

- 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.

4 SUPPORTING DOCUMENT 3: PROVISION OF INFORMATION

4.1 PROVISION OF INFORMATION

Dairy Australia sees that there is currently regulatory clarity provided by Nutrition, Health and Related Claims Standard 1.2.7 regarding ingredient and health claims for infant formula.

4.1.1 CLAIMS ABOUT INGREDIENTS

For infants that cannot be breast fed, we understand that formulated products will never be able to replicate breast milk or subsequently the benefits breast milk delivers to both mother and child. However it is still important that the message that 'breast milk' is the best source of nutrition is both reinforced and balanced through policies, regulations and standards that are supportive of innovation, research and ongoing development of infant formula ingredients that collectively deliver improved health outcomes that lessen the gap between formula-fed infants and the benchmark of breast fed infants or address specific infant nutritional concerns such as allergies and intolerances.

Dairy Australia suggests that an evidence based assessment, including cost benefit analysis be undertaken in regards to permissions for content claims in infant formula, and this be used to inform development of the best regulatory options.

Innovation cannot be supported if there is no way for caregivers and health professionals to differentiate between available formulas to recognise those that provide basic adequate nutrition from those that provide a lesser gap in nutrition and health outcomes against the bench mark of breast milk.

The ability to make ingredient related content claims would provide minimal factual information to caregivers and health care professionals to enable a level of differentiation between products on the market.

4.1.2 DECLARATION OF PERMITTED NUTRITIVE SUBSTANCES

Dairy Australia recognises not all infant formulas are the same. Inadequate information on labelling could lead to misleading of consumers about the quality and effectiveness of an infant formula (e.g. 'home made' infant formulas being preferred to infant formula produced in compliance with regulatory standards).

There are a number of permitted optional ingredients/nutritive substances that can be added (e.g. probiotics, prebiotics, lutein, omega LCPUFAs DHA/AA). There are a variety of different sources of macronutrients that can be utilised to enhance the nutritional profile from the base mandated adequate nutritional requirements and/or meet the particular nutritional needs of specific infant circumstances. For example, whey protein concentrates and isolates to create a whey dominant protein composition.

4.1.3 NUTRITION DECLARATION REQUIREMENTS

Dairy Australia is aware that health care professionals may at times recommend infant formulas based on specific nutrient content, for example whey dominant infant formulas. Macronutrient subgroups contribute to the overall information on pack available to health professionals to make an informed recommendation and consumers and informed choice of product.

Dairy Australia interprets that Standard 2.9.1 already includes permissions to declare factual nutritional information about macronutrient subgroups.

Our interpretation leads to a conclusion that there is no explicit prohibition of sub-group(s) of a macronutrient in a nutrition information statement for infant formula. To avoid ambiguity, regulatory clarity and the inclusion of expressed permissions in Standard 2.9.1 to declare nutrition information about macronutrient subgroups in the nutrition information statement is suggested.

Dairy Australia supports flexibility in the inclusion of macronutrient subgroups. It is important and should be included in the nutrition information statement to help caregivers and health care professionals differentiate between different infant formulas

Dairy Australia suggests that if macronutrient subgroups are declared, then the levels of those macronutrient subgroups should also be declared in order not to be misleading. In such circumstances the average quantity should be met.

The overarching principle would be supportive of product differentiation and subsequently innovation that reduces the gap of infant formulas more broadly with the bench mark of breast milk regarding nutrition and health outcomes.

4.1.4 INTER-RELATIONSHIP BETWEEN DECLARATIONS IN THE NUTRITION INFORMATION STATEMENT AND THE INGREDIENTS LIST

Dairy Australia is not aware of any evidence that indicates caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations. It would be helpful in considering this issue to recognise that that ingredients lists and nutrient lists are fundamentally different. **Dairy Australia is not in support of aligning the names of ingredients with nutrient declarations in the nutrition information statement**. The information serves different purposes.

4.1.5 BASE UNITS OF EXPRESSION

Dairy Australia supports the retention of the requirement that nutrition information be expressed per 100ml. A voluntary option for manufacturers to include the base units of per 100g would also be supported. Dairy Australia is not aware of any evidence that indicates there currently is an issue with confusion. **The voluntary use of the base unit of per 100kJ is also supported**

Mandating the inclusion of such information would result in a higher cost for any label changes since another column of label information must be checked.

4.1.6 AVERAGE AMOUNT

Dairy Australia considers that 'Average Amount' is more consistent with a 'Plain English' approach. An appropriate option to address the issue, would be to define 'Average Amount' in the Food Standards Code.

4.1.7 FORMAT OF THE NUTRITION INFORMATION STATEMENT

Dairy Australia recommends further, full consumer research to be undertaken, with a specific focus on different population groups, maternal nutrition knowledge, education levels and socio economic status. A literature review undertaken by Dairy Australia on labelling and interpretation of nutrition information to guide informed purchase decisions, identified a very limited research base. We are unaware of any clear indications that there is either a need for greater consistency

4.1.8 NUTRITION CONTENT CLAIM AND HEALTH CLAIM PROHIBITION

As outlined above when considering claims about ingredients, for infants that cannot be breast fed, we understand that formulated products will never be able to replicate breast milk or subsequently the benefits breast milk delivers to both mother and child. However it is still important that the message that 'breast milk' is the best source of nutrition is both reinforced and balanced through policies, regulations and standards that are supportive of innovation, research and ongoing development of infant formula ingredients that collectively deliver improved health outcomes that lessen the gap between formula-fed infants and the benchmark of breast fed infants or address specific infant nutritional concerns such as allergies and intolerances.

Dairy Australia suggests that an evidence (including consumer research) based, and alignment with policy and regulatory principles assessment (including cost benefit analysis) be undertaken in regards to permissions for content claims in infant formula. This should be used to inform development of the best regulatory options.

Innovation cannot be supported if there is no way for caregivers and health professionals to differentiate between available formulas to recognise those that provide basic adequate nutrition from those that provide a lesser gap in nutrition and health outcomes against the bench mark of breast milk.

The ability to make nutrient content claims would provide minimal factual information to caregivers and health care professionals to enable a level of differentiation between products on the market.

A key consideration in this issue, is the evidence in relation to the reasons why women choose to breast feed or not or partially breast feed. There is some evidence in countries similar to and including Australia indicating that the decision to not breast feed, partially breast feed or stop breastfeeding is made well before considering which formula to choose and exposure to an infant formula label. [99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109]

[99] Growing Up In Australia (2016). Annual Report 2006-2007. Available: http://www.growingupinaustralia.gov.au/pubs/ar/ar200607/breastfeeding

[100] Australian Institute of Health and Welfare (2011). Australian national infant feeding survey: indicator results. Cat. No. PHE 156. Canberra. Available: http://www.aihw.gov.au/publication-detail/?id=10737420927&tab=2

[101] Centers for Disease Control and Prevention. HealthStyles Survey – Public Beliefs and Attitudes About Breastfeeding. Available: http://www.cdc.gov/breastfeeding/data/healthstyles_survey/survey_2010.htm

[102] Centers for Disease Control and Prevention (2016). Report on the Infant Feeding Practices Study II. Chapter 6. Sources of Information. Available: http://www.cdc.gov/breastfeeding/data/ifps/results.htm#Information.

[103] Palo Alto Medical Foundation (2015). Breastfeeding Survey Outcomes. Available: http://www.pamf.org/babes/outcomes.html#stopping

[104] Augustin A, Donovan K, Lozano E, Massucci D, Wohlgemuth F. Still nursing at 6 months. MCN Am J Matern Child Nurs. 2014;39(1):50-55.

[105] Brown CR, Dodds L, Legge A, Bryanton J, Semenic S. Factors influencing the reasons why mothers stop breastfeeding. Can J Public Health. 2014;105(3):e179-85.

[106] Li R, Fein S, Chen J, Grummer-Strawn L. Why mothers stop breastfeeding: Mothers' self-reported reasons for stopping during the first year. Pediatrics. 2008;122(Supplement):S69-S76.

[107] Kair LColaizy T. When Breast Milk Alone Is Not Enough: Barriers to breastfeeding continuation among Overweight and Obese Mothers. J Hum Lact. 2015;32(2):250-257.

[108] Stuebe A, Horton B, Chetwynd E, Watkins S, Grewen K, Meltzer-Brody S. Prevalence and risk factors for early, undesired weaning attributed to lactation dysfunction. J Womens Health. 2014;23(5):404-412.

[109] Odom E, Li R, Scanlon K, Perrine C, Grummer-Strawn L. Reasons for earlier than desired cessation of breastfeeding. Pediatrics. 2013;131(3):e726-e732.

4.1.9 INGREDIENT CLAIMS

No.	Section of the SD	Question
Q3.1	2.1	Should claims about specific ingredients be permitted on packaged infant formula? • If no, then why not? • If yes, then how should they be regulated?

For infants that cannot be breast fed, we understand that formulated products will never be able to replicate breast milk or subsequently the benefits breast milk delivers to both mother and child. However it is still important that the message that 'breast milk' is the best source of nutrition is both reinforced and balanced through policies, regulations and standards that are supportive of innovation, research and ongoing development of infant formula ingredients that collectively deliver improved health outcomes that lessen the gap between formula-fed infants and the benchmark of breast fed infants or address specific infant nutritional concerns such as allergies and intolerances.

Dairy Australia suggests that an evidence (including consumer research) based and alignment with policy and regulatory principles assessment (including cost benefit analysis) be undertaken in regards to permissions for 'content claims' in infant formula, and this be used to inform development of the best regulatory options.

Innovation cannot be supported if there is no way for caregivers and health professionals to differentiate between available formulas to recognise those that provide basic adequate nutrition from those that provide a lesser gap in nutrition and health outcomes against the bench mark of breast milk.

The ability to make nutrient or ingredient content claims would provide minimal factual information to caregivers and health care professionals to enable a level of differentiation between products on the market.

We recognise the importance of ensuring the message that 'breast milk is the best source of nutrition for infants'. All factors contributing to this message must be carefully considered and balanced against unintended compromises to improving the nutrition and health outcomes of some infants. Such a risk and benefit analysis must include interrogation of the key reasons care givers make the decision to fully or partially breast feed or not. We would hope that such a decision is made in consultation with a doctor or other appropriately qualified health care provider.

A key consideration in this issue, is the evidence in relation to the reasons why women choose to breast feed or not or partially breast feed.

There is some very consistent evidence [110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120] in countries similar to and including Australia indicating that the decision to not breast feed or partially breast feed are for reasons unrelated to labelling or perceptions of infant formula.

Study and survey results are generally very consistent with the *Australian Institute of Health and Welfare (2011). Australian national infant feeding survey: indicator results, Indicator 6: Proportion of children receiving non-human milk or formula at each month of age 0 -12 months (p 12) Attitudes and Barriers to Breast Feeding data (p38 – 39).*[115] provided below:

In this survey population, breast feeding was initiated for a total of 95.9% of children aged 0-2 years, just over 90% of infants received any breast milk in the first month, steadily declining each month.

Indicator 6: Proportion of children receiving non-human milk or formula at each month of age, 0–12 months[115]

Based on only 30 responses for infants in the less than 1 month age group, 26.5% had received formula or non-human milk in the last 24 hours (Table 2.5 and Figure 2.5). ***For those aged 4 months, 48.4% had received formula or non-human milk*** *in the last 24 hours, and for* ***those aged 6 months the proportion was 55.1%****. This was only marginally higher for each month of age between 7 and 12 months.*

Like Indicator 5, the definition for this indicator requires a child to have received non-human milk or formula within the last 24 hours, hence this indicator is reported using 'current' status – the feeding status of the infant at the time of survey completion. Again, time-to-event results for this indicator are presented in the next chapter, where the constraint of using the 'last 24 hours' is not applied.

[110] Growing Up In Australia (2016). Annual Report 2006-2007. Available: http://www.growingupinaustralia.gov.au/pubs/ar/ar200607/breastfeeding
[111] Australian Institute of Health and Welfare (2011). Australian national infant feeding survey: indicator results. Cat. No. PHE 156. Canberra. Available: http://www.aihw.gov.au/publication-detail/?id=10737420927&tab=2
[112] Centers for Disease Control and Prevention. HealthStyles Survey – Public Beliefs and Attitudes About Breastfeeding. Available: http://www.cdc.gov/breastfeeding/data/healthstyles_survey/survey_2010.htm
[113] Centers for Disease Control and Prevention (2016). Report on the Infant Feeding Practices Study II. Chapter 6. Sources of Information. Available: http://www.cdc.gov/breastfeeding/data/ifps/results.htm#Information.
[114]Palo Alto Medical Foundation (2015). Breastfeeding Survey Outcomes. Available: http://www.pamf.org/babes/outcomes.html#stopping
[115] Augustin A, Donovan K, Lozano E, Massucci D, Wohlgemuth F. Still nursing at 6 months. MCN Am J Matern Child Nurs. 2014;39(1):50-55.
[116] Brown CR, Dodds L, Legge A, Bryanton J, Semenic S. Factors influencing the reasons why mothers stop breastfeeding. Can J Public Health. 2014;105(3):e179-85.
[117] Li R, Fein S, Chen J, Grummer-Strawn L. Why mothers stop breastfeeding: Mothers' self-reported reasons for stopping during the first year. Pediatrics. 2008;122(Supplement):S69-S76.
[118] Kair LColaizy T. When Breast Milk Alone Is Not Enough: Barriers to breastfeeding c ontinuation among Overweight and Obese Mothers. J Hum Lact. 2015;32(2):250-257.
[119] Stuebe A, Horton B, Chetwynd E, Watkins S, Grewen K, Meltzer-Brody S. Prevalence and risk factors for early, undesired weaning attributed to lactation dysfunction. J Womens Health. 2014;23(5):404-412.
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Table.1: Proportion of children who had received formula or non-human milk in the last 24 hours, by current age

Age (completed months)	Per cent
0 (less than 1 month)	26.5
1	40.3
2	43.1
3	46.0
4	48.4
5	52.9
6	55.1
7	61.8
8	68.4
9	68.2
10	75.3
11	78.1
12	79.5

Note: The proportion for infants aged 0 months is based on 30 responses only.

The reasons for introduction of formula or non-human milk are outlined below, only 26% of women who did not give any breast milk gave the reason for doing so of *'formula is as good as breastmilk'*, this reason was not included in reasons given for discontinuing breast feeding.

Attitudes and barriers to breastfeeding[115]

Reasons for giving child breastmilk

The survey asked mothers/carers to give the reasons why they breastfed their child. This question was asked only of those mothers/carers whose child had ever had breastmilk. Respondents were offered several response alternatives, and could choose as many responses as were applicable to them.

The most cited reasons for breastfeeding their child was 'breastfeeding was healthier for child' (94%), followed by 'convenience' (64%), 'helps with mother–infant bonding' (64%), and 'healthier for mother' (58%). Less than half cited 'cheaper than infant formula' as the reason they were breastfeeding their child (Table 4.1).

Table.2: Mother's/carer's reasons for giving child breastmilk (per cent)

Reason	Per cent
Healthier for child	93.7
Convenient	64.4
Helps with mother–infant bonding	63.9
Healthier for mother	58.1
It felt right/motherly instinct/cultural reason	57.1
Cheaper than infant formula	47.1
Advised or encouraged by midwife	26.5
Encouraged by partner	22.7
Encouraged by family	19.0
Advised or encouraged by ante-natal class instructors	18.0

Note: The question wording was 'What were your reasons for giving your child breastmilk?' Respondents were offered several response alternatives and could choose as many responses as were applicable to them.

Reasons for not continuing breastfeeding[115]

The survey asked mothers/carers of children who were currently not breastfeeding their child to give their reasons for discontinuing breastfeeding. This question was only asked of mothers/carers who were no longer providing any breastmilk to their child. The respondents were able to cite more than one reason. The figures shown in the Table 4.2 are independent of each other, and only the top 10 most cited reasons are shown.

The most cited reason for not continuing breastfeeding was 'not enough breastmilk for child'. However, this reason was cited by only of 13% mothers/carers whose child stopped receiving breastmilk after 12 months of age, compared with 56% of mothers/carers whose child stopped receiving breastmilk when aged 6 months or less (Table 4.2). Those children who stopped receiving any breastmilk when they were aged more than 12 months did so because 'child was old enough to stop' (63%) or 'child lost interest' (33%).

Table.3: Mother's/carer's reasons for not continuing to give child breastmilk (per cent)

	Age (in completed months) child stopped receiving any breastmilk			
Reason	**0–6**	**7–12**	**>12**	**Total**
Not enough breastmilk for child	56.3	31.2	12.5	41.0
Child lost interest	11.2	33.8	33.2	19.2
Child was old enough to stop	1.8	32.0	63.0	17.2
Baby was unsettled	24.2	5.1	2.4	15.0
Child was not attaching properly	25.2	1.7	0.6	14.4
Return to work	8.7	24.4	10.6	12.7
Breastfeeding was too painful	18.4	3.0	1.6	11.1
It was time for child to have other foods	4.5	21.7	18.0	10.5
Expressing milk to feed child was too hard	14.2	6.9	2.3	9.9
Child was biting	4.0	21.3	13.6	9.5

Note: The question wording was 'What were your reasons for not continuing to give your child breastmilk?' Respondents were offered several response alternatives and could choose as many responses as were applicable to them.

Reasons for not breastfeeding[115]

The survey collected information from mothers/carers about why their child was never breastfed. The survey showed that 4% of children aged 24 months or less were never breastfed (Table 3.1).

The top 10 most cited reasons for never breastfeeding the child include 'previously unsuccessful experience with breastfeeding' (38%) and 'so my partner can share feeding' (29%). One in four mothers/carers cited 'infant formula as good as breastmilk' as one of the reasons for not giving their child breastmilk.

Table.4: Mother's/carer's reasons for not giving child breastmilk (per cent)

Reason	**Per cent**
Previously unsuccessful experience with breastfeeding	37.9
So my partner can share feeding	28.5
Infant formula as good as breastmilk	26.0
Medical reasons for mother	19.8
Other reasons	17.2
I would not feel comfortable breastfeeding in public	16.1
I was not breastfed as a baby	9.1
Return to work	7 8
Medical reasons for child	3 8
I did not want the shape of my breasts to change	3.3

Note: The question wording was 'What were your reasons for not giving your child breastmilk?' Respondents were offered several response alternatives and could choose as many responses as were applicable to them.

This evidence we have looked at from a number of surveys and studies indicates that the decision to not breast feed or partially breast feed is made for reasons other than the view that formula is as good as breast milk and unrelated to any information provided on infant formula labels.

Creating a situation that constrains the research and development of infant formula nutrition and health outcomes does not seem likely to influence the rates of breast feeding, however will compromise broader improvement in available nutrition and health outcomes for infants that are not breast fed or are only partially breast fed.

To address concerns regarding the influence of infant formula labels on breast feeding, we suggest that a full review of the evidence in this area be undertaken to determine what the main barriers and influences are to the caregiver decision to breast feed or introduce formula.

4.2 NUTRITION INFORMATION ABOUT MACRONUTRIENT SUBGROUPS

Q3.2	2.3	Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?

Dairy Australia is aware that health care professionals may at times recommend infant formulas based on specific nutrient content, for example whey dominant infant formulas. Any on-pack information that could help the caregiver to identify products recommended by the health care professional that contain these is helpful for caregivers to make an informed choice and appropriate product selection.

Macronutrient subgroups contribute to the overall information on pack available to health professionals to make an informed recommendation and consumers and informed choice of product. Macronutrients are more complex than simply protein, fat and carbohydrate. Through advances in nutritional science and technology, infant formulas offer different types of proteins, fats and carbohydrates for formula-fed infants.

This information contributes to informing health care professionals and consumers about the formulation of specific products.

Q3.3	2.3	Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set out in clause 16 of the existing Code and section 2.9.1–21 of the revised Code) in the nutrition information statement?

Dairy Australia interprets that Standard 2.9.1 already includes permissions to declare factual nutritional information about macronutrient subgroups.

Our interpretation leads to a conclusion that there is no explicit prohibition of sub-group(s) of a macronutrient in a nutrition information statement for infant formula. To avoid ambiguity, regulatory clarity and the inclusion of expressed permissions in Standard 2.9.1 to declare nutrition information about macronutrient subgroups in the nutrition information statement is suggested.

In support of this position the following must be taken into consideration. There is a significant difference between the provisions for general foods and infant formula in this area. For general foods, a nutrition information panel is required and is regulated under Standard 1.2.8 – Nutritional Information Requirements. Standard 1.2.8 sets out the manner in which such information must be provided and Schedule 12 sets out the mandatory format. The format clearly shows that for fat and protein it refers to 'total' fat and 'total' protein. Standard 1.2.8 provides a definition of fat used in Standards 1.2.7 and 1.2.8, and Schedules 4 and 11, and is defined as 'total fat'.

The note under section 1.2.8—2 states that:

"*Information provided voluntarily in a nutrition information panel is a nutrition content claim*".

This is reiterated in Standard 1.2.7 which states that:

"*inclusion of voluntary information in nutrition information panel might constitute a nutrition content claim*".

- Hence, for general food, voluntarily declaring macronutrient subgroups and macronutrient specific nutrients in the nutrition information panel is expressly prohibited if the claim is not qualified but this prohibition is clearly **not** applicable to infant formula.

For infant formula, a nutrition information panel is not required but instead, a statement of nutrition information is required.

- Standard 2.9.1—21 lists the information that must be included but it makes no reference to ***total*** protein or ***total*** fat. Standard 2.9.1—21(1)(a)(ii) states:

  "*the average amount of protein, fat and *carbohydrate expressed in g/100 mL*";

  This does not state "... average amount of the **total** protein and **total** fat".

- Standard 2.9.1—21(1)(a)(iii) requires nutritive substances, which include optional ingredients, to be declared. This is illustrated in the Guidelines for the Nutrition Information relating to infant formula. Optional ingredients, are 'voluntary' by nature. These are not typically mandatory references in a nutrition information statement.
- Under "Prohibited Representations" in Standard 2.9.1—24(1)(f), a reference to the presence of any nutrient (and this would include sub-groups of a macronutrient), or any substances that may be used as a nutritive substance, is permitted in a declaration of nutrition information, and the prohibitions relate only to a reference of a nutrient or nutritive substance outside a list of ingredients or nutrition information panel. As such, it expressly allows a reference to the presence of any nutrient to be made as a declaration of nutrition information.

Lastly, it is important to consider that the labels of infant formula must state that parents or carers should consult their Health Care Professional before deciding on formula feeding and choosing an appropriate formula. The breakdown of the protein in an infant formula, for example the whey : casein ratio, is an extremely important consideration for Health Care Professionals when advising a parent or carer. Health care professionals must have easy access to the ingredients and nutrition profiles to guide their clients/patients. In the example of whey : casein ratios, this information is not available in a list of ingredients.

To explicitly prohibit such declarations would create further confusion with caregivers as information on pack is already extremely limited. There is little information permitted on the label to enable either consumers or caregivers to differentiate between different infant formulas in the market. To not enable differentiation stifles the improvement of the nutritional contribution of formulas more broadly to health outcomes for infants that are not going to be breast fed or will only be partially breast fed due to decisions made prior to even considering which infant formula to choose.

Q3.4	2.3	Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alpha-lactalbumin etc.), or specific proteins (only whey and casein).

Dairy Australia supports flexibility in the inclusion of macronutrient subgroups. It is important and should be included in the nutrition information statement to help caregivers and health care professionals differentiate between different infant formulas. However **Dairy Australia does not support mandating only specified macronutrient subgroups** as not all infant formulas are the same. Mandating only specified macronutrient subgroups is not supportive of product differentiation.

The status quo and the provision for macronutrient subgroups to be added to nutrition information as needed is supported

Q3.5	2.3	If only specified macronutrient subgroups, what principles should be applied to determine which nutrients may be declared (e.g. for those fats with a specific compositional requirement, or for those nutrients that caregivers have a general understanding of their nutritional purpose in foods).

Dairy Australia suggests that if macronutrient subgroups are declared, then the levels of those macronutrient subgroups should also be declared in order not to be misleading. In such circumstances the average quantity should be met.

The overarching principle would be supportive of product differentiation and subsequently innovation that reduces the gap of infant formulas more broadly with the bench mark of breast milk regarding nutrition and health outcomes.

Prescriptive principles, for nutrition information statements, particularly since infant formula already requires an extensive range of mandated requirement are not supported. Space limitations in the nutrition information statement, means that additional prescribed requirements would be difficult to accommodate.

While the education process with health care professionals communicates this information, voluntary inclusion can allow identification of the ingredients, all of which are safe, to supplement and inform the health care professionals' information.

Q3.6	2.3	If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?

Dairy Australia does not agree that the inclusion of information about macronutrient subgroups has potential to mislead caregivers about the nutritional value of the formula. Any information provided would need to be truthful and accurate, regardless of whether the presentation of the information includes subgroups.

Q3.7	2.3	What would the cost and trade implications of mandating macronutrient subgroups or conversely expressly prohibiting them?

Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. Dairy Australia is **not aware of evidence that would either support mandating or against the voluntary use of macronutrient subgroups** on infant formula labels. **All prescribed label changes require a packaging change which involves revised artwork and cost.**

In terms of trade impacts, **such a requirement would be inconsistent with other jurisdictions and would effectively present as a non-technical barrier to trade**. This would decrease the likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply of product to a vulnerable population group. Product labels are not the only means of communicating information to consumers, and consideration should be given to other options ahead of mandating labelling requirements for information that is not deemed to convey vital food safety information.

Infant formula is most often packaged in high value printed metal cans which are only made by a very limited number of suppliers in Australia. Label changes involve a significant lead time to prepare new artwork, and then coordinate with supplier production schedules in order to have new packaging available for use.

4.3 INGREDIENT AND NUTRITION INFORMATION DECLARATIONS

Q3.8	2.4	Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?

Dairy Australia is not aware of any evidence that indicates caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations. It would be helpful in considering this issue to recognise that that ingredients lists and nutrient lists are fundamentally different.

Currently the practice is for the more complex nutrients to be used in the ingredients list, *together* with the common term and the common term to be used in the nutrition information statement.

Declaration of the more complex term aligned to permitted forms, is a practical solution to enable the relevant enforcer to readily see that permitted forms of an ingredient are being used. On the other hand the ingredients list groups vitamins and minerals and other substances according to use, which may allow for more information for the consumer with the view to minimise 'confusion'.

The nutrition information statement is relevant only to specific vitamins and minerals but is more general in relation to macronutrients. Nutrients come from a wide range of sources and often the summation is in the nutrition information statement whereas the sources are usually listed in the ingredients list.

Q3.9	2.4	Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?

Dairy Australia is not in support of aligning the names of ingredients with nutrient declarations in the nutrition information statement. The information serves different purposes and as noted above, the ingredients list includes additions of, for example vitamins and minerals, while the nutrition information statement includes total amounts (naturally occurring and added) and not necessarily information about its source.

4.4 BASE UNITS OF EXPRESSION

Q3.10	2.5	Which base units of expression do stakeholders find to be of greatest value?

Dairy Australia supports the retention of the requirement that nutrition information be expressed per 100ml. A voluntary option for manufacturers to include the base units of per 100g would also be supported. This would be particularly useful for those markets that have adopted the Codex provision of using per 100g allowing harmonisation with those requirements on an as needs basis.

Q3.11	2.5	Is there any evidence that caregivers are confused by the use of different base units of expression?

Dairy Australia is not aware of any evidence that indicates there currently is an issue with confusion.

Q3.12	2.5	In addition to the current requirement to declare nutrition information per 100 mL as consumed, should it be mandatory or voluntary to declare per 100 g of powder (or per 100 mL for liquid formula) as sold?

Dairy Australia believes the provision to declare per 100 g of powder (or per 100 mL for liquid formula) as sold should be voluntary. Mandating the inclusion of such information would result in a higher cost for any label changes since another column of label information must be checked. Health care professionals can get the information elsewhere should it be required and can always contact the company concerned. Currently companies voluntarily provide base unit 100 kcal or /100kJ where requested outside of the label.

Q3.13	2.5	What would the cost and trade implications be of mandating these base units?

Mandating additional information in the nutrition information statement would require significantly more checking and rechecking values for substances involved. This is hugely resource intensive when labels are changed to ensure errors haven't been introduced inadvertently. It would also be particularly difficult to find the space on smaller pack sizes and still maintain the mandated font size for relevant information.

Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. **All prescribed label changes require a packaging change which involves revised artwork and cost.**

In terms of trade impacts**, such a requirement would be inconsistent with other jurisdictions and would effectively present as a non-technical barrier to trade**. This would decrease the likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply of product to a vulnerable population group. Product labels are not the only means of communicating information to consumers, and consideration should be given to other options ahead of mandating labelling requirements for information that is not deemed to convey vital food safety information.

Infant formula is most often packaged in high value printed metal cans which are only made by a very limited number of suppliers in Australia. Label changes involve a significant lead time to prepare new artwork, and then coordinate with supplier production schedules in order to have new packaging available for use.

Q3.14	2.5	Should the voluntary use of the base unit of per 100 kJ be permitted?

Dairy Australia supports the voluntary use of the base unit of per 100kJ

Q3.15	2.6	What impacts, if any, would there be if the declaration requirements for macronutrients, micronutrients, nutritive substances, inulin-type fructans and galacto-oligosaccharides are based on 'average quantity', instead of 'average amount'?

Dairy Australia considers the expression 'Average Amount' is likely more suitable for the consumer in the sense that, 'average amount' is more consistent with a 'Plain English' approach. An appropriate option to address the issue, would be to define 'Average Amount' in the Food Standards Code.

If average quantity is determined to be the better option, this would require a label change. Over time, this would have to be implemented in conjunction with any other label changes resulting from the review of Standard 2.9.1.

4.5 NUTRITION INFORMATION FOR USE BY CAREGIVERS AND HEALTH PROFESSIONALS

Q3.16	2.7	Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?

Dairy Australia recommends further, full consumer research to be undertaken, with a specific focus on different population groups, maternal nutrition knowledge, education levels and socio economic status.

A literature review undertaken by Dairy Australia on labelling and interpretation of nutrition information to guide informed purchase decisions, identified a very limited research base**.** The literature was not specific enough to enable extrapolation of consumer purchasing behaviours or interpretation of information on infant formula labels to guide informed purchase decisions. The literature did suggest that higher education level and income influenced mothers nutrition knowledge and ability to read product labels, whereas women on lower incomes and with lower levels of education were at greatest risk for low maternal nutrition knowledge and not reading product labels.[121]

Q3.17	2.7	Would a consistent approach to format across product labels assist consumer understanding of this information?

Dairy Australia is unaware of any clear indications that there is either a need for greater consistency or that a consistent approach would deliver benefits clearly above and beyond costs.

Q3.18	2.7	If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?

Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. **All prescribed label changes require a packaging change which involves revised artwork and cost.**

In terms of trade impacts, **such a requirement would be inconsistent with other jurisdictions and would effectively present as a non-technical barrier to trade.** This would decrease the likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply of product to a vulnerable population group. Product labels are not the only means of communicating information to

[121] Wojcicki j, Gugig R, Kathiravan S, Holbrook K, Heyman M. Maternal knowledge on infant feeding guidelines and label reading behaviours in a population of new mothers in San Francisco, California. Matern Child Nutr. 2009;5(3):223-233.

consumers, and consideration should be given to other options ahead of mandating labelling requirements for information that is not deemed to convey vital food safety information.

Infant formula is most often packaged in high value printed metal cans which are only made by a very limited number of suppliers in Australia. Label changes involve a significant lead time to prepare new artwork, and then coordinate with supplier production schedules in order to have new packaging available for use.

Q3.21	2.8	What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?

Dairy Australia suggests that the product label is not the only means of communicating with caregivers and health professionals. As such, a mandatory standardised approach to a product reformulation on infant formula packages is not supported.

It is important that the current flexibility that exists for communicating any reformulation be retained. Such flexibility would permit the use of a combination of communication media to provide more detailed information to caregivers and health professionals. For example, a reformulation could be indicated on a product package with the use of a sticker on the can or under the over cap by a simple statement as “New Formula”, and this message then supported by more detailed information about the reformulation being provided via a secondary medium such as the product website.

Infant formula already has a significant quantity of mandated requirements and additional requirements need to be based on strong evidence. **All prescribed label changes require a packaging change which involves revised artwork and cost.**

In terms of trade impacts, **such a requirement would be inconsistent with other jurisdictions and would effectively present as a non-technical barrier to trad**e. This would decrease the likelihood that imported products would enter the Australian and New Zealand markets and potentially jeopardise supply of product to a vulnerable population group. Product labels are not the only means of communicating information to consumers, and consideration should be given to other options ahead of mandating labelling requirements for information that is not deemed to convey vital food safety information.

Infant formula is most often packaged in high value printed metal cans which are only made by a very limited number of suppliers in Australia. Label changes involve a significant lead time to prepare new artwork, and then coordinate with supplier production schedules in order to have new packaging available for use.