Comments from the Victorian Departments of Health and Human Services, Education and Early Childhood Development and Economic Development, Jobs, Transport and Resources

The Victorian Departments of Health & Human Services, Education & Early Childhood Development and Economic Development, Jobs, Transport & Resources (the departments) welcome the opportunity to respond to the issues raised in the Consultation paper for Proposal P1028 – Infant Formula, reviewing Standard 2.9.1.

The departments recognise that FSANZ has completed an extensive review of the issues with the current regulations for infant formula products. The body of work undertaken by FSANZ in preparation for this consultation is acknowledged.

Comments on the process for P1028 – Infant Formula

The size of the consultation paper

The departments have found it challenging to adequately review the consultation paper and the issues raised by FSANZ in the time provided due to the breadth of issues to consider and the detail involved. Ideally we would have preferred this consultation paper to have been split into three separate consultation papers covering the three components in this paper (composition, safety and food technology and provision of information) to enable us to focus more fully on each aspect.

Engagement of key stakeholders

While the public consultation process encourages interested stakeholders to provide their views, the departments have been made aware that few health professionals or professional bodies involved in supporting infant feeding have been able to adequately consider or prepare a response to this consultation paper. Health workers have a vital role in supporting breastfeeding and informing caregivers about the use and preparation of infant formula, when necessary. This group of health professionals may include paediatric dietitians, maternal child health nurses and academics with expertise in infant feeding. The breadth of issues has required considerable technical expertise within very short timeframes to respond to the questions posed in this proposal. This may have presented barriers for some individuals and groups in commenting, particularly when this work would need to be completed outside of normal working hours.

The departments therefore highlight that broad (and key) stakeholder views may not be represented in the responses received to Proposal P1028. We are concerned that submissions may be dominated almost completely by the industry and the regulators of infant formula, and that a balance of these views may not necessarily reflect those of other key stakeholders involved in supporting infant feeding. Key stakeholder groups' views may be missing from the submissions received by FSANZ. Hence, it is imperative that FSANZ consider ways to seek these views to inform Proposal P1028.

Consideration of optimising final outcomes for P1028

The breadth of technical and policy issues presented by Proposal P1028 may hinder consideration of the final Approval Report by members of the Australia and New Zealand Forum on Food Regulation. To facilitate the progression of the review of Standard 2.9.1, FSANZ should consider separating the composition and labelling issues into two distinct proposals, for instance, for simultaneous progression. If there was one particular contentious issue leading members of the Forum to request a review, this separation would enable the remaining proposal to progress. As far as we are aware, the labelling and composition requirements are sufficiently independent that gazettal of these changes at different times should not pose an issue. However we acknowledge that there may be cost impacts on industry related to label changes (unless an adequate transition period is in place).

Supporting Document 1: Definitions and Nutrient Composition

General comments:

Having regard to the principles set out under the FSANZ Act 1991

The departments have considered the issues under Supporting Document 1 – definitions and nutrient composition in the context of the five principles outlined under the *FSANZ Act 1991*. Particularly significant is the need for standards to be based on risk analysis using the best available scientific evidence and relevant written policy guidelines, in addition to the promotion of consistency between domestic and international food standards. This latter point has been a significant focus of this Proposal by FSANZ. Our consideration has been underpinned by the Ministerial Policy Guideline – Regulation of Infant Formula Products, which places the health and safety of infants, and the recognition that breastfeeding is the normal and recommended way of feeding infants, at the centre of decisions for infant formula regulation.

Promotion of consistency between domestic and international food standards

The Codex Alimentarius Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex STAN 72-1981) was last reviewed in 2007, with minor amendments in 2011 and 2015. At the time of FSANZ's last public consultation on infant formula in 2012, the departments supported alignment of Standard 2.9.1 with Codex STAN 72-1981, given it was based on more recent scientific evidence than Standard 2.9.1 (including the recommendations for infant formula composition by the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) expert group)[1]. This would also have facilitated trade.

Since then, an updated scientific paper examining the essential composition of infant formula was prepared by the European Food Safety Authority Panel on Dietetic Products, Nutrition and Allergies (EFSA NDA) in 2014. This has led to the European Union regulations (EU 2016/127) being updated in 2016. In many cases, the updated EU regulations have resulted in changed nutrient limits from those that were previously aligned with the levels set in Codex STAN 72-1981.

For many of the nutrients discussed in this Proposal, **the departments recommend aligning with the EU regulations (EU 2016/127)**, because these are based on the most up-to-date scientific evidence about infant nutritional requirements and how these should be met by infant formula.

Many of the Australian market leaders in infant formula are based in Europe, or supply the European market, and will need to reformulate to meet the new EU regulations in that market. The departments believe there is a risk in aligning with the Codex standard, which has not been reviewed since 2007, and is not based on the most recent scientific opinion. Given the infrequency with which Standards in the Food Standards Code are reviewed (the last review of infant formula occurring in 2002), it would be prudent to adopt more up to date regulations where it is appropriate to do so (acknowledging some differences in the European and Australian populations).

Minimum values as target values

The departments note that a key message in the recent EFSA NDA scientific opinion paper reiterated the position made in the expert ESPGHAN paper that care needs to be taken to not place a burden on infants' metabolism by the use of unnecessary substances or unnecessarily large amounts of substances in infant formula [1, 2]. The EFSA NDA paper specifically highlighted that the minimum levels of nutrients proposed for infant formula should be viewed as target levels as these levels meet the nutritional needs of virtually all healthy infants born at term [2]. The paper emphasizes that there

is no need to exceed these amounts in formula, as nutrients which are not used or stored have to be excreted and this may place a burden on infants' metabolism. For that reason, the EFSA NDA paper recommended that **maximum amounts should be interpreted not as target values but rather as upper limits of a range which should not be exceeded**. **The departments support this approach in line with expert scientific opinion.**

We understand that it is common practice for industry to add higher amounts of nutrients (or overages) to allow for losses and to ensure that the amounts indicated on the tin are present at the end of the shelf life. We would like to see information on the levels of nutrients in infant formula at the start of its shelf life. We would also like to see information from the infant formula industry on usual turnover of product and an indication of how usual it is for infant formula to be used near the beginning of its shelf life versus at the end. If nutrient content levels are frequently approaching maximal levels, we would like further consultation on how the recommendations from the EFSA NDA and ESPGHAN could be encouraged.

The questions posed by FSANZ have been answered below. Further comments on individual nutrients have been added to the relevant sections.

Section 2 - Definitions and Terminology

Q1.2 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**

Option 3 **with** Option 2, "**satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding and, as part of a progressively diversified diet, of infants from *around* 6 months of age**" best describes the role and scope of infant formula. We recommend the addition of the '*around* 6 months of age' as this is more consistent with national feeding advice [3] and includes those infants who may start solids just before 6 months of age.

Infant formula is intended to provide a suitable replacement for breastmilk from birth to twelve months of age, which includes meeting all nutritional requirements of young infants, and, with solid foods, meeting the nutritional requirements for older infants. Neither the current definition nor Option 1 make it clear that infant formula is suitable (and necessary for those not breastfed) after the introduction of solids (around 6 months).

Section 3 - Protein

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

We cannot provide any further evidence to support or reject the higher minimum protein level of 0.5g/100kJ for isolated soy protein-based formula. As the rationale is that a higher minimum is required in order to meet the essential amino acids not normally contained in soy protein, and due to the lower digestibility of plant proteins, we do not

object to continuing the higher minimum for these protein sources.

Additional comments on protein permissions:

Maximum protein level

The departments support the EFSA NDA 2014 recommendation to reduce the maximum protein level to 0.6 g/100kJ rather than continue the proposed maximum protein level of 0.7 g/100kJ (equivalent to 12% of energy) given there is no evidence of a physiological need for protein intakes at the amounts of 0.7g/100kJ [2]. The European Scientific Committee on Food 2003 stated that formula should not provide more than 12% of energy as protein to ensure that the potential renal solute load was not unacceptably high [4].

EU 2106/127 has since reduced the maximum level of protein from 0.7g/100kJ to align with this recommendation. Aligning with the EU regulations would ensure the percentage of energy as protein does not exceed 12%. FSANZ's analysis has shown that this should not create an issue for the infant formula industry given the current protein quantities in infant formula in Australia range between 0.46 and 0.54 g/ 100 kJ (as labelled).

Protein source

Standard 2.9.1 does not specify the source of protein that can be used. The definition of infant formula product requires that the product must be based on 'milk or other edible constituents of animal or plant origin'.

FSANZ's preliminary view is that the permitted sources of protein do not need to be specified in the Standard. **The departments do not support FSANZ's preliminary view.**

We note FSANZ's comment that further consideration may be given to this as work on novel foods and nutritive substances progresses. Under the EU regulations, the permitted sources of protein in infant formula are specified and include cow and goat's milk proteins or isolated soy proteins. In considering protein derived from plant sources, the EFSA NDA panel discussed various anti-nutrient factors in plants that can interfere with protein digestion and nutrient absorption (and in the case of soy, recommend that specific substances be kept as low as possible)[2].

The departments do not support FSANZ's preliminary view as this would enable new sources of protein to be used in infant formula without undergoing pre-market assessment. **This is inconsistent with the Ministerial Policy Guideline on Infant Formula Products that clarified that all new substances used in infant formula in Australia and New Zealand require pre-market assessment.** Without pre-market assessment it is not clear how it would be decided whether specific plant sources are suitable for infant formula and whether consideration has been given to specific anti-nutrient substances present that may interfere with the digestibility of the formula.

For example, the international brand, Novolac, produces an infant formula that is based on rice protein (Novorice). Infant formulas based on rice protein are not currently available in Australia. It is not clear how enforcement agencies would be able to determine whether an infant formula based on rice protein (or proteins from any other plant sources) had been assessed in terms of safety and suitability and therefore in compliance with Standard 2.9.1.

The labelling of the protein sources is discussed further in comments to Supporting Document 2.

Amino acid content

The departments support FSANZ's preliminary approach for the amino acid content to align the majority of the minimum amino acid levels with Codex STAN 72-1981 with the exception of the sulphur amino acids and aromatic amino acids.

Section 4 - Fat

Q1.4 Do you support retaining the current minimum requirement for LA[1] (9% total fatty acids) in infant formula? Please provide your rationale.

No. The departments support aligning the minimum requirement for LA with the scientific opinion provided by the EFSA NDA panel and the level set in EU 2016/127, that is, the minimum LA value should be 120mg/100kJ, equivalent to 4.5% of energy [2]. The EFSA NDA opinion is based on adequate infant intakes and breastmilk concentrations of well-fed mothers as primary references for these values and this rationale would be relevant for Australian infants. The composition of infant formula should reflect breastmilk (and infant requirements) unless there is a sound basis for providing an alternative level. The levels set in Codex STAN 72-1981 and in the current Standard 2.9.1 do not meet infant requirements for the first six months and there is no clear basis for aligning with the Codex level of 70mg/100kJ. From the FSANZ label survey, it appears a number of formulas do not meet the current minimum in Standard 2.9.1. Of those that do (the majority of formulas reviewed), all but one would already meet the minimum value of 120 mg/100kJ.

The departments support a Guideline Upper Level (GUL) for LA of 300mg/kJ, which also aligns with the EU reg 2016/127 and the 2014 EFSA NDA opinion [2]. This reflects the highest amounts found in breastmilk. The opinion that higher amounts are not likely to pose a risk to infants is a not sufficient rationale to maintain a higher level of a nutrient when there is no physiological reason (or apparent technical reason, assuming formulas in the EU abide by the regulations) to do so.

Q1.5 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

The departments do not have a position on whether the current approach to the regulation of the source of fat is appropriate.

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

N/A

Additional comments on fat permissions:

DHA permissions

In contrast to FSANZ's preliminary view, the departments support specifying a mandatory minimum level for DHA[2] given the recent scientific review and rationale offered by the EFSA NDA paper and since legislated by EU 2016/127 [2].

EFSA's NDA paper acknowledges that there is no convincing evidence that the addition of DHA to infant formula and follow-on formula has benefits beyond infancy on any functional outcomes. However there is a lack of long-term follow-up data on specific aspects of cognitive and behavioural function from adequately powered randomised control trials of DHA addition to infant formula. The departments similarly note the limitations of the published data in drawing strong conclusions on the effects of added DHA on functional outcomes. The available data from randomised clinical trials varies in terms of the amounts of DHA, age of infants at follow-up and the functional outcomes measured. However, as reviewed in the EFSA NDA paper, the intake of preformed DHA generally results in an erythrocyte (red blood cell) DHA status more closely resembling that of a breast-fed infant than is achieved with its precursor, alpha linolenic acid (ALA), alone.

[1] Linoleic acid
[2] Docosahexaenoic acid

The EFSA NDA paper also notes:

- DHA is an essential structural component of the nervous tissue and the retina, and is involved in normal brain and visual development;
- the developing brain has to accumulate large amounts of DHA in the first two years of life;
- Considering all of these factors, it seems prudent to provide pre-formed DHA to formula-fed infants in similar amounts as breastfed infants, even though benefits beyond infancy of this practice cannot be established based on the currently available data.

The Ministerial Policy Guideline for the Regulation of Infant Formula Products specifies that the composition of infant formula must strive to achieve as closely as possible the normal growth and development of healthy full term exclusively breast fed infants. This is measured by appropriate physiological, biochemical and/or functional outcomes and, ideally, uses breastmilk as a primary reference. Therefore, the **departments recommend the mandatory addition of DHA to infant formula**.

FSANZ's label survey indicates that the majority of infant formula surveyed already contains DHA.

Minimum and maximum levels for DHA

The EFSA NDA proposes a minimum of 4.8mg/100kJ (approximately 0.36-0.49% fatty acids) with an upper level based on the highest levels in breastmilk of 12mg/100kJ (approximately 0.90 – 1.23% fatty acids). These levels were adopted in EU 2016/127. We support these limits.

The departments are concerned that the maximum guideline level of 0.5% fatty acids set by Codex STAN 72- 1981 (and supported by FSANZ) which will apply to voluntarily added DHA is around the minimum level recommended by the EFSA NDA paper. **The departments support aligning permissions with the current evidence, irrespective of whether DHA becomes mandatory or remains a voluntary permission.**

Medium chain triglycerides

The departments support FSANZ's preliminary view that the current limitations on Medium Chain Triglycerides (MCTs) in Standard 2.9.1 should remain, despite no position on MCTs having been expressed in Codex STAN 72-1981.

Phospholipids

The departments support FSANZ's view that the amount of phospholipids in infant formula should not exceed the amount that normally occurs in breast or cow's milk (approximately 0.25g/L) due to their potential bioactivity, lack of safety data and insufficient evidence of their benefit. This would mean setting a level below that set by Codex STAN 72-1981 (2g/L).

Section 5 – Carbohydrate

Q1.7 Should the concept of dietary fibre or its prescribed methods of analysis apply to infant formula?

The departments do not have sufficient information to form a view on this at this time.

Q1.8 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.

The departments do not support the current approach, which is to have no provisions regarding the source of carbohydrate. We support instituting restrictions; that is, **for standard infant formula, sucrose, fructose and glucose should not be permitted**. The addition of these to specialised formula based on protein hydrolysates is outside the scope of this proposal and should be considered separately.

This position is in line with the scientific opinions by the ESPGHAN in 2005 and by EFSA NDA in 2014 which indicate that sucrose, glucose and fructose should not be added to infant formula as sucrose and fructose do not have any advantage over lactose and pose a serious risk to infants with hereditary fructose intolerance and saccharase deficiency. Glucose is considered unsuitable as it may form Maillard products and increases the osmolality of infant formula [1, 2].

This position is consistent with the EU regulations on infant formula, and consistent with the (non-mandatory) approach taken in Codex STAN 72-1981.

General comments on carbohydrate permissions

The departments agree that the definitions and the method of calculation for carbohydrate in the revised Code are appropriate for infant formula.

Section 6 – Energy

The departments support FSANZ's view to reduce the upper bound of the energy density range to 2950 kJ/L to align with Codex STAN 72-1981. This is consistent with the scientific opinion provided by the EFSA NDA, which also notes that infant formula should be designed such that its energy content tends towards the lower bound of the range, provided that infants are fed *ad libitum*. The departments would like more information on the average energy content of infant formula in Australia from FSANZ's label survey as to whether further guidance should be offered to industry on energy density.

Section 7 – Micronutrient composition

Approach to setting guidelines or maximum amounts

The departments note the discussions about Guideline Upper Levels (GULs) and whether these voluntary maxima should sit within Standard 2.9.1 or outside of the Standard as guidance material. Maximum amounts are prescribed when there is a clear, significant risk associated with consuming any specific nutrient in excess. GULs serve to minimise any potential risk of adverse health effects from the consumption of nutrients that exceed an infant's requirements more generally. As noted by FSANZ, adverse effects can result when excess nutrients have to be excreted by an infant, placing a burden on metabolic and other physiologic functions. An excess of one nutrient may also interfere with metabolic and physiologic functions of other nutrients. GULs are set where there is insufficient evidence of risk to set a prescribed maximum amount. However, the EFSA NDA noted that there is a lack of studies designed to investigate the short- or long-term health consequences of the consumption of formula containing the currently permitted maximum amounts of nutrients [2].

We note that the infant formula industry supports the inclusion of GULs in addition to prescribed maximum amounts. We also note FSANZ's preliminary view is to retain GULs (and convert some mandatory maximum amounts to GULs) in Standard 2.9.1. **The departments support the inclusion of GULs in Standard 2.9.1 to aggregate all compositional information together.**

We note FSANZ's comment that managing tight specifications for a large number of nutrients can be a challenge for infant formula companies and that the GUL approach provides flexibility. In light of the emphasis that EFSA placed on its recommendations that maximum bounds should not be exceeded due to the potential burden on infants' systems [2], the departments would like FSANZ to seek further information from infant formula companies on how often GULs are exceeded and what action can be taken to minimise such events.

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

Yes, the minimum folate requirement should include naturally occurring folate given that cow's milk and milk powder contain folate naturally and that up to 40% of the folate in the finished infant formula product can be naturally occurring. Excluding this from calculated folate content would encourage unnecessary amounts of folate.

Q1.10 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.

The departments support the application of DFEs. This is consistent with the latest scientific opinion of EFSA NDA and the updated EU regulations [2]. The difference in bioavailability between folate and folic acid and the use of DFEs are concepts that are well accepted by nutrition professionals in Australia. Applying a minimum folic acid level for infant formula (to be consistent with Codex STAN 72-1981) does not represent the nutritional needs of infants, given infants have no requirement for folic acid *per se* (i.e. the synthetic form);and Codex STAN 72-1981 does not account for naturally occurring folate. Listing folate without applying the conversion factor for folic acid is misleading and would also lead to an underestimate of folate levels.

Consultation with paediatric dietetic professionals indicates that these professionals would assume that folate represents DFEs.

While the Food Standards Code has yet to be updated with the 2006 Nutrient Reference Values for Australia and New Zealand [5] and include the concept of DFEs, this does not provide sufficient justification to retain out-of-date and inaccurate values for folate. Changing the units to take into account the relative activities of the natural and synthetic forms of folate is also consistent with the approach FSANZ has taken for vitamin E.

Q1.11 Is it appropriate to amend the maximum phosphorus amount in Standard 2.9.1 to a GUL and align with the lower minimum Ca:P ratio? Please provide a rationale in support of your view.

The departments support amending the lower minimum calcium to phosphorus ratio to 1: 1 to align with Codex STAN 72-1981 (this is also consistent with the European regulations EU 2016/127).

The maximum phosphorus amount listed in Standard 2.9.1 (and Codex STAN 72-1981) is set higher than is needed (25mg/100kJ) to allow for the lower availability of phosphorus from soy-based formulas. The Scientific Committee on Food has recommended a maximum level of 17mg/100kJ [4]. We note that European regulations set separate minimum and maximum levels of phosphorus for soy-based formulas, to account for the reduced availability, rather than have these levels apply to all formulas. As soy-based formulas present a very small minority of the infant formulas on the market, **a separate phosphorus range for soy formulas should be provided**. The departments support this approach.

The departments do not support changing to a GUL to align with Codex given evidence exists of hypocalcaemia in neonates fed infant formula. While a number of factors, such as vitamin D deficiency, were implicated in some of the cases, it was concluded that the use of infant formula was associated with hypocalcaemia in neonates [6].

Q1.12 Should the GUL amount for vitamin C be increased to 17mg/100kJ? If not, is the current GUL in Standard 2.9.1 appropriate? Please provide a rationale in support of your view.

No. The departments support retaining the current GUL of 5.4mg/100kJ because, at this level, the losses of vitamin C quoted over the shelf life are unlikely to result in insufficient amounts of vitamin C for infants. The FSANZ nutritional assessment of vitamin C indicates that the amount of vitamin C in infant formula reduces over the shelf life; its losses are highest in liquid formulas (which are not routinely available outside hospital settings in Victoria) and typically range from 30-50 % (but up to 75% loss was also reported by FSANZ). It is noted that losses from powdered formula (most commonly used in Australia) are less but these have not been quantified.

If a formula contained the GUL of 5.4mg/100kJ vitamin C and the upper end of typical losses of 50% occurred, this would leave a vitamin C content of 2.7mg/100kJ, which is still above the minimum of 0.96mg/100KJ which EFSA NDA considered to meet the nutritional needs of most infants (by providing a level three times the amount needed to prevent scurvy) [2]. If a loss of 75% of vitamin C occurred, the resulting vitamin C content would be 1.35mg/100kJ which remains well above the level that EFSA NDA considered as sufficient for the majority of infants. Given most infant formula available is in powdered form, losses would be expected to be less than this. Providing a GUL amount that would take an infant's intake over the adapted upper level set by the U.S. Institute of Medicine [7], risks placing an unnecessary burden on infants' physiological systems.

In terms of the minimum permissions, **the departments support aligning with the Codex STAN 72-1981 level of 2.5 mg/ 100 kJ** given this provides an amount similar to that quoted in breastmilk (55 mg/day at this level versus 48mg/day in breastmilk [2]). Taking into account maximal losses (assuming losses in powdered formula will be lower) a loss of 50% would still provide 1.25mg/100kJ which is above the minimum requirement set by EFSA NDA.

Q1.13 Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.

No. The departments support aligning with the minimum iron permission of 0.1 mg/100 kJ in Codex STAN 72-1981 (providing 2.7mg/L). The recent EFSA NDA scientific opinion states that providing 2mg/L is adequate to maintain iron status for the first 6 months of life, and is supported by the theoretically calculated iron value for infant formula of 1.5mg/day based on iron concentrations in breastmilk and differences in absorption efficiency [2]. This is also above the required minimum set by European regulations which is 0.07mg/100 kJ (equivalent to 1.9mg/L).

We note that the level prescribed in Codex STAN 72-1981 provides an iron intake which is just below the Adequate Intake (AI) set by the NHMRC Australian New Zealand Nutrient Reference Values (once differences in absorption from infant formula are accounted for). However, the Australian and New Zealand Nutrient Reference Values (NRVs) were determined in 2005 and have yet to be reviewed. The 2014 EFSA NDA scientific opinion provides more current evidence for iron requirements.

The departments would like to emphasise that the setting of iron limits for infant formula should **use breastmilk and breastfed infants as the primary reference** (taking into

account differences in absorption efficiency), consistent with the Ministerial Policy Guideline on the Regulation of Infant Formula Products.

The approach taken by FSANZ appears to seek to address potential iron inadequacies in some populations by adding iron to infant formula above levels required for infants, when breastmilk and breastfed infants are used as the primary reference (after allowing for absorption differences). This approach implies that breastmilk from a well-fed mother does not have sufficient iron to support normal infant growth and development. Supplementing infant formula above the nutritional reference of breastmilk and breastfed infants to reduce iron deficiency anaemia in infants does not align with the Ministerial Policy Guideline and risks undermining breastmilk as the ideal and preferred source of nutrition.

Breastmilk has sufficient iron to meet the needs of infants until around 6 months of age, and as part of a progressive diversified diet that includes solid foods, until 12 months and beyond. There is no evidence that the prevalence of iron deficiency in populations is because breastmilk has inadequate iron, and is likely due to other factors such as inadequate dietary iron after 6 months of age and the relatively recent obstetric practice of early clamping of umbilical cords. A move to return to delayed clamping of umbilical cords where possible has begun with a 2013 Cochrane review supporting the practice and indicating that it results in reduced iron deficiency anaemia of infants [8]. Discussions with individual Victorian-based obstetricians indicate this has not yet become routine practice.

If iron deficiency is established to be a widespread issue in infants in Australia and New Zealand, then a comprehensive review of the causes and appropriate solutions is required by the appropriate body. **It is not appropriate to use infant formula as a treatment modality when there is no evidence that the cause of iron deficiency is due to inadequate amounts of iron in breastmilk or infant formula**. Given that studies cited by FSANZ indicate that formula-fed infants have better iron status than breastfed infants (due to the higher iron content of formula), continuing the practice of providing greater iron in formula than breastmilk could lead to the impression that formula is preferable to breastmilk. This also sets a future precedent to fortify formula with a substance above the levels found in breastmilk from well-nourished mothers (adjusting for bioavailability differences) in order to manage the nutritional status of infants.

As discussed by FSANZ, recent literature suggests that iron supplementation in iron-replete infants can lead to impaired growth and development and increased risk of infections. This indicates that caution should be taken when determining the appropriate iron levels in infant formula; these should aim to reproduce the iron intake of breastfed infants of well-nourished mothers.

The departments note that the recent recommendation by the ESPGHAN Committee on Nutrition for Infant Formula was a higher level of iron at 4-8mg iron/L (not 4-8mg/day as quoted in FSANZ proposal). However, this was not based on infant requirements but on the premise that most formula in Europe currently provided that level of iron and the prevalence of iron deficiency in Europe is currently very low, so it was considered appropriate to continue to provide these levels [9]. The paper also notes that studies show that feeding a formula at 2mg iron/L showed no significant difference in iron status at 6 months of age compared to infants fed formula at higher iron levels. The EFSA NDA also considered the ESPGHAN paper in their review and still concluded that a minimum level of 2mg/L was adequate [2].

Maximum level for iron

The maximum set in EU regulations 2016/127 is 0.31mg/100kJ (equivalent to 8.45mg/L), which is consistent with the upper range of iron found in European formulas. This limit was set using a risk based approach, taking into account overages (personal communication with EFSA). **The departments support aligning the maximum level**

with the EU regulations.

Iron limits for soy formula

We note that EU 2016/127 sets slightly higher levels for iron in soy formula due to the reduced availability. The departments support this approach.

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

The departments are yet to form a preferred view on the minimum and maximum limits for selenium in infant formula.

For the minimum amount of selenium, we note the variability in international regulations with Codex setting the lowest minimum level of selenium at 0.24µg/100kJ (similar to Standard 2.9.1 at 0.25µg/100kJ), followed by the U.S. at 0.48µg/100kJ and then EU at 0.72µg/100kJ.

The departments support an approach whereby the minimum level is comparable to the breastmilk concentration of a selenium-sufficient population. However, it is unclear what constitutes a selenium-sufficient population. The proposal indicates that the selenium concentration of Australian breastmilk is 10.7µg/L, providing 8.3µg/day (for an infant under 6 months), which would not meet the Australia and New Zealand Adequate Intake of 12µg/day (a level which is similar to the requirements set by the EU and the U.S.).

However, the studies reported by FSANZ have also noted that the selenium status of Australian infants, while lower than that for international infants, is not associated with any clinical or adverse effects, which casts some doubt on the requirements that have been set. We would like further information on whether the Australian population is considered to have a sufficient or insufficient selenium status.

We would also recommend careful consideration of setting a minimum amount of selenium that is above that provided by breastmilk from a selenium-sufficient population, as this risks positioning infant formula as a better source of nutrients than breastmilk. A rationale to permit setting a minimum amount above a comparable amount in breastmilk would have to be based on a recognition that the Australian population is deficient in selenium (that is, similar to the situation for iodine). The minimum amount should then be set on the estimated requirements and levels found in breastmilk from a selenium-replete population. This should be accompanied by a recommendation for consideration of broader initiatives to address selenium insufficiency for the population (and for breastfeeding women in particular).

Q1.15 Do you support moving the maximum [selenium] amount to a GUL? Please provide your rationale

We note that Codex sets a GUL for selenium that, as reported by FSANZ, represents a less restrictive maximum and potentially allows exceedance of the UL, however, there is an absence of data to indicate that the Codex GUL is unsafe.

While there is some debate internationally about the level that should be set as the UL, an UL currently exists for selenium in Australia, New Zealand and in the U.S. **The departments support retaining a mandatory maximum on the basis that generally a UL should not be exceeded**. The maximum set should be based on a level that results in intakes of selenium that are below the Australia and New Zealand UL of 45µg/day. We note the maximum level in the EU of 2µg/100kJ provides 44µg/day, whereas the Codex level of 2.2µg/100 kJ provides 48µg/100kJ. As the Codex maximum allows infants to exceed the Australia and New Zealand UL for selenium (and the U.S.

UL), and the EU maximum ensures intakes of selenium fall under this UL, **we support aligning the maximum level with the EU regulations**.

Q1.16 Do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL [for iodine]? Please provide your rationale.

Minimum level for iodine

The departments support setting a higher minimum amount of iodine to align with the EU regulations EU 2016/127 and the current scientific opinion of EFSA NDA (a level of 3.6µg/100kJ). This amount of iodine provides 86-118µg/day taking into account the quoted range of iodine in Australian water. This amount of iodine better meets the estimated requirements of infants, set as 90µg/day in the Australia and New Zealand NRVs or 70µg/day based on the most recent scientific opinion of EFSA NDA [2].

In comparison, the minimum level set in Codex STAN 72-1981 provides 63-95µg/day (including a water contribution of 8-40µg/day in Australia). The current level in Standard 2.9.1 of 1.2µg/100kJ only provides 34-66µg/day (allowing for water contribution).

We note the recent study quoted by FSANZ that indicated formula-fed infants in Australia have a sufficient iodine status (based on mean urine iodine levels) despite the minimum amount in formula not meeting the AI for iodine [10]. While this iodine status might be reasonably attributed to infants across South Australia, **we do not believe that it can be assumed that all formula-fed infants in Australia would have a sufficient iodine status, given iodine status (and water content of iodine) varies based on location.** Before iodine fortification, South Australia was one of the states in Australia that was considered iodine replete [11]. This would indicate that soil and water levels of iodine are likely to be higher in South Australia than other states with lower iodine status.

As 61% of the Australian population resides in states known to be iodine deficient prior to fortification (ABS September 2015 [12]) the results by Huynh cannot be assumed to apply to the majority of the Australian population.

Maximum level for iodine

Regarding changing the maximum permitted amount to a voluntary GUL and increasing it from 10µg/100kJ to 14µg/100kJ, the departments note the EU recently reduced their maximum amount to 6.9µg/100kJ on the basis of the UL of 200µg/day for one to three year olds. This level was set by the Scientific Committee on Food (SCF) in 2002 based on biochemical changes noted in thyroid-stimulating hormone levels [13]. While there is uncertainty with the extrapolation of this level to infants, FSANZ does not refer to this UL but notes that no UL has been set in Australia or in the U.S. The current maximum level in Australia would provide 218µg/day (226-258µg/day including water contribution), while the Codex maximum would provide 305µg/day (313-345µg/day with water).

On the basis that it is closer to the UL set by the SCF which is based on clinical effects, the **aligning with the EU regulations.** Given it slightly exceeds the UL quoted, the departments support retaining the mandatory maximum.

Q1.17 Can you provide data on the chromium levels in commercially available infant formula in Australia and New Zealand? This information can be provided as 'Commercial in confidence' if required.

N/A

Q1.18 Can you provide any data on the molybdenum levels in commercially available infant formula in Australia and New Zealand? This information may be provided as confidential commercial information.

N/A

Q1.19 What information can you provide on the phytic acid content of soy-based infant formula?

N/A

Q1.20 Are there any technical issues if the lower Codex minimum and maximum levels for copper were to be incorporated into the Code?

N/A

General comments on copper requirements

The FSANZ nutritional assessment has indicated that while the minimum level set by Codex STAN 72-1981 (8.5µg/100 kJ) provides only 186µg/day for infants and does not meet the daily requirement of 200µg/day, infants' copper needs are met by the additional copper present in Australian potable water (providing a total of 465µg/ day of copper once the formula has been made up). **While the departments support this approach for powdered formula, consideration needs to be given to the amount of copper in liquid, ready-made formula.**

In many Victorian hospitals it has become common practice to use liquid, ready-made infant formula to reduce the risk of bacterial contamination. We assume that even if manufacturers of liquid formulas use Australian water, they will align the final composition to the limits set in the Standard. If these formulas align with the minimum level in the Standard (as is generally desirable), then infants' requirements would not be met. **The departments suggest that a provision for liquid, ready-made formulas should be made, and that for liquid formula, the current minimum of 14µg/100kJ should be retained.**

Q1.21 Should a Zn:Cu ratio be retained. If so, what should it be and why? If not, what is your rationale?

The departments do not have a firm position on the Zn:Cu ratio. We note that neither Codex STAN 72-1981 nor the recently updated EU 2016/127 address the need for a Zn:Cu ratio. We note that breastmilk has a Zn:Cu ratio of 10:1 and **support the principle that infant formula should be primarily based on the composition of breastmilk**. FSANZ's nutrition assessment did not provide information on the ratio of Zn:Cu in formula currently on the Australian market. If formula already provides a similar ratio of Zn:Cu to breastmilk, and this would not change with any changes in the levels set for copper and zinc, then a Zn:Cu ratio would probably not be required.

General comments on Zinc

The minimum levels for zinc are aligned across Standard 2.9.1, Codex STAN 72-1981 and EU 2016/127, but we note the maximum levels vary considerably at 0.43, 0.36 and 0.24mg/100 kJ respectively. The UL is currently 4mg/day for infants aged 0 to 6 months. The Standard 2.9.1 level results in daily intakes of 9.4mg/day, Codex results in an intake of 7.8mg/day and the EU regulations result in an intake of 5.2 mg/day. The EU value was previously aligned with Codex and reduced recently. **The departments support aligning with the EU 2016/127 level** given this is the closest to the UL, and this level was determined recently, based on a risk based approach, taking into account technical considerations (EFSA personal communication).

We note that EU 2016/127 lists separate limits for formula based on soy protein for iron phosphorous and zinc, due to the reduced availability of these nutrients. **The departments support this approach.**

Additional comments on micronutrient composition

Vitamin K

The departments note that vitamin K is not being reviewed as it met the assessment criteria and there was no scientific evidence that the amount should be changed. **The**

2014 EFSA NDA opinion (now legislated in EU 2016/127) recommended reducing the minimum vitamin K content to 0.24µg/100kJ as this level meets the levels of vitamin K considered adequate [2]. Given minimum values are designed to cover the nutritional needs of virtually all healthy infants, **the departments would support aligning the minimum level of vitamin K with EU 2016/127**. Being lower than current permissions, reducing the minimum level would have minimal impact on the infant formula industry.

Biotin

Similar to the situation for vitamin K, FSANZ did not review biotin in P1028. **The departments note EU 2016/127 has reduced the minimum level of biotin to 0.24µg/100kJ** (compared to the current permitted range in Standard 2.9.1: 0.36 – 2.7µg/100kJ) based on the recommendation by EFSA NDA and justification that this level meets the nutritional needs of most infants [2]. **The EU 2016/127 has also set a lower maximum level of 1.8µg/100kJ, and this should be considered as part of this review**.

Vitamin E

The departments support changing the units used for vitamin E from mg alpha-tocopherol to mg alpha-Tocopherol Equivalents to take into account the relative activities of natural and synthetic forms of alpha-tocopherol.

The departments support FSANZ's approach to retaining the requirements in Standard 2.9.1 for vitamin E relative to polyunsaturated fatty acid content rather than adopting the Codex STAN-72 factors of equivalence, given that this has minimal effect on the levels prescribed.

Vitamin D

The departments support retaining the current permissions for vitamin D. We acknowledge that recent international expert panels have recommended higher minimum levels of vitamin D, in order to meet the requirements of infants with minimal sunlight exposure [2]. Recommendations for vitamin D will be influenced by local conditions (e.g. sunlight exposure) and these international recommendations have occurred in areas with lower levels of sunlight exposure than Australia. While vitamin D-deficiency rickets has been measured in high risk infants in Australia, it is recommended practice (in Victoria) for any high risk infant to start vitamin D supplementation within a few days of birth. High risk infants include those that born at < 37 weeks gestation; babies with birth weight < 2kg; dark skinned babies (even if maternal vitamin D levels were normal in pregnancy); babies of mothers with known vitamin D deficiency in pregnancy and babies of untreated mothers who had been at risk of vitamin D deficiency in pregnancy [14]. Thus **we do not deem it necessary for infant formula to address the vitamin D needs of these infants.**

In terms of permitted forms of vitamin D, we note that Codex does not permit vitamin D_2 due to uncertainty about its bioavailability in infants. FSANZ has provided evidence that is largely based on studies that are not relevant to infants, and relied on a single study that provided vitamin D in supplement form well above the amount provided in formula. **The departments do not support retaining vitamin D_2 permissions unless there is clear evidence that the amounts present in infant formula are equally bioavailable as D_2 or D_3**.

Thiamin

FSANZ did not review thiamin. **The departments support aligning the minimum permission for thiamin with EU 2016/127 rather than with Codex**. EU 2016/127 sets a level of 9.6µg/100kJ (similar to the current permission in Standard 2.9.1), which provides 209µg/day. This is consistent with the adequate intake of thiamin (200µg/day) and the amount present in breastmilk. By aligning with the Codex minimum, which is a

level well above the adequate intake, there is a risk of adding unnecessary nutrients to formula and placing a burden on infants' systems.

Riboflavin

FSANZ did not review riboflavin. Similar to the situation for thiamin, **the departments support aligning with the EU 2016/127 level of 14.3µg/100kJ** rather than aligning with the Codex STAN 72-1981 level of 19µg/100 kJ. This level would provide infants with 312µg/day of riboflavin compared with 414µg/day that would apply under the Codex Standard. The adequate intake of riboflavin is 300µg/day. The Codex range would provide 414 – 2594µg/day, which is well above the usual amount received from breastmilk and risks placing an unnecessary burden on infants' systems.

We note that the maximum limits set in Australia, for Codex and in Europe all differ: 86, 95.6 and 119µg/100kJ respectively. Without information on the losses of riboflavin over the shelf life of infant formula, **the departments would support aligning with the more recently set EU value of 95.6µg/100kJ**.

Vitamin B6

FSANZ did not review vitamin B6. The **departments support aligning the minimum level of vitamin B6 with the EU regulations 2016/127 level of 4.8µg/100kJ** as this represents the level required by infants and is consistent with the average amount found in breastmilk. Adopting the higher minimum in Codex STAN 72-1981 (8.5µg/100 kJ) would provide unnecessary amounts of vitamin B6.

Given the similarity between the maximums set by Codex and in the EU, aligning with the Codex value of 45µg/100kJ would be acceptable.

Section 8 - Permitted forms of vitamins, minerals and electrolytes

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

The departments recommend aligning with Codex and EU regulations and not permit β-carotene to be included in the calculation of vitamin A activity due to uncertainties regarding the bioavailability of β-carotene in infants. Therefore β-carotene should not be retained as a provitamin A form. Given there is no specific nutritional requirement for β-carotene in infants, there should be no specific permission to add β-carotene to infant formula products.

Maximum limit for vitamin A

The departments note the EU has recently lowered the maximum level for vitamin A from 43µg RE (Retinol Equivalents)/100 kJ (aligned with Codex and Standard 2.9.1) to 27.2µg RE/100 kJ, taking to account the UL of 800µg RE/ day set for one to three year olds, based on the risk of hepatotoxicity and teratogenicity extrapolated to children [2]. We note that FSANZ quoted a study by Maclean *et al* 2010 that showed concentrations of vitamin A in infant formula in Europe at the time provided 27-36µg RE/100kJ, which exceeded the UL (but was still below the Australia and New Zealand maximum). These levels were not associated with observed adverse effects. However, this observation should be qualified as it does not appear that studies were performed to assess any adverse effects from consuming levels of vitamin A above the UL. As infant formula available in the EU is now required to have a vitamin A level below 27.2µg RE/100kJ and that generally the ULs are not intended to be exceeded, **the departments support lowering the vitamin A maximum to 27.2 µg RE/ 100 kJ to align with the EU**.

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

N/A

Section 9 – Other optional substances

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

Yes. However **the departments support setting a minimum level of 6mg/100kJ, which aligns with the level set in the EU regulations 2016/127** (and supported by the EFSA NDA scientific opinion). This level provides 130mg/day which would meet the Australia and New Zealand AI of 125mg/day for choline and is consistent with the average amount found in breastmilk of 128mg/day [2]. FSANZ has not, in the departments' view, provided sufficient justification for retaining the lower amount of 1.7mg/100 kJ when this provides only 37mg/day (thus meeting only a third of the requirement for choline). FSANZ's justification for providing insufficient amounts of choline appears to be based on its view that companies will be more likely to provide the midpoint in the permitted range so setting a higher level in a standard is not required. This is not consistent with the approach taken for other nutrients and risks permitting infant formulas that do not meet the essential nutritional needs of infants. FSANZ also indicates that there is an absence of evidence showing choline insufficiency in the ANZ population with the current permissions, however there is no indication that studies have been performed to assess choline sufficiency in Australian and New Zealand infants fed formula at the minimum level.

The departments support FSANZ's preliminary view to align with the Codex maximum of 12mg/100 kJ and to make this **mandatory**.

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

N/A

Q1.26 If you have provided a technological justification for these forms of choline can you provide:

(a) reference to a specification for choline citrate and/or choline hydrogen tartrate in an internationally accepted monograph of specifications (including those referenced in Standard 1.3.4)?
N/A

(b) evidence to demonstrate safety can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?
N/A

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

Yes. The departments support FSANZ's proposed range of 0.3 – 0.8 mg/100 kJ as this is consistent with the level found in breastmilk and the amount considered adequate for infants. This also aligns the minimum level in Codex STAN 72-1981 and EU 2016/127. We note that neither Codex nor EU regulations set a maximum level but support FSANZ's approach on the basis of uncertainty around the safety of excess L-carnitine.

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

N/A

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?

N/A

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

Yes. The departments note in FSANZ's nutritional assessment that dietary inositol (that is, from milk) is required to meet infants' metabolic requirements, in addition to that which is made endogenously. However, it is noted that the minimum level set in both domestic and international regulations is well below the amount typically found in breastmilk (providing approximately 20mg/day from infant formula versus the lower range value of 104mg/day found in breastmilk). It would appear **prudent to align the amounts in formula with those found in breastmilk (130 mg/L), and the departments would like FSANZ to explain why this is not desirable.**

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

Yes.

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

The departments do not believe there to be any issues with the clarity of the revised Code for nucleotides.

General comments on optional substances

The departments recognise that the addition of optional ingredients is intended to encourage industry to innovate to improve infant formula and move the health outcomes of formula-fed infants closer to breastfed infants. Consideration should be given to managing these optional ingredients within the regulatory framework to enable routine reviews of the evidence supporting their use. Where this evidence does become available for optional ingredients, the regulatory framework should support timely updates to the composition requirements in the Code to ensure all infants can benefit from innovations in infant formula.

Supporting Document 2 – Safety and Food Technology

The departments have considered the issues raised by FSANZ in Supporting Document 2 on Safety and Food Technology. Comments on FSANZ's preliminary views to the issues and responses to the questions posed are provided below.

Section 3 – Preparation, use and storage directions to manage microbiological hazards

Direction to prepare bottles individually

The departments support FSANZ's preliminary view to retain the labelling requirement to direct caregivers to prepare bottles individually. The departments agree that this assists in addressing microbiological safety as well as reducing the risk of incorrect proportions of formula to water being used. As stated, it is also consistent with the *WHO Guidelines - Safe Preparation, Storage and Handling of Powdered Infant Formula 2007* [15] and the infant feeding guidelines for Australia [16] and New Zealand [17].

Directions for the storage of made up formula

The departments support FSANZ's preliminary view to retain the current requirement to include a direction instructing that if a bottle of prepared formula is to be stored before use, then it must be refrigerated and used within

24 hours. We note this is consistent with the Australian and New Zealand guidelines [16, 17] (and the WHO Guideline [15]) and FSANZ's rapid evidence assessment.

Directions on water used to reconstitute powdered infant formula

The departments support FSANZ's preliminary view to retain the current requirement to use cooled, previously boiled water given there are no health and safety concerns and this is consistent with the Australian and New Zealand infant feeding guidelines [16, 17] and scientific opinion, as described by FSANZ.

Discarding leftover formula

The departments support FSANZ's preliminary view to retain the requirement for instructions to discard formula left in the bottle to reduce the risk of microbiological hazards.

Standardised directions for preparation and use

The departments are not aware of evidence to support a clear stance on whether to prescribe instructions for 'preparation and use' or to retain the current requirement that does not prescribe the wording and pictures for the instructions.

The departments note the comments by a consumer group that supported standardised wording particularly to aid those who are disadvantaged socioeconomically or with a lack of health literacy. The departments note that the lack of prescribed wording for the storage of prepared formula has led to a range of conflicting instructions on different formula, which is likely to confuse caregivers.

We also note that industry likes the flexibility of the current (non-prescribed) requirements and have stated it is not clear to them what benefits prescribed wording and/ or pictures would provide for consumers. While the departments support providing flexibility for manufacturers, we also acknowledge that the primary aim of providing directions for preparation and use is to ensure that all caregivers can safely prepare infant formula using the instructions on the tin. If there are reports that some groups of consumers find the variety in instructions between brands confusing, then consideration should be given to clarifying these instructions, which may include prescribed wording.

Section 4 – Other safe preparation and storage issues

Q2.2 For all views presented in section 4, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons and evidence as appropriate. If not, indicate this in your submission and provide your reasons including further relevant evidence, current practice, impact on manufacture, or other relevant information.

Date marking of food

The departments support FSANZ's preliminary view to maintain the existing requirement for date marking to appear on all infant formula.

Storage instructions for opened infant formula

The departments support FSANZ's preliminary view that the current requirement for storage instructions covering the period after the product has been opened is appropriate.

Measuring scoop

The departments would like the issue of scoop sizes and dilution recipes to be considered further. It appears that there are two different issues relating to unintentional errors when changing formula:

1. Different scoop sizes; scoops from one brand may be incorrectly used with another formula.

2. Different recipes of ratio of formula to water; most brands advise either 1 scoop to 30 mL of water or 1 scoop to 60 mL of water. If a caregiver is familiar with one recipe, they may incorrectly prepare a new formula by using the wrong recipe, even if they use the correct scoop supplied with the tin.

The departments note that industry states that due to differences in bulk density of products that a standardised scoop size is not possible without extensive reformulation.

The departments note the dearth of formal evidence about the misuse or misunderstanding of the differences in scoop sizes and recipes between products despite consistent anecdotal reports from health professionals about issues with varying scoop size. We also note there is no discussion of the impact of varying scoop size and recipes for preparing formula on low literacy or non-English speaking groups. For example, recent discussions with health professionals have indicated that in some indigenous communities, where literacy levels are low, the varied scoops and recipes are problematic and caregivers are instructed to use only one brand of formula and are verbally taught how to prepare this formula by maternal health nurses. However problems can often arise when caregivers change the formula and are unable to read the tin to determine that a different ratio of water is required.

Caregivers with the lowest levels of education and socioeconomic status are less likely to initiate and continue to breastfeed (and therefore are more likely to use infant formula) [18]. Discussions with the Victorian Maternal and Child Health Line[3] service have also indicated that some caregivers, particularly those with financial difficulties, take advantage of infant formula brands that are on sale and as such may be more likely to switch brands. The departments suggest the safe and appropriate preparation and use of infant formula by these groups is considered in reviewing scoop use and recipes.

The departments have also been informed that clinical paediatric dietitians will often use the same quantity of infant formula, irrespective of brand, to fortify breastmilk when required. For example, a standard fortification recipe is 1 metric teaspoon of infant formula per 100 mL of breastmilk. It is considered by paediatric dietitians that this provides sufficiently similar nutrients regardless of the brand of formula.

In order to better understand the obstacles for industry in achieving standardised scoop sizes and recipes, the departments would like industry to provide more information on the differences in bulk density and energy density between different brands. Specifically we would like to know, for a set quantity of formula, how much the nutrient content actually varies, and whether the variation in nutrient content is greater than would occur naturally over the shelf life of the product. We would also like more information about how it is that infant formula companies in the UK have a standard preparation ratio of one scoop of formula to 30 mL of water, despite not being regulated, while this is unable to be achieved in Australia.

If standardised scoop sizes are not possible, **the departments suggest consideration be given to requiring a consistent ratio of formula to water recipe across all brands** (e.g. 1 scoop to 30 mL), as is seen in the U.K., to simplify infant formula preparation and ultimately reduce the risk of errors. This would require changing the scoop sizes in some formula (for example a scoop size in a 1 scoop to 60 mL formula would need to be halved in size if a consistent 1 scoop to 30 mL was to be instituted) but would not require reformulation of the product itself.

Section 5 – Warning, advisory and other statements

Legibility requirements for warning statements

The departments do not have any information on inadequacies of the current legibility requirements.

[3] http://www.education.vic.gov.au/childhood/parents/support/Pages/mchline.aspx

Q2.3 What evidence can you provide that could be used to estimate the prevalence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand?

Recent consultation with the Victorian Maternal and Child Health service indicates that the addition of foods to infant formula is an ongoing issue with some caregivers. For example, reports were given of caregivers adding rice cereal to both infant formula and expressed breastmilk fed by bottle. Reportedly, it was not more common in any particular cultural group, and occurred for feeding infants of 6 weeks of age and onwards.

Some cultural groups reportedly hold beliefs about particular foods and their benefit for the baby. One example given was that arrowroot biscuits traditionally have been favoured by some carers in the Greek-Australian community to add to infant formula in the quest to achieve a desirably fat baby. The arrowroot biscuits made of wheat flour, arrowroot flour, sugar and other common ingredients dissolve easily into the milk.

Another example was the addition of brown sugar to infant formula. The Maternal and Child Health service noted that babies fed infant formula can become constipated. Feeding infants brown sugar with water is often recommended by maternal nurses as a one-off method to relieve this condition. Carers sometimes continue to add brown sugar to feeds of infant formula in the mistaken belief this will prevent further constipation.

Anecdotally, the practice of adding food is considered to be widespread. The departments are, however, unable to provide evidence to estimate the prevalence of caregivers adding other foods to infant formula at this stage.

The departments support a warning statement instructing any caregivers not to add anything to formula, similar to the approach taken for 'ready to drink' formula.

Q2.4 What evidence can you provide as to whether this practice is more common with powdered infant formula products compared to liquid concentrate or 'ready to drink' products?

We are not aware of any evidence indicating whether the practice of adding other foods to infant formula is more common for powdered infant formula products or liquid concentrate or 'ready to drink' products. It should be noted that liquid concentrate or 'ready to drink' infant formula products are not widely available in the Australian market at present.

Q2.5 What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?

Anecdotal evidence from discussions with dietitians and members of the Victorian Maternal and Child Health service indicated that caregivers can add other foods to infant formula, or dilute the formula, to reduce the cost of the feed. It may prove difficult to estimate the prevalence of this cost-saving strategy as primary carers of infants can be reluctant to offer information about food insecurity to maternal and child health nurses and to researchers, as caregivers may feel it suggests a lack of care. Food insecurity in Australia is widespread, with 1 in 20 people living in metropolitan Melbourne experiencing it at some stage [19].

Certain groups experience food insecurity at a higher rate than the general population including: indigenous people (24%); unemployed people (23%); single parent households (23%); low-income earners (20%); rental households (20%); and young people (15%) [20]. Caregivers from lower socioeconomic groups and young age groups are overrepresented in those who use infant formula, with Australian surveys consistently indicating that breastfeeding rates are lowest (and therefore formula feeding

rates highest) at birth and up to 12 months in those in the lowest quintiles for socioeconomic status and age and for single parents [18].

With the cost of a typical 900g tin of powdered infant formula ranging from $15-$30 and infant consumption (0-6 months old) relying on approximately one to two tins a week, food insecurity could contribute to practices such as adding other foods to reduce the cost of the feed, or extending the feed.

Statement on protein source

The departments support FSANZ's preliminary view to maintain the current requirement to label the protein source to enable caregivers of infants with allergies or intolerances to correctly identify suitable products.

As discussed under SD1, **and in contrast to FSANZ's view, the departments believe that Standard 2.9.1 should mandate a list of permitted protein sources**, as occurs in the EU. If specific permitted protein sources are not listed, this enables new protein sources to be used without pre-market assessment, which is not consistent with the Policy Guideline on the Regulation of Infant Formula Products. Soy protein is known to contain substances that interfere with the absorption of nutrients, and measures are taken to address this. Other sources of protein may present similar issues. For this reason it is important that new protein sources also undergo independent (rather than manufacturer-based) pre-market safety and suitability assessments.

Q2.6 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?

The departments have no evidence that caregivers have difficulties finding protein source information. However, in reviewing leading brands of infant formula available for purchase, it is apparent that (to the lay person) the plethora of information in small type can be confusing and difficult to read. With new Country of Origin Labelling laws requiring an additional logo on infant formula products, this is likely to pose further issues for the clear presentation of information for consumers.

Q2.7 What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?

The departments have no specific evidence to demonstrate the benefit of such consistent placement. However, it is reasonable to assume that a consistent location of the protein source information would enable caregivers to find this information more easily.

Q2.8 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?

The departments support FSANZ's preliminary view to retain the existing requirement that the protein source statement must be immediately adjacent to the name of the food. Further consultation with caregivers is required to determine whether the position of the statement of protein source on the label should be prescribed.

Q2.9 What are the cost and trade implications of prescribing the position of the statement of protein source on the label?

N/A

Warning statement about following instructions directly

As previously discussed, **the departments support extending to powdered formula the requirement for the warning to not add anything to formula** (currently only on ready-to-drink formula). The department supports consistency in the Food Standards Code regarding warning statements about the importance of following instructions directly for both ready-to-drink and powdered infant formula.

Warning statement that 'breast is best'

The **departments support FSANZ's preliminary view to retain the current 'breast is best' warning statement** rather than change to a risk-based statement about the risks to infant health of not breastfeeding. While the departments do not necessarily agree with the reasons provided by FSANZ, there is insufficient evidence to support changing the statement at this time.

Statement that infant formula product may be used from birth

The **departments support FSANZ's preliminary view to maintain this statement**.

Statement about age to offer foods in addition to formula

We **support FSANZ's preliminary view to retain this statement without change** given it is consistent with Australian and New Zealand infant feeding advice.

Guidance statement about additional vitamin and mineral supplementation

The departments note that FSANZ will be considering this issue in greater detail in a future report. We await more detailed discussions before forming a view on the relevance of the voluntary advice on labels that vitamin or mineral preparations are not necessary. However, in forming its view, FSANZ should consider the amount of vitamins and minerals provided by infant formula, given that the minimum level usually represents the amount that meets the needs of virtually all healthy infants, and that infant formula will usually provide more than this. This should also be considered in the context of the position provided by EFSA NDA and ESPGHAN that excess amounts of substances can be a burden on infant systems [1, 2].

Q2.10 What evidence can you provide on the prevalence of vitamin and mineral preparation use by Australian and/or New Zealand infants, either with or without medical supervision?

At the 2016 national Dietitians Association of Australian conference, data was presented by Curtin University on the prevalence of supplement use in Australia using data from the 2011 Australian Health Survey. With a sample size of 742 infants, the data indicated that 8% of female and 6% of male infants aged 0- 12 months used vitamin supplements (O'Brien *et al*, unpublished). There are also two Victorian-based research projects looking at nutrition in infants: the Barwon Infant Study and the Melbourne InFANT (Infant feeding activity and nutrition trial). These researchers may also have data on vitamin and mineral supplementation in infants.

Q2.11 Is the prevalence of vitamin and mineral preparation use higher in formula-fed infants than breastfed infants (or vice versa)?

The departments are unable to provide information on this.

Q2.12 What data are available on intake levels of vitamins and minerals for Australian and New Zealand infants due to use of supplements (in addition to their normal diets)?

The departments cannot provide evidence on this but recommend that FSANZ directly contact researchers in this area who may have data (published or unpublished).

Q2.13 What advice is given by health care professionals and/or state and territory government agencies on whether vitamin and mineral supplementation is needed for formula-fed (or breastfed) infants?

Government endorsed websites that provide information on infant feeding, such as the Victorian Better Health Channel and the Raising Children Network do not state whether vitamin and mineral supplementation should, or should not, be given to formula-fed or breastfed infants.

Discussions with paediatric dietitians and maternal and child health care nurses indicate that supplements would not normally be recommended for infants unless there was a

specific reason to do so (for example the infant being in the category for high risk of vitamin D deficiency). However we have no information on the advice offered by health practitioners working in complementary medicine.

A recent Australian study indicated that the largest reported information source for infant feeding was relatives and friends (78%) compared with 69% seeking advice from health care professionals. The television and internet were also significant information sources [21]. As such, vitamin and mineral supplementation practices may not be driven by health care professionals' advice.

Q2.14 What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?

N/A

Prescribed name

The **departments support FSANZ's preliminary view to retain the prescribed name, 'infant formula'**.

Section 6 – Nutritive substances and novel foods in infant formula

Q2.15 Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

The **departments support the overarching regulatory approach for infant formula that is outlined in Ministerial Policy Guideline on the Regulation of Infant Formula Products**. Specifically, this guideline recognises that there is a greater level of risk to be managed with infants compared to other population groups and therefore the regulatory framework for infant formula products should include requirements commensurate with this level of risk.

Policy principle (i) sets out the expectations of Ministers in relation to the pre-market assessment of substances being added to infant formula:

(i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that:

i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or
ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.

This principle should underline the regulatory approach taken to the addition of new substances to infant formula. The departments note FSANZ's assessment that the approach taken to pre-market assessment in Australia is similar to that in other similar economies.

We note regulatory clarity may be needed due to a variety of interpretations that are being made about permissions for the addition of substances. For example, FSANZ has noted that subclause 6(1)(b) permitting substances *naturally present in an ingredient of the infant formula product* has been taken to mean that a nutritive substance that occurs naturally in milk can be extracted, purified and added back in to milk, either at the level naturally found or at higher levels. The **departments' view is that the intention of subclause 6(1)(b) was to prevent the unintentional requirement that the individual components of milk, that naturally occur in infant formula when milk is used as the base, would need to be assessed**. However, it is our view that a new extraction and re-addition of a substance from milk, for the purposes of innovation for a specific nutritional or physiological purpose, is not consistent with the original intention

of subclause 6(1)(b) and such processes should be subject to pre-market assessment of safety and suitability.

The departments would also like further discussion on ensuring substances that are not "nutritive", but are added for a physiological or health effect rather than technical function (such as fibre) **are captured in the requirement for pre-market assessment**.

The **departments support FSANZ's plan to consider the regulation of nutritive substances and novel foods for infant formula separately to P1024, which considers these regulations for the general food supply**. The vulnerability of infants in terms of immature physiological systems, and the significant consumption of infant formula by its users, requires that such additions of new substances be considered separately from those for the general food supply. However, it is important that, in the development of P1028 and P1024, consideration is given to ensuring consistency of terms across the Code.

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

N/A

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

While the departments support a precautionary pre-market assessment approach as outlined in the Policy Guideline, we have been made aware that infant formula manufacturers are concerned that any short term, minor ingredient changes caused by supply issues may not be possible if an all-encompassing prohibition on new substances is required. The **departments would support in principle allowing the substitution of otherwise identical substances as we would not necessarily consider these as new substances**. We believe this is consistent with the Policy Guideline where only those substances with a different form or structure, or made by a substantially different technique, would need pre-market assessment.

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

We would require further information from infant formula manufacturers on minor ingredient changes to determine how these substances might be characterised and permitted without pre-market assessment, while ensuring their safety and suitability for infants.

Section 7 – Contaminants

Q2.19 What evidence can you provide as to whether this proposed ML (Maximum Level) would/would not be achievable in soy-based formula? Reference should be made to relevant concentration data in soy-based formula products where possible.

N/A

Q2.20 What are the cost and trade implications of reducing the ML for aluminium in soy-based formula?

N/A

Q2.21 What are the cost and trade implications of reducing the ML for lead in infant formula?

N/A

Q2.22 What if any, issues are associated with not including the Codex ML in the Code for melamine?

The departments are not aware of any issues at this time.

Q2.23 Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.

The departments support FSANZ's preliminary view to apply all MLs for infant formula to a reconstituted ready-to-feed form, rather than to a product prior to drying, dehydration or concentration. We assume this would account for any contaminants typically present in Australian potable water.

Q2.24 Should the contaminant definitions for the contaminant which apply specifically to infant formula (aluminium) be addressed as part of a future review of Standard 1.4.1?

No, in line with FSANZ's preliminary view **they should be addressed now as part of P1028.** The contaminant definitions are critical to provide clarity regarding the analyte in question.

We also support moving the MLs for aluminium from Standard 2.9.1 to Standard 1.4.1 Schedule 19-4. This then provides a contaminant definition for aluminium which would include each chemical species of aluminium.

Q2.25 Should the contaminant definition for those substances which apply to general foods, including infant formula, be considered later as part of a review of metal contaminants in standard 1.4.1?

Yes, in line with FSANZ's preliminary view. This agreement is contingent on the MLs for aluminium in infant formula products being moved to Schedule 19-4 under Standard 1.4.1.

Section 8 – Food additives

Q2.26 What is the technological purpose for using the following 12 substances in the production of infant formula – INS 339i, 339ii, 339iii, 340i, 340ii, 340iii, 500i, 500ii, 501i, 501ii, 524 and 525? i.e. are they best described as food additives, processing aids or permitted forms of minerals? Please explain and provide examples of how they are used in the manufacture of infant formula.

N/A

Q2.27 What justification can manufacturers and suppliers of infant formula in Australia and New Zealand provide to expand the permission for the food additive citric and fatty acid esters of glycerol (INS 472c) to all infant formula?

N/A

Q2.28 What, if any, information can you provide to support an assessment of an extension of use of a food additive in infant formula?

N/A

Q2.29 To what extent is 472c used in IFPSDU? Is it widely used, and are the levels used close to the maximum permitted level in the Code?

N/A

Q2.30 What, if any issues would a lack of consistency in the nomenclature of food additive names for infant formula cause?

The departments do not envisage any significant issues associated with the lack of consistency with Codex. However, alignment with Codex is desirable but should be considered as part of a full review of the regulation of food additives.

Q2.31 Will lowering the MPL of hydroxypropyl starch to 5000mg/L create any

difficulties for infant formula companies?

N/A

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

No. The **departments support FSANZ's stated preliminary view that the carry over principle should not apply to infant formula**.

We consider this to be consistent with the initial intent of Standard 1.3.1 and also with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) opinion that children should not be exposed to food additives before the age of twelve weeks, and that the Acceptable Daily Intake (ADI) does not apply to children below the age of 12 weeks. The EC Scientific Committee on Food endorsed the general principle that technological additives should not be used in food for infants and young children (2006).

Under the previous Code (Standard 1.3.1, Schedule 1 under 13.1 – Infant formula products), it was stated that '*Additives in Schedules 2, 3, and 4 must not be present in infant formula products unless expressly permitted below'*. This differs from certain other products where the wording is, '*Additives in Schedules 2, 3, and 4 must not be added to…*' However, this prohibition appeared to be contradicted by the carry over provisions in clause 7 of Standard 1.3.1.

The revised Code does not include the phrase 'must not be present'. The current provision under Section 1.1.1 - 11 states:

> '*(6) Unless expressly permitted by this Code, food for sale must not have as an ingredient or a component, any of the following:*
>
> *(a) a substance that was *used as a food additive;'*

In our view, this wording allows for the carry over provision to apply to infant formula. This should be addressed.

Q2.33 Is there a technological justification for permitting carrageenan in liquid soy-based infant formula products?

N/A

Q2.34 Do submitters believe the current permissions in the Code permit carrageenan in soy-based infant formula?

The departments' view is that, as it is currently worded, the Code does not permit carrageenan in soy-based infant formula. We would support the use of carrageenan in any infant formula as per the JECFA 2014.

Q2.35 Will the correction of the hydroxypropyl starch Maximum Permitted Level (MPL) to the lower level of 5000 mg/L cause any issues? Are you aware of any infant formula marketed in Australia and New Zealand that uses hydroxypropyl starch as a food additive at levels above?

N/A

Supporting Document 3: Provision of Information

The departments have considered the issues raised by FSANZ in Supporting Document 3 – Provision of Information. Underpinning our comments is the understanding that innovation by infant formula companies is important to enable infant formula to improve and achieve health outcomes closer to those of breastfed infants. However, care needs to be taken to ensure that infant health outcomes, rather than marketing strategies, remain the central purpose of innovation for infant formula. This is consistent with the

Ministerial Policy Guideline on the Regulation of Infant formula which places the health and safety of infants, and the recognition that breastfeeding is the normal and recommended way of feeding infants, at the centre of decisions for infant formula regulation. Comments on FSANZ's preliminary views to the issues and responses to the questions posed are provided below.

The differentiation of infant formula from other products on the market

The departments note that FSANZ is not considering the issue of "line marketing" (the labelling of infant formula as stage 1, follow-on formula as stage 2 and toddler milk as stage 3) because it involves products other than infant formula. However, consideration needs to be given within P1028 to ensuring that infant formula is **sufficiently differentiated** from other products to ensure a safe and appropriate formula can be chosen for infants. Anecdotal evidence suggests that caregivers can mistakenly choose the wrong stage of formula because the tins are almost identical. This could represent a safety issue. The difficulties in differentiating between infant formula and other products for older infants is also demonstrated by research that shows consumers fail to distinguish between advertising for infant formula and for toddler milk because of the similarity in packaging [22].

Section 2 Issues under consideration

Claims about ingredients

Q3.1 Should claims about specific ingredients be permitted on packaged infant formula? If no, then why not? If yes, then how should they be regulated?

The **departments are of the view that if ingredients are added to an infant formula for a nutritional reason or a health effect, as opposed to a technological function, then label claims made about these ingredients are for all intents and purposes nutrient content or health claims**.

The current position in the Code is that nutrient content and health claims are prohibited for infant formula, with the exception of a limited number of content claims to identify formula appropriate for specific conditions or disorders. This regulatory stance is consistent with the principles outlined in the Ministerial Policy Guidelines for Nutrient, Health and Related Claims, and for the Regulation of Infant Formula Products.

The departments support the ongoing restriction of nutrient content and health claims in infant formula for the following reasons:

1. *Health claims:*

   Health claims on foods have a specific purpose that cannot be applied to infant formula products. An adult diet comprises many different foods and eating patterns can vary greatly. Nutrition claims on foods are designed to highlight certain ingredients and health effects to help consumers select those foods that will benefit their individual health. Infants who are not breastfed must consume infant formula products which are *all* formulated to meet the essential nutrient requirements of infants. Development is a normal event during infancy and consumers have a basic expectation that consumption of any infant formula will lead to health outcomes such as brain, eye or immunological development.

   Highlighting an individual health effect on certain infant products implies that the developmental effect is specific to that product and may mislead consumers to believe that normal development will not occur unless they consume this product, or that heightened development will occur with this product. This differentiation could be misleading if it is not based on sufficient evidence or if the consumer does not have enough information to correctly interpret the claim in relation to other products available. This practice appears to be particularly common to optional ingredients.

Health claims are used predominantly to highlight optional ingredients in premium products as a point of difference. Compared with nutrients that are deemed essential for infants, there is insufficient evidence to support the need for these optional nutrients. Therefore highlighting these ingredients could be considered the provision of misleading information rather than providing informed choice.

Health claims on infant formula products risk undermining health messages about breastfeeding by minimising the differences between infant formula and breastmilk, presenting infant formula as a healthy, benign alternative to breastmilk [22]. Studies have shown that women who are more comfortable with the idea of formula feeding are less likely to intend to breastfeed [23]. With Australia's breastfeeding rates at a record low it is imperative that the marketing of infant formula products does not counter national efforts to increase breastfeeding rates.

2. *Content claims*

Content claims place a disproportionate emphasis on individual components contained in formula, particularly those not considered essential for infant growth and development. Highlighting individual ingredients suggests to carers that a specific formula can be chosen to suit their child's nutritional needs. This implies that some infants have a different requirement for these individual ingredients, or will benefit from consuming them, which is misleading in the absence of convincing evidence.

While the highlighted ingredients attempt to mimic similar components in breastmilk, content claims do not make it clear that they usually do not result in the same health outcomes as the same ingredients found in breastmilk.

Content claims may also act as *de facto* health claims in combination with other health information that is available about the health impacts of individual substances.

FSANZ's review of current labels of packaged infant formula and the observation that some products appear to contain nutrient content claims despite the express prohibition under Standard 1.2.7 is noted. The current **practices observed on product labels around ingredient claims suggest a need for regulatory clarity**.

Declaration of permitted nutritive substances

In Standard 2.9.1, subclause 5(2) outlines that:

'A label may include words or other indications to the effect that the product contains a substance that is listed in Column 1 or Column 2 of the table to section S29—5 only if the amount of the substance in the product (including any naturally-occurring amount) is at least the corresponding amount listed in Column 3 of that table'.

FSANZ has indicated that some stakeholders suggest that this could be interpreted as a permission to refer to nutritive substances outside the statement of ingredients and nutrition information statement, which could constitute content claims. The departments believe the Standard **has to be read in its entirety** and that clarity is provided by paragraph 24(2) which states that reference to any nutrient or nutritive substance can only be made in (i) a statement of ingredients; and (ii) declaration of nutrition information. **The departments do not believe further clarification is required**.

Nutrition declaration requirements

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

Discussions with paediatric dietitians indicate that the provision of information about macronutrient subgroups in the nutrition information statement is not valuable for informing product choice for caregivers; in contrast, it is thought that this information has the potential to confuse caregivers.

The nutrition information statement currently is required to list macronutrients and micronutrients, including optional ingredients. **The departments support listing these components, along with the quantities present**.

Q3.3 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?

Standard 2.9.1 mandates the types and ratios of macronutrients and their subgroups required to be present in infant formula to meet the nutritional needs of infants. In the absence of evidence that justifies the need, the departments question why declaration of selected elements of these requirements in the nutrition information statement is necessary. It is likely that the ability to interpret the relevance of this information would be limited to experts in paediatric nutrition. The vast majority of caregivers are unlikely to have the skills to interpret this information and paediatric dietitians have indicated that it can lead some caregivers to make erroneous decisions in the belief that for example, the lactose content, or casein content, is important and relevant to their baby.

An objective of the Ministerial Policy Guideline in reviewing the regulation of infant formula products is the provision of adequate information to enable consumers to make an informed choice. While this is usually considered in terms of adding information to labels, **consideration needs to be given to the impact of providing unnecessary (or overly complex) information and the confusion this can create for caregivers.**

Paediatric dietitians have also indicated that the information on infant formula tins is not commonly used to make clinical decisions. Infant formula companies provide detailed reference nutrition information to paediatric dietitians; this would provide any relevant information on macronutrient subgroups. The departments therefore question what additional benefit is provided by providing detailed nutrition information (in terms of breakdown of macronutrient subgroups) on labels.

While industry innovation is encouraged to close the gap between the health outcomes of formula and breastfed infants, the variation of infant formula composition should only be performed in the context of the Ministerial Policy Guideline on the Regulation of Infant Formula Products. That is, changes should consider breastmilk as the primary reference, outcomes should be based on those of breastfed infants and substances should only be added for a nutritional or health effect if they have a substantiated beneficial role in the normal growth and development of infants. This should ultimately lead to improvements in infant formula products in general. Presenting a variety of products with different levels of various macronutrient subgroups in products on the market, and declaring this information to enable ‘informed choice’ does not appear to be consistent with this approach. If there is no clear scientific evidence for a particular macronutrient subgroup composition in infant formula, asking caregivers to choose a formula on the basis of specific macronutrient subgroups is an unreasonable expectation, and cannot be considered ‘informed choice’.

Whey:casein ratio in formula

With regard to protein, the current revised standard specifies the required amount of protein and individual amino acids in infant formula. However, it does not require amounts of the two main protein sub-fractions to be declared. Human and cow's milk differ substantially in the ratio of whey to casein protein (≈ 60:40 in human milk and ≈ 20:80 in bovine milk) and in the proportions of specific proteins including alpha-lactalbumin [24].

The departments are concerned about the variety in whey: casein ratios of protein in infant formula, and the marketing of these varying levels to caregivers. It is expected that the quality and composition of protein will attempt to reflect that of breastmilk, or outcomes of breastfed infants, as much as possible. A search for literature about the basis for offering formulas with different levels of whey to casein proportions revealed little to no evidence to support this practice. Concern was also raised by paediatric dietitians about the tendency for infant formula companies to vary the whey: casein ratio in infant formula and market high casein formulas as suitable for "hungry babies", on the basis that casein is slower to digest, and delays hunger. **The idea that a hungry baby should not have normal formula, but needs one that is harder to digest is troubling; babies have an innate ability to regulate their own appetites.**

The departments are particularly concerned that permitting the declaration of macronutrient subgroups may encourage **undesirable innovation or reformulation** of formula; that is, the production of a variety of different formulas which are not based on convincing scientific evidence (using breastmilk and health outcomes of the breastfed infant as the primary references). The intention of innovation with infant formula is to improve infant formula to achieve health outcomes closer to breastfed infants. It is unclear how the infant formula industry is achieving this intention if it markets a variety of different compositions of infant formula, with no active monitoring of infant populations consuming the various formulations to determine which achieve health outcomes most similar to breastmilk. It would appear that such innovation is purely for marketing and business purposes, and not for the overall improvement of infant formula. If industry's innovation was intended to ultimately improve infant outcomes, it would also be assumed that if an optional variation made to infant formula had been used for a sufficient time and deemed not to be essential for infants, then it should be removed. This does not seem to occur.

Q3.4 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).

On the basis of discussions with paediatric dietitians, **the departments are of the view that the only macronutrient subgroup information that should be permitted on labels is that supported by convincing evidence that certain infants may benefit from an alternative version for specific reasons**. The only subgroup we are aware of that meets this hurdle at this stage is the lactose component of carbohydrate. As further evidence becomes available, other macronutrient subgroups may warrant being declared.

Q3.5 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).

See Q 3.4

Q3.6 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?

See Q3.3

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

The departments cannot provide information on this.

Inter-relationship between declarations in the nutrition information statement and the ingredients list

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

The departments have no evidence that there is confusion between the differences in ingredient declarations and nutrition information declarations. The differences between a declaration of nutritional information versus a listing of ingredients occurs for all foods in the food supply, not just infant formula, and we would expect that caregivers are accustomed to these.

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

As noted by FSANZ, the purpose of the two labelling elements differs. In maintaining consistency within the Code, the departments recommend the current provisions under Standard 1.2.4 and 2.9.1 for labelling of ingredients and the nutrition information statement are maintained.

Base units of expression

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

FSANZ's identification of the issues regarding base units of expression are noted, recognising the use of the nutrition information statement by caregivers in making comparisons between products and that a mandatory requirement to include per 100g information provides limited benefit to caregivers given the differences in bulk density that may exist. The departments recommend that information provided on an 'as consumed' basis (per 100mL) provides the most relevant information and supports accurate comparison between products. A continued mandatory requirement for nutrition information to be expressed per 100mL for ready-to-drink products and powdered and concentrated products is supported in providing helpful information to caregivers and facilitating comparison between products.

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

The departments do not have specific evidence that caregivers are confused by the use of different base units. However, we support the provision of nutrition information in the simplest form possible, given all infant formulas are manufactured to meet the compositional criteria deemed essential for normal growth and development, and **caregivers should not be placed in the position to make decisions relating to**

this nutritional breakdown.

Paediatric dietitians have indicated that they use reference material provided by infant formula companies, rather than labels, to calculate altered concentrations of formula when required. It was mentioned that providing nutrition information by additional base units is likely to make the tin label more complicated, and is unlikely to be of use to caregivers.

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

The **departments do not support a mandatory requirement to declare per 100g powder**. A voluntary permission to declare per 100g of powder should only occur with sufficient rationale; this might be justified for trade reasons but the departments cannot provide information on this. However we note FSANZ's comment that labels for standard infant formula tend to be specific to Australia and New Zealand and not shared with other countries.

In addition, **the departments seek further clarity** on the mandatory base units of expression to be used on infant formula products in the Standard. Standard 2.9.1 – 21 requires that nutrition information is expressed per 100mL yet also refers to S29-10, which provides a recommendations that the nutrition information table include the average amount (or average quantity as discussed below) per 100g of powder. Note 2 to Section S29-10 then explains that the column referring to 100g of powder should be deleted for formulas sold in 'ready to drink' form. This further suggests a requirement to include per 100g powder for those products sold in a powdered form.

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

The departments are unable to provide information on this.

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

Similar to our position on the voluntary use of per 100g, voluntary declaration of nutrition information per 100kJ of powder should be permitted only with sufficient rationale, such as for trade reasons.

Average amount

Q3.15 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'?

In promoting consistency within the Food Standards Code, **the departments recommend the use of the term 'average quantity'**. This provides clarity in defining terms used in the Food Standards Code and particularly for special purpose foods. However, the departments do not believe all of the accepted methods listed under the definition of "average quantity" are suitable for infant formula. Specifically, '*(3)(c): calculation from generally accepted data relevant to that food'* should not apply to infant formula. Each calculation should be specific to a formula and not based on other brands, for example. The **definition should be amended to clarify this option does not apply to infant formula.**

Format of the nutrition information statement

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

The departments are not aware of research indicating the extent to which nutrition information is used to inform purchase decisions. We acknowledge that with the prohibition on nutrient content and health claims, both the nutrition information statement and the ingredients list are the primary sources of information about the ingredients in infant formula at the point of purchase.

Discussions with stakeholders suggest that generally caregivers can be brand loyal once a product has been selected. In informing an initial purchase decision, the nutrition information statement enables ready access to the necessary information to inform choice of infant formula. It is not clear however whether those caregivers who do use the nutrition information to inform their purchases understand that all formulas are manufactured to meet the essential composition requirements and any optional ingredients present do not have the same level of evidence to show they are of benefit to infants. Where this evidence does become available for optional ingredients, the regulatory framework should support timely updates to the composition requirements in the Code to ensure all infants can benefit from innovations in infant formula.

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

A consistent approach to the nutrition information statement is likely to assist caregivers in understanding this information. The observations reported by FSANZ in section 2.7.4 of Supporting Document 3 are noted. Further clarity on the required elements of the nutrition information statement provides consistency in the Food Standards Code and aligns with the nutrition information provided for general purpose foods. This also provides consistency for consumers who may be familiar with the nutrition information panel on foods at the point of purchase.

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

The departments cannot provide information on this.

Notification of product reformulation

Q3.19 How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?

We do not have a view on this at this stage.

Q3.20 What information about the change in composition would caregivers and health professionals find useful?

Changes to formulations are currently communicated to health care professionals in reference material. It is not considered that a different practice is required. Further details regarding the change in composition may be addressed on associated website or marketing material.

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

The departments cannot provide information on this.

Section 3 Requirements proposed to remain unchanged

Nutrition content claims and health claim prohibition

The departments support the continued prohibition on nutrient content and health claims. Refer to Q3.1 for further rationale.

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