

Supporting Document 1

Definitions and Nutrient Composition – Proposal P1028

Infant Formula

Executive summary

This Supporting Document (SD1) discusses the nutrient composition of infant formula (suitable for infants from 0–<12 months of age). The approach to this preliminary assessment for nutrient composition aligns with objectives of P1028, specifically that the health and safety of infants is protected, that there is consistency with advances in scientific knowledge, and that industry innovation or trade is not hindered.

This assessment primarily considers whether it is appropriate to align the composition provisions for infant formula of Standard 2.9.1 – Infant Formula Products (and Schedule 29 in the revised Code) with those in the *Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex STAN 72-1981). Previous consultation in 2012 indicated that submitters generally support alignment of the Code with compositional requirements in Codex STAN 72-1981.

For some essential nutrients there are some differences between Standard 2.9.1 and Codex STAN 72-1981, including: minimum and maximum amounts, permitted forms, and the means or units of expression. Also, for some micronutrients, maximum amounts are mandatory in Standard 2.9.1, whereas Codex provides a voluntary guidance upper limit (GUL).

The assessment also compares the forms of vitamins and minerals permitted in the *Codex Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (Codex GL 10-1979) with Standard 2.9.1.

FSANZ has undertaken a nutrition assessment which reviews the evidence underpinning the composition for infant formula recommended in the Codex STAN 72-1981, and considers whether consumption of formula manufactured according to the composition requirements in the Codex standard would pose nutritional health risk to Australian and New Zealand infants. Using a systematic comparative approach involving several defined criteria, all essential nutrients and several nutritive substances were assessed for nutritional safety and adequacy. The nutrition assessment is at Attachment 1, with a brief conclusion for each nutrient included in this SD.

In general, it is FSANZ's preliminary view that amending the compositional requirements in Standard 2.9.1 to align with Codex STAN 72-1981 appears to be appropriate for most nutrients because:

- Most of the Codex nutrient amounts and other prescribed factors such as permitted forms and nutrient ratios were found to be consistent with scientific evidence and are unlikely pose a risk to infant health.

- The composition of a sample of infant formula products, as declared on the label, indicates that for the majority of nutrients the contents already lie between the Codex minimum – maximum amounts. This suggests that the impact of any change to align with Codex on current manufacturing practice may not be large.

No compositional changes to Standard 2.9.1 are formally proposed. Instead, FSANZ provides its preliminary view on whether aligning the Code with Codex STAN 72-1981 for each of the essential nutrients is appropriate in the Australian and New Zealand context. FSANZ is seeking stakeholder views on its preliminary positions for these essential nutrients, and also on associated issues that have been identified.

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See separate documents for:

Appendix 1: Labelled composition available on the retail market in Australia & New Zealand
Attachment A1.1 – Nutrition Assessment

1 Introduction

Infants are a vulnerable population group. Breastfeeding is the recommended way to feed an infant; however a safe and nutritious substitute for breast milk is required for infants who are not breastfed. Infant formula may provide the sole source of nutrition for formula-fed infants during the first months of life and then serve as the principal liquid source of nourishment in a progressively diversified diet for older infants. Infant formula must be safe for consumption and must also provide all the essential nutrients, in adequate amounts, to support the growth and development of formula-fed infants.

The nutrient composition of infant formula is regulated in Standard 2.9.1 – Infant Formula Products in the *Australia New Zealand Food Standards Code* (the Code). Regulation of the composition of infant formula is appropriately prescriptive to ensure that infant formula provides sufficient energy and nutrients to promote normal growth and development of formula-fed infants, without posing a risk to infant health.

FSANZ has developed and approved a revised version of the Code, which takes effect and replaces the current version of the Code on 1 March 2016¹ (for more information refer to our [website](#)). In this SD, the relevant sections in the revised Code are noted (in brackets) following any reference to a specific provision of the current Code.

1.1 Scope of consideration

The main purpose of this Supporting Document 1 (SD) is to consider the infant formula nutrient composition outlined in Standard 2.9.1 (Standard 2.9.1 and Schedule 29 in the revised Code). We are considering whether or not to align these with relevant Codex texts, as the Codex texts are generally consistent with current scientific knowledge. During this consideration we have had regard to relevant Ministerial policy guidance². This SD therefore considers product definitions and the nutrient composition of infant formula for healthy, term infants aged 0-<12 months).

This SD does not propose any drafting since the views presented are preliminary in nature. Amendments to the Code may be drafted after further assessment has been made and a decision taken for the purposes of sections 59 and 60 of the FSANZ Act. Any proposed amendments will be subject to further public consultation.

Some issues raised by submitters in response to the 2012 Consultation paper that are noted in section 10 are outside scope and are therefore not addressed in this SD. Also outside scope are requests for new optional substances as these should be sought through applications to amend the Code.

1.2 Background

1.2.1 Current regulation of composition

Standard 2.9.1 (Standard 2.9.1 and Schedule 29 in the revised Code) sets out the mandatory energy and macronutrient requirements and calculations, as well as the mandatory and advisory requirements for vitamins, minerals and electrolytes and their permitted range and forms. The Standard also regulates the optional addition of several other substances.

¹ <http://www.foodstandards.gov.au/code/Pages/Food-Standards-Code-from-1-March-2016.aspx>

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Documents/Infant%20Formula%20May%202011.pdf>

The compositional requirements in Standard 2.9.1 were based on the best scientific evidence available at the time of its development over a decade ago as well as alignment with the then Codex infant formula standard and European regulations.

1.2.2 International and overseas regulations

There are several Codex Standards and Guidelines that are relevant to the nutrient composition of infant formula.

Codex STAN 72-1981 sets out the essential composition of infant formula including recommended minimum and maximum nutrient amounts. This Standard guides member countries when establishing the essential composition of infant formula, and takes account of safety, nutrient adequacy, promotion of growth and development, bioavailability, levels of naturally occurring nutrients, and the inherent variability of nutrients within ingredients and in water.

Codex STAN 72-1981 was revised in 2007 and amended in 2011 and 2015 to reflect more recent scientific understanding of nutritional needs of infants, and methods of infant formula production. The revision was completed by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), based on advice from international scientific experts in infant nutrition. The experts, coordinated by the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), published a report with recommendations for the composition of infant formula based on the then current scientific evidence (Koletzko et al. 2005). Therefore, Codex STAN 72-1981 is based on a more recent review of the evidence than Standard 2.9.1.

The Codex *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) lists the forms of nutrients (and some optional ingredients) permitted for use in infant formula. This advisory list was last updated in 2008.

1.2.3 Ministerial policy guidance

The Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (Policy Guideline) (ANZFRMC, 2011) contains the following Specific Policy Principles relating to composition of infant formula:

- (d) *The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.*
- (f) *The essential composition of infant formula and follow-on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants*
- (g) *Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.*
- (h) *The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on 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:*
- does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or*
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.
- (j) *Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.*

1.3 Approach

FSANZ's previous consultations indicate that submitters generally support aligning the compositional requirements in Standard 2.9.1 with Codex texts. Thus the approach taken in this SD is to initially consider the evidence which underpins Codex STAN 72-1981 and Codex GL 10-1979, also the implications of potential alignment with these Codex texts.

The issues considered in this SD have been identified from a range of sources including FSANZ's nutrition assessment, international reviews, stakeholder consultation, other FSANZ projects, and regulatory and policy activities at a national and international level. Generally, the issues identified relate to:

- nutritional safety and the applicability of the Codex compositional requirements for the Australian and New Zealand population
- consistency with current scientific knowledge
- potential impacts on international trade
- clarity and enforceability of the Code.

This SD is organised into sections that discuss the product and nutrient definitions and nutrient compositional issues for the following related nutrient groups: macronutrients and energy; vitamins and minerals; permitted forms; other nutritive substances. For each nutrient, the type and value of the prescribed minimum and maximum is discussed plus related information such as calculations.

Consideration of each issue includes discussion of the current requirements in the Code and international standards, the conclusions of the nutrition assessment, submitter views, and information from a label survey. The approach taken supports the objectives of this Proposal outlined in the main paper that:

- the health and safety of infants are protected
- there is consistency with advances in scientific knowledge

- industry innovation or trade is not hindered.

1.3.1 Nutrition assessment

The nutrition assessment is provided at Attachment 1. The assessment used a set of criteria to establish whether adoption of the Codex provisions would pose a potential risk to infant growth or development. The criteria identified whether the Codex provisions for each nutrient were:

1. comparable to the nutrient content measured in breast milk
2. appropriate compared to the *Nutrient Reference Values for Australia New Zealand* (NRVs) (NHMRC and MOH 2006) for adequate and excess intakes of infants
3. based on sound physiological, biochemical or functional outcomes
4. sufficient or whether new or emerging scientific evidence should be considered to determine a different nutrient minimum or maximum amount from that set in the Codex standard.

To enable comparison of the Code and the Codex provisions for each nutrient, many calculations had to be completed to convert everything to common units. As a result there may be small differences due to rounding.

As infant formula is suitable for infants within the first year of life, the composition must be suitable to meet an infant's requirements throughout this period. The NRVs establish the nutritional requirements for infants, often as two groups: younger infants 0–6 months of age and older infants 7–12 months of age. The nutrition assessment takes both age ranges into consideration.

1.3.2 Previous submitter views

The 2012 Consultation paper invited comment from stakeholders on issues related to the composition of infant formula. FSANZ specifically sought views on consideration of alignment of the composition provisions with those in Codex STAN 72-1981. The issues and views raised in submissions have been taken into consideration as relevant to each topic throughout this SD.

1.3.3 Label survey of products

FSANZ is aware that managing the levels of multiple individual nutrients within different ranges can provide a challenge for the manufacture of infant formula. To obtain an initial indication of any potential impacts to infant formula companies if composition changes were to be made; we reviewed label information of a sample of products available in the Australian and New Zealand retail market in 2013–2014. The collated information has been used to consider the average range of composition on products on the market. This assists us to consider potential impact on the manufacture of infant formula if compositional requirements in Standard 2.9.1 for nutrients declared in labelling were to be amended to align with Codex STAN 72-1981.

We purchased a range of types of infant formula available on the retail market at the time in Australia and New Zealand. Information was then collated from the nutrition information statements and ingredient lists on product labels. The information was collected from a small convenience sample of products available to us, thus there are limitations from this information. The reported nutrient composition (as labelled) of the products are indicative only, but provide a useful 'snapshot' of the potential implications to infant formula companies

of any changes to the current composition. The details and results of the survey are at Appendix 1 of this SD.

1.3.4 FSANZ's preliminary views and questions to submitters

From this consideration, FSANZ has formed a preliminary view which is set out for each nutrient. For most of the nutrient composition, the preliminary view is that the Proposal's objectives are expected to be supported by alignment with Codex. However, for some aspects, these objectives may be better met by retaining the Code's current arrangements. Occasionally, insufficient information is available to form a preliminary view.

Further information is sought from stakeholders through an overarching question below and subsidiary questions at relevant sections of the SD. In general, if alignment with Codex STAN 72-1981 is unlikely to adversely affect infant health.

One overarching question is posed here that applies to every section of the SD. Stakeholders are invited to respond to each of FSANZ's preliminary views. In providing a response, submissions should number comments according to the SD1 subsection number of the relevant topic e.g. 4.4.3 -- for comments on DHA.

Overarching Question to Submitters:

Q1.1 For all views presented in this SD, do you agree with FSANZ's preliminary view?

* If so, indicate this in your submission and provide your reasons where appropriate.

* If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

2 Definitions and terminology

The relevance of the scope and definitions in Codex STAN 72-1981 standard are considered. Several definitions are relevant to infant formula, both within Division 1 of Standard 2.9.1 (section 2.9.1—3 in the revised Code) and the rest of the Code. Similarly Codex STAN 72-1981 includes several definitions relating to product descriptions. This section discusses the issues identified with these definitions in the Code. Infant is defined as a person under the age of 12 months.

2.1 Definition of infant formula product

The definition of *infant formula product* in Standard 2.9.1 is an overarching definition which includes all products regulated by the Standard. The definition was recently clarified through Proposal P1025 – Code Revision, without modifying intent. There is no similar overarching definition in Codex STAN 72-1981. A definition for infant formula product is included in the current Code, the revised Code and the Ministerial Policy Guideline (summarised in Table 2.1).

The 2012 Consultation paper sought comments from stakeholders on whether the infant formula product definition was fit for purpose. Feedback generally supported retaining the definition although government submissions suggested aligning with the version in the Policy Guideline. Two new alternative overarching terms were proposed during consultation: *formulated infant foods* or *infant feeding products for general dietary use*. Proposal P1025 also received submissions on the definition. Submissions to P1025 generally supported the

proposed amendments to the definition which clarified that this product category comprised products as a sole, as well as a principal, source of nutrition for infants depending on their age.

Given the general support for the current definition, FSANZ considers that introducing completely new overarching terms or further revising the definition in the revised Code is not warranted at this stage. FSANZ's preliminary view is that the revised definition of infant formula product in the revised Code is appropriate and should be retained.

Table 2.1: Current definitions of infant formula product and infant formula

| Definitions | | |
|------------------------------|--|---|
| Document | Infant Formula Product | Infant Formula |
| Current Standard 2.9.1 | A product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants | An infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months. |
| Standard 2.9.1 revised Code | A product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants depending on the age of the infant. | An infant formula product that: (a) is represented as a breast milk substitute for infants; and (b) satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months. |
| Codex STAN 72-1981 | No definition | A breast milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding. |
| Ministerial Policy Guideline | A manufactured product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants. | An infant formula product represented as a breast milk substitute for infants and which satisfies, as the sole source of nourishment, the nutritional requirements of infants up to six months of age. |

2.2 Definition of infant formula

The intent of the current and revised Standard 2.9.1 is that infant formula is safe and suitable for consumption by infants aged less than 12 months; and when consumed as a sole source of nutrition, by infants aged less than 4 to 6 months. Thus the Code's definition of infant formula relates to product representation and purpose in the diet of infants up to a certain age.

As shown in Table 2.1, the Code's definition of infant formula differs slightly from that given in Codex STAN 72-1981. The Codex definition does not include an age range for providing the sole source of nutrition; instead it refers to the introduction of complementary feeding to allow for regional differences around the world. FSANZ is aware of some confusion about the age range for which infant formula is suitable. The modified definition of infant formula in the revised Code clarifies:

- (a) infant formula as a breast milk substitute is applicable to infants of any age
- (b) the nutritional role of infant formula as a sole source of nutrition applies to infants aged less than 4 to 6 months.

The scope and definitions for *infant* and *infant formula* in Codex STAN 72-1981 has also led to differing interpretations of the intended age range for infant formula internationally. This is because the definitions of *infant* and *infant formula* refer to two different endpoints – stage for consumption as a sole source of nutrition, and age for any consumption. One view is that infant formula is intended for infants defined by age i.e. not more than 12 months whereas the other view is that infant formula is suitable up to the age of introduction of complementary feeding.

Submissions to the 2012 Consultation paper commented on two aspects of the definition of infant formula: the role as a ‘sole source’, and the suitable ‘age range’. Several submissions commented on the confusing nature of the current age ranges, where infant formula is suitable from birth up to 12 months of age; which overlaps with the age range for follow-on formula (from 6–<12 months). This overlap has caused confusion about whether infant formula is suitable for use only in the first 4–6 months i.e. prior to introduction of complementary feeding, or is suitable for use by infants less than 12 months of age. Industry submissions generally supported the current definition.

Table 2.2: Summary of submissions on the definition of infant formula

| Comment | Submitter | FSA NZ response |
|--|--------------------------------|---|
| If infant formula is suitable for the entire first 12 months (as stated in the NHMRC draft Infant Feeding Guidelines), this needs to be clearly stated in the definition and included in product labelling. | Multiple submitters | Noted, refer to discussion |
| Should consider aligning with the recommendation in both the Australian and New Zealand infant feeding guidance (NHMRC, 2012; MoH, 2008) for timing of the introduction of solid foods at ‘around 6 months of age’. | Multiple submitters | Considered in P274 |
| Specifying a 4-6 month age range in the definition implies that infant formula can be ceased at 4 months of age. These submitters noted that while solids may be introduced from 4-6 months, an infant formula must be continued during this time. | Multiple submitters | Considered in P274 (relates to complementary feeding) |
| Consider the current definitions are fit for purpose. | Multiple industry submitters | Noted |
| Alignment with the infant formula definition in Codex STAN 72-1981 is clearer as it acknowledges infant formula as the sole source of nourishment. This reduces confusion around the age of introduction of solids and could minimise the potential risk of caregivers supplying an inappropriate choice of formula. | Multiple submitters | Noted, refer to discussion |
| Support the adoption of the definition from the <i>Policy Guideline for the Regulation of Infant Formula Products</i> as it is clearer in describing the product as the sole source of nourishment. | Multiple Government submitters | Noted, refer to discussion |

| Comment | Submitter | FSANZ response |
|--|------------|----------------------------|
| Proposes new modified version of the policy guideline definition: “Infant formula: means an infant formula product which is formulated to meet, as the sole source of nourishment, the nutritional requirements of infants up to six months of age and, as part of a progressively diversified diet, from six to 12 months of age.” | Government | Noted, refer to discussion |
| Definitions should avoid the use of terminology “represented as...”. Such a statement does not confer a real meaning. Instead, the definition should clearly state what the product is intended to do, i.e. provide the sole or principal source of nutrition for infants. | Government | Noted |

There are strengths and limitations of the many definitions of infant formula. Both Codex STAN 72-1981 and Policy Guideline define infant formula as providing a sole source of nourishment for infants in the first months of life; only the Policy Guideline specifies an age – up to 6 months. Neither definition clarifies that the product is also suitable for infants during the second half of the first year of life – the full age range of an infant.

The inclusion of up to 4 to 6 months of age establishes the oldest age at which infant formula should satisfy the nutritional requirements of infants when it is fed as a sole source of nutrition and before complementary feeding begins. FSANZ recently considered the evidence for the appropriate age of introduction of solid food in [Proposal P274 – Review of Minimum Age Labelling of Foods for Infants](#)³. The assessment concluded that there is no difference in risk of harm from the introduction of solids from ‘4 months of age’, relative to introducing solids at ‘around 6 months’ of age (FSANZ, 2014).

The Codex definition of infant formula specifies “up to the introduction of appropriate complementary feeding” instead of a maximum age for consumption as a sole source. This approach allows for global variation in recommendations about the introduction of complementary feeding. FSANZ’s preliminary view is that this wording is consistent with the maximum age range of 4–6 months in Standard 2.9.1. Its adoption, or merely deleting the “4-“ in the revised Code definition, could eliminate the confusion around age range for sole source as “under the age of 6 months” includes younger months.

In relation to clarifying the suitability of infant formula for infants of any age, some submitters suggested extending the definition to include “and, as part of a progressively diversified diet, from 6 to less than 12 months of age” or similar wording. With or without this extension, the intention is that infant formula is suitable for infants (defined term) of any age. We seek further views from stakeholders to inform a proposed approach.

Questions to submitters:

- 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”

³

<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp274reviewofminimumagelabellingoffoodsforinfants/Default.aspx>

- | | |
|-----|--|
| (2) | “satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding “ |
| (3) | <i>Option 1 or 2 followed by</i> and, as part of a progressively diversified diet, of infants from 6 months of age |
| (4) | no change |

2.3 Definitions in other parts of the Code relevant to infant formula

Several definitions are relevant to infant formula although not specifically referenced in Standard 2.9.1. For example, several definitions in the current Code are located in Standard 1.2.8 – Nutrition Information Requirements. Although the labelling *requirements* in Standard 1.2.8 do not apply to infant formula (as Standard 2.9.1 contains its own labelling provisions), the *definitions* in clauses 1 and 2 of Standard 1.2.8 were specifically applied to infant formula as they were considered appropriate to apply to its compositional requirements (through clause 1 of Standard 2.9.1). FSANZ acknowledges this has been confusing.

The revised Code has removed this confusion as all definitions that have Code-wide application in one place (Standard 1.1.2) and for other definitions relevant to infant formula; the location of the relevant definition is signposted. This rearrangement of the definitions within the Code was intended to address confusion and will provide clarity for Standard 2.9.1 and thus it is FSANZ’s preliminary view that no further amendments are required. Table 2.3 shows all the definitions relating to infant formula located in standards other than Standard 2.9.1 in the current and revised Code.

Table 2.3: Summary of relevant definitions in the current and revised Code

| Definition | | Current Code location | Revised Code location* |
|--------------------------------------|--|-----------------------|------------------------|
| Carbohydrate | means – (a) ‘carbohydrate by difference’, calculated by subtracting from 100, the average quantity expressed as a percentage of water, protein, fat, dietary fibre, ash, alcohol, and if quantified or added to the food, any other unavailable carbohydrate and the substances listed in column 1 of Table 2 to subclause 2(2); or (b) ‘available carbohydrate’, calculated by summing the average quantity of total available sugars and starch, and if quantified or added to the food, any available oligosaccharides, glycogen and maltodextrins. | Std 1.2.8 | – |
| Carbohydrate |, means available carbohydrate or available carbohydrate by difference | – | Std 1.1.2 |
| Available carbohydrate | means available carbohydrate calculated in accordance with section S11—3 | – | Std 1.1.2 |
| Available carbohydrate by difference | means available carbohydrate by difference calculated in accordance with section S11—3 | – | Std 1.1.2 |

| Definition | | Current Code location | Revised Code location* |
|-----------------------------|--|-----------------------|------------------------|
| Dietary fibre | means that fraction of the edible part of plants or their extracts, or synthetic analogues that – (a) are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and (b) promote one or more of the following beneficial physiological effects – (i) laxation; (ii) reduction in blood cholesterol; (iii) modulation of blood glucose; and includes polysaccharides, oligosaccharides (degree of polymerisation > 2) and lignins. | Std 1.2.8 | Std 1.1.2 |
| Galacto-oligosaccharides | means a mixture of the substances produced from lactose by enzymatic action, comprised of between two and eight saccharide units, with one of these units being a terminal glucose and the remaining saccharide units being galactose, and disaccharides comprised of two units of galactose. | Std 1.1.1 | Std 1.1.2 |
| Inulin-type fructans (ITF) | means mixtures of saccharide chains that have β -D-(2→1) fructosyl-fructose linkages with or without a terminal α -D-(1→2) glucosyl-fructose linked glucose unit. | Std 1.1.1 | Std 1.1.2 |
| Fat | means total fat. | Std 1.2.8 | Std 1.1.2 |
| Polyunsaturated fatty acids | means the total of polyunsaturated fatty acids with cis-cis-methylene interrupted double bonds and declared as polyunsaturated fat. | Std 1.2.8 | Std 1.1.2 |
| Monounsaturated fatty acids | means the total of cis-monounsaturated fatty acids and declared as monounsaturated fat. | Std 1.2.8 | Std 1.1.2 |
| Saturated fatty acids | means the total of fatty acids containing no double bonds and declared as saturated fat. | Std 1.2.8 | Std 1.1.2 |
| Trans fatty acids | means the total of unsaturated fatty acids where one or more of the double bonds are in the trans configuration. | Std 1.2.8 | Std 1.1.2 |

Std 1.2.8: Standard 1.2.8 - Nutrition Information Requirements

Std 1.1.1: Standard 1.1.1 - Preliminary Provisions

Std 1.1.2: Standard 1.1.2 - Definitions used throughout the Code (revised Code only)

*Comes into effect 1 March 2016

2.5 Definitions that remain unchanged

FSANZ is not aware of any issues with several relevant definitions in Standard 2.9.1 (Standard 1.1.2 in the revised Code) listed in Table 2.4. On that basis, it is FSANZ's preliminary view that these should not be further considered in this Proposal.

Table 2.4: Definitions in Standard 2.9.1 that are not proposed to be considered further

| Term | Definition |
|----------------------------|---|
| Infant | a person under the age of 12 months. |
| Soy-based formula | an infant formula product in which soy protein isolate is the sole source of protein. |
| Medium chain triglycerides | triacylglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0. |

Definitions listed in Table 2.5 are outside the scope of this Proposal because they relate to other types of infant formula product in Standard 2.9.1.

Table 2.5: Definitions in Standard 2.9.1 outside scope of this Proposal

| Term | Definition |
|--|--|
| Pre-term formula | means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight. |
| Protein substitute | means – (a) L-amino acids; or (b) the hydrolysate of one or more of the proteins on which infant formula product is normally based; or (c) a combination of L-amino acids and the hydrolysate of one or more of the proteins on which infant formula product is normally based. |
| Lactose free formula and low lactose formula | means infant formula products which satisfy the needs of lactose intolerant infants. |

3 Protein

Protein plays a key role in infant nutrition to support normal growth and development of the infant. Several aspects of protein regulation are discussed in the following sections.

3.1 Protein content and range

Standard 2.9.1 and Codex STAN 72-1981 both require total protein content for infant formula in the range of 0.45 g/100 kJ (minimum) to 0.7 g/100 kJ (maximum). However, Codex also includes a footnote which states:

The minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) applies."

Standard 2.9.1 only defines soy-based formula and requires, as with any other protein source, that it is nutritionally adequate to meet the infant protein requirements.

The higher minimum for isolated soy protein formula is to ensure that amino acid levels can be met, as soy (and other plant proteins) has a different amino acid profile. In addition the digestibility of plant proteins can be less than that of milk proteins (EC SCF, 2003). Recent EFSA (2014) recommendations are consistent with the Codex approach.

Several submitters on the 2012 Consultation paper noted overseas developments towards lowering the minimum protein amount. Some submitters also referred to recent publications suggesting that lowering protein content could reduce the risk of obesity in childhood or later life. Industry submissions also noted that the provision of lower protein formulas in Australia

and New Zealand may be constrained by the current minimum requirements for amino acids in Standard 2.9.1.

The nutrition assessment provides a review of current research and expert opinions, concluding that the evidence for the association between high protein in infant formula and risk of obesity in later childhood is uncertain. It is noted that most of the research in this area has originated from a single large multi-centre trial (European Childhood Obesity Trial or ECOT (Koletzko et al. 2009)). The high protein formulations in this trial (which gave rise to increased growth compared to breastfed infants) contained the maximum permitted protein amount (0.7 g/100 kJ) for the first 6 months of age then a follow-on formula) containing 1.1 g/100 kJ for 612 months. In addition, the high protein test formulations contained protein at 12% of energy for infants up to 6 months, then 18% for infants aged 6–12 months. The low protein test formula provided protein at 7% of energy (infants aged up to 6 months) and 9% of energy (for 6–12 months). Comparatively, our assessment estimates the protein amount contained in infant formula in Australia and New Zealand consumed over the course of a year would be an average between minimum and maximum amounts (0.45–0.7 g/100 kJ). This average protein content (0.50 g/100 kJ) corresponds to approximately 8.5% of energy (based on label information of infant formula sold in Australia and New Zealand – refer to Appendix 1), similar to the energy contribution from the low protein formulations used in the studies. On this basis, the nutrition assessment concludes that the current protein range is unlikely to adversely affect infant health, thus the protein minimum and maximum amounts should be retained as currently specified in Standard 2.9.1 and Codex STAN 72-1981. There are no indications that soy-based formulas formulated under either standard are unable to meet nutritional needs to support normal growth and development.

FSANZ's label survey indicates that infant formula contains protein in amounts within the current range of both Codex STAN 72-1981 and Standard 2.9.1. The product survey suggests that the current range allows for infant formula companies to consider using a lower protein content within the current range for some products.

Standard 2.9.1 regulates infant formula to be suitable for the first year of life, thus regulatory requirements must be appropriate across this age range and feeding regimens. FSANZ considers that more evidence is required to demonstrate the advantages of lower protein intakes for infants. Thus our preliminary view is to retain the current total protein content and range in Standard 2.9.1 consistent with Codex STAN 72-1981. However we are seeking further information on the need for a higher protein minimum for isolated soy protein of 0.5 g/100 kJ instead of .045 g/100 kJ.

Questions to submitters:

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

3.2 Calculation of protein: nitrogen conversion factors

The protein content in foods can be estimated by multiplying the nitrogen content by a nitrogen-to-protein conversion factor. The result is generally referred to as 'crude' protein. Different nitrogen conversion factors exist for different foods depending on the amino acid composition of foods.

Standard 2.9.1 (paragraph 2.9.1—4(2)(b) and section S29—3 in the revised Code) prescribes the equation and two nitrogen conversion factors for calculating the protein content of infant formula products depending on the protein source used in the product. For milk proteins and their partial hydrolysates, a conversion factor of 6.38 is prescribed whereas a factor of 6.25 is prescribed for all other protein sources.

Codex STAN 72-1981 lists a single nitrogen conversion factor of 6.25. However, a footnote states “a different factor can be used for a particular product where there is scientific justification” and notes the factors of 6.38 as generally established by Codex for other milk products, similarly 5.71 for soy products.

The 2012 Consultation paper sought feedback on whether Standard 2.9.1 should continue to prescribe two nitrogen conversion factors, or if not, which one would be recommended. Submitter views were mixed with half supporting alignment with Codex i.e. prescribe the factor of 6.25 with the ability to use other conversion factors with scientific justification. Some of these also noted it would be useful for the revised Standard to provide greater clarity about the use of the other conversion factors. Most other submitters supported retaining the two conversion factors currently in the Code to recognise the different quality of the protein sources. Several considered that the current situation (2 conversion factors) is effectively aligned with Codex STAN 72-1981. Some submitters also supported adding the conversion factor for soy protein (5.71) to the Code to further reflect the Codex standard.

The current factors in Standard 2.9.1 were included with the intent of covering all potential mammalian milks used in the manufacture of infant formula, and to provide for partial protein hydrolysates or for specialised formula which may be based solely on amino acid mixtures. FSANZ recently discussed measurement of protein content in [Application A1074 – Minimum L-histidine in Infant Formula Products⁴](#), and this is further discussed in the nutrition assessment at Attachment 1 (FSANZ, 2013). The A1074 nutrition assessment concluded there is minimal effect on the total protein content if the 6.38 conversion factor is used instead of 6.25 for cow’s milk protein. The current nutrition assessment supports this point, noting that both 6.38 and 6.25 have been considered acceptable for some time. However, there is a greater difference for soy as a protein source. Based on this difference, Codex STAN 72-1981 specifies a higher minimum protein content in soy-based infant formula. The nutrition assessment notes that soy proteins have different structures due to side chain glycosylation (which impacts on the protein molecular weight) and supports 5.71 as the appropriate nitrogen conversion factor.

We note that CCNFSDU (2015) agreed to seek advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS) on the validity of 5.71 as the nitrogen conversion factor for soy isolates (REP16/NFSDU).

Given the minimal practical effect of the alternative factors applied to milk, 6.25 is the preferred factor because the majority of infant formulas are based on mammalian milk and it is the general Codex factor. The factor of 5.71 can be supported by scientific evidence for soy protein. It is FSANZ’s preliminary view that only two factors should be specified and continuing to list conversion factors for mammalian milk and plant protein sources is appropriate such that 6.25 should apply to mammalian milk and 5.71 to soy protein.

3.3 Protein source

Sources of protein in infant formula available in Australia and New Zealand include cow’s milk protein, goat’s milk protein, protein hydrolysates of one or more proteins normally used in infant formula, and isolated soy protein (ISP).

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 food

⁴<http://www.foodstandards.gov.au/code/applications/Pages/applicationa1074mini5583.aspx> – Minimum L-histidine in Infant Formula Products

constituents of animal or plant origin". Similarly, Codex STAN 72-1981 defines infant formula as a product based on "milk of cows or other animals or mixture thereof and other ingredients proven to be suitable for infant feeding". Both standards set minimum requirements for protein content and essential amino acid amounts to align with the reference protein i.e. breast milk, regardless of protein source. Codex STAN 72-1981 sets out certain specific differences in protein requirements that relate to protein source e.g. different minimum amounts are listed for cows' milk protein and soy protein, noting that other minimums may apply to non-cows' milk protein.

One submission on the 2012 Consultation paper suggested that Standard 2.9.1 should include a list of approved protein sources for use in infant formula. Other submissions noted that, as dairy processing technology develops, the protein components used in formula manufacture can be increasingly fractionated and combined with smaller quantities of non-fractionated traditional ingredients. Some submissions suggested that consideration should be given to future proofing the new standard in relation to new technologies applicable to infant formula. It was suggested that more detail may be required in the standard to specify particular aspects of ingredients that make up the essential composition. These general issues are discussed in Supporting Document 2 (SD2), as part of the consideration of the pre-market assessment approach of novel and nutritive substances. It was also suggested that FSANZ could consider including a 'reference' or benchmark based on cow's milk protein or include a list of acceptable ingredients that could be used for manufacture.

During assessment of Proposal P93, ANZFA considered the regulation of protein source, including the evidence for whey dominant or casein dominant formulas, since casein dominant formula had previously been prohibited in Australian Standard R7. P93 determined that it was not necessary to regulate the protein source if quality and quantity of protein content were regulated (ANZFA 2002). However, it was decided that Standard 2.9.1 should require the protein source to be clearly shown on the label e.g. as cow's milk or soy protein isolate to provide carers with information (labelling requirements for protein source are discussed in SD2). It was also considered that the pre-assessment requirements of novel foods and novel sources of ingredients would manage any potential risks of new ingredients (i.e. new sources of proteins) in infant formula (ANZFA 2002).

FSANZ's preliminary view is that the current sources of protein are appropriate. However, given the current work on novel foods and substances used for a nutritive purpose, further consideration will be given to the regulation of protein source as this Proposal progresses.

3.4 Protein quality

Protein quality is assessed by the ability of a protein source to provide amino acids which meet an infant's requirements. The interrelationship between protein content and protein quality is significant for infants, particularly if the total protein content of an infant formula were to be lowered. Both Standard 2.9.1 and Codex STAN 72-1981 regulate the protein quality through mandating minimum amounts of the amino acids considered essential (and semi essential) for infants.

Some submissions suggested that FSANZ consider harmonisation with the recent FAO/WHO report on protein quality assessment and revised methodology (FAO, 2013) to ensure currency with the evidence regarding protein quality calculation methodology. The FAO report recommended that the Digestible Indispensable Amino Acid Score (DIAAS) replace the Protein Digestibility Corrected Amino Acid Score (PDCAAS) as the preferred method of measuring protein quality in food. However, neither Standard 2.9.1 nor Codex STAN 72-1981 apply an amino acid scoring approach to protein quality; instead, both standards mandate minimum amounts of key amino acids.

The nutrition assessment supports the continued use of minimum amino acid amounts to ensure protein quality. The assessment discusses the PDCAAS and DIAAS protein scoring systems, noting that very limited data currently using the DIAAS method exists. The assessment concludes that when data become available, it is unlikely to dramatically alter the quality protein scores for infant formula as the main ingredients are already high quality protein.

It is FSANZ’s preliminary view that the amino acid composition of breast milk should remain the reference for determining minimum amino acid requirements in infant formula. This approach aligns with Codex i.e. the minimum recommendations of Codex STAN 72-1981 are based on the average amount of amino acids present in breast milk, rather than a protein scoring system. Therefore, it appears appropriate not to adopt the PDCAAS or DIAAS methods.

3.5 Amino acid content

Both the Table to clause 22 of Standard 2.9.1 (section 2.9.1—10 and section S29—6 in the revised Code) and Codex STAN 72-1981 specify minimum amounts of 11 essential and semi-essential amino acids (in L-amino acid form). Both standards specify that isolated amino acids should be added to infant formula only to improve its nutritional quality. However, differences in the minimum amounts of some amino acids exist between the two standards, as shown in Table 3.1.

The minimum requirements for amino acids in infant formula are mainly based on ‘typical’ amino acid profiles of breast milk. As noted in the nutrition assessment, infants may be unable to synthesize cysteine (or cystine) and tyrosine from their amino acid precursors (methionine and phenylalanine, respectively), thus these amino acids are considered to be semi-essential amino acids for infants and minimum amounts are also set for them.

The protein content and composition of mammalian milk can vary as can the amino acid content (Khaldi et al. 2014). To account for this, manufacturers typically adjust the whey to casein fractions of the base milk ingredient to at least meet the minimum amount of each essential amino acid in the final infant formula. Alternatively single amino acids may be added to meet the minimum requirements.

Table 3.1: Minimum amounts of amino acids in Standard 2.9.1 and Codex (mg/100 kJ)

| Essential amino acids | Standard 2.9.1 | Codex STAN 72-1981 |
|----------------------------------|-----------------|--|
| Histidine | 10 | 10 |
| Isoleucine | 21 | 22 |
| Leucine | 42 | 40 |
| Lysine | 30 | 27 |
| Cysteine* | 6 | 9 |
| Methionine | - | 6 |
| Cysteine, cystine and methionine | 19 ^a | Sum of Cys + Met (=15) ^b if Met:Cys<2:1 |
| Phenylalanine | 17 | 19 |
| Tyrosine* | - | 18 |
| Phenylalanine and tyrosine | 32 ^c | Sum of Phe + Tyr (=37) ^d |

| Essential amino acids | Standard 2.9.1 | Codex STAN 72-1981 |
|-----------------------|----------------|--------------------|
| Threonine | 19 | 18 |
| Tryptophan | 7 | 8 |
| Valine | 25 | 22 |

* semi-essential amino acids

^a Minimum methionine by difference is 13 mg/100 kJ

^b Summed value using the listed minimums of Cys and Met

^c Minimum tyrosine by difference is 15 mg/100 kJ

^d Summed value using the listed minimums of Phe and Tyr

For the two sulphur amino acids (SAA), Standard 2.9.1 specifies a minimum amount of cysteine (or cystine⁵) or these combined, as well as a minimum summed value of methionine and cysteine (and cystine).

Codex STAN 72-1981 differs slightly from Standard 2.9.1 in that methionine and cysteine each have a listed minimum value, with the following footnote: “The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1, the suitability of the formula has to be demonstrated by clinical testing”. The footnote for the cysteine to methionine ratio in Codex STAN 72-1981 is open to interpretation. One interpretation is that the minimum summed value in combination with the Met:Cys ratio <2:1 can replace the individual minimums for methionine and for cysteine. The summed minimum of methionine and cysteine is then 15 mg/100 kJ. Application of the maximum ratio to this sum results in reversing the individual methionine amount to 9 (mg/100 kJ), and the cysteine amount to 6 (mg/100 kJ), which equates to the minimum amount in Standard 2.9.1.

During assessment of Proposal P93, ANZFA considered several factors to determine an appropriate expression of minimum requirements for SAA in infant formula. The proposed approach was to set an absolute minimum value for cysteine as it was considered essential for very young infants. This approach corresponded with the level required by the EC and equated to an approximate minimum ratio of cysteine to methionine of 1:2 in line with LSRO Report (ANZFA, 1999a).

For the aromatic amino acids (AAA) phenylalanine and tyrosine, Standard 2.9.1 specifies a minimum amount of phenylalanine and a summed value of phenylalanine and tyrosine. Standard 2.9.1 minimum for these AAA were expressed as a summed value because breast milk concentrations of phenylalanine and tyrosine had not been reported individually at the time of the previous review (ANZFA 1999a). Codex STAN 72-1981 lists a minimum for each because they were measured individually in breast milk using a more recent methodology (EC SCF, 2003). However a footnote that notes “nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together”. Again the footnote is open to interpretation in that it is not clear if summing the the two AAAs overrides the listed individual minimums. Theoretically, summing the two without a minimum ratio allows for the phenylalanine content to be zero and does not ensure that phenylalanine requirements are met.

The nutrition assessment notes the Codex minimum amino acid requirements are based on more recent data of breast milk composition. For SAA they also follow the EC SCF recommendation that the methionine: cysteine ratio be no more than 2:1 in line with breast milk which typically contains SAA in a 1:1 ratio. It also notes it is appropriate to determine the

⁵ Cysteine is the sulphhydryl form, cystine is the disulphide form. The two forms are interconverted through an redox reaction, are nutritionally equivalent, and across various reports are referred to interchangeably.

amounts of methionine and cysteine in infant formula by difference i.e. subtracting either from the measured total SAA amount. Alignment with these requirements is unlikely to pose a risk to infant health. For aromatic amino acids (AAA) – phenylalanine (essential) and tyrosine (semi-essential) – the nutrition assessment notes that because phenylalanine (essential) is present in high abundance in most proteins and tyrosine is converted to phenylalanine in infants, AAAs measured in IF as the summed amount would enable infant amino acid requirements to be met. Thus, use of Codex minimum amounts for phenylalanine and tyrosine is unlikely to pose a risk to infant health. It also concludes that the minimum amounts of the other essential amino acids in Codex STAN 72-1981 are unlikely to pose a risk to infant health.

During consultation some submitters considered that the data used to specify minimum amounts of essential amino acids are derived from a relatively limited and aging data pool e.g. the amino acid data used in the 2007 revision of Codex STAN 72-1981 was from publications published between 1985 and 1998. The nutrition assessment has taken this into account.

Several submitters commented that infant formula companies are challenged to minimise the quantities of amino acids that are currently in excess of requirements, while also trying to meet the minimum amino acid amounts specified in regulation. At the time of consultation, histidine, leucine, lysine and valine were noted to be a particular concern as Standard 2.9.1 requirements are higher than those in Codex STAN 72-1981. Submitters considered that the minimum required amounts of these amino acids may restrict the ability to provide lower protein formulas in Australia and New Zealand, or result in unnecessary amino acid fortification. They noted that fortification does not reflect the growing evidence linking high protein intake in infancy with potential long-term negative health consequences. Others commented that the trend for lower protein content in infant formula means that it is important that minimum requirements for amino acids are not overstated.

Industry submitters also noted that compliance is not straightforward due to the natural variations in amino acid content of milk ingredients. This, coupled with the variability in analytical results for amino acid creates issues such as for the current minimum requirements for cysteine, and for methionine plus cysteine. The minimum required amounts fall within the variation of the analysis results for these amino acids. It was suggested that this potential compliance issue would be resolved if Standard 2.9.1 amino acid requirements aligned with the current Codex infant formula standard.

FSANZ's preliminary view is that aligning the minimum amounts of isoleucine, leucine, lysine, threonine, tryptophan and valine with Codex STAN 72-1981 is appropriate as it is unlikely to pose a risk to infant health; and is generally supported by submitters. However, FSANZ's preliminary view is to maintain the current expression for SAA and AAA in specifying the minimum for Cys and Phe and the summed values of SAA and AAA because the expression is clear and not subject to possible misinterpretation. In addition, our view is to retain the current minimums for the SAA and AAA in Standard 2.9.1. However, feedback from submitters will assist in further assessment.

Table 3.2: Current and preliminary proposed minimum amounts of amino acids (mg/100 kJ)

| Essential amino acids | Current | Proposed |
|-----------------------|---------|----------|
| Isoleucine | 21 | 22 |
| Leucine | 42 | 40 |
| Lysine | 30 | 27 |

| Essential amino acids | Current | Proposed |
|----------------------------------|-----------------|-----------------|
| Threonine | 19 | 18 |
| Tryptophan | 7 | 8 |
| Valine | 25 | 22 |
| SAA | | |
| Cysteine* | 6 | 6 |
| Methionine | - | - |
| Cysteine, cystine and methionine | 19 ^a | 19 ^a |
| AAA | | |
| Phenylalanine | 17 | 17 |
| Tyrosine* | - | - |
| Phenylalanine and tyrosine | 32 ^c | 32 ^c |

4 Fat

Fats (or lipids) are the main energy source in infant formula. The fat content in infant formula is determined by the need for energy for growth and for the supply of essential fatty acids (EFSA, 2014).

In Standard 2.9.1, clauses 21 and 23 (section 2.9.1—9; 2.9.1—11 and section S29—8 in the revised Code):

- specify mandatory minimum and maximum requirements for total fat and the essential fatty acids linoleic acid (LA) and α -linolenic acid (ALA)
- specify maximum limits and certain ratios for long chain polyunsaturated fatty acids (LC-PUFA)
- limit the presence of various other fatty acids.

Codex STAN 72-1981 specifies similar mandatory requirements for total fat and the essential fatty acids, includes specific requirements for certain fatty acids, and places limits on the presence of saturated fats and phospholipids.

Figure 4.1 provides an overview of the complex infant formula fat composition between the Code and Codex. There are many variations between the two standards which are discussed in the following sections. FSANZ is seeking input from stakeholders on a number of issues.

4.1 Fat content

As shown in Table 4.1, Standard 2.9.1 and Codex STAN 72-1981 prescribe the same minimum for total fat; however there is a marginal difference in the prescribed maximum fat.

Table 4.1: Fat content (g/100 kJ)

| Standard | Min | Max |
|--------------------|------|-----|
| Standard 2.9.1 | 1.05 | 1.5 |
| Codex STAN 72-1981 | 1.05 | 1.4 |

No submissions were received on the fat content of infant formula. FSANZ's nutrition assessment concludes that the difference between the maximum amounts appears to be due to rounding and is considered minor. Recent EFSA (2014) recommendations are also consistent with the Codex provisions for total fat content. We conclude that alignment with the Codex maximum for fat content is unlikely to pose a risk to infant health. FSANZ's product survey indicated that the labelled fat content of current infant formula ranges from 1.2–1.33 g/100 kJ which is within the range of Codex STAN 72-1981.

Our preliminary view is to align with Codex STAN 72-1981 which would slightly lower the maximum fat content.

4.2 Units of expression

During assessment of P93, ANZFA considered whether the amount of fatty acids should be expressed as absolute values per 100 kJ of energy, or as a proportion of the total fatty acids. It was noted that most relevant scientific reports about infant fatty acid requirements at that time expressed them as a percentage of total fatty acids, rather than as absolute values or per 100 kJ. ANZFA considered it appropriate to use a proportional unit of expression for inter-related fats, in recognition of the complexity of essential fatty acid metabolism (ANZFA, 2002). Additionally, setting a specific value per unit of energy was problematic where a range of fat content (1.05–1.5 g/100 kJ) in formula was established; this was further confounded by the interplay of protein and carbohydrate levels (ANZFA, 2002).

No comments were received on the units of expression on fatty acids in submissions to the 2012 Consultation paper.

At this preliminary stage, we consider that the rationale from our previous assessment is still valid although we note that lowering the maximum fat content slightly may potentially affect the amount of fat in infant formula and have flow on effects on fatty acid requirements. Therefore, our preliminary view is to continue requiring the amount of particular fatty acids to be expressed as a percentage of total fatty acids, as this expression refers to the overall fatty acid profile that is independent of the energy content of the formula.

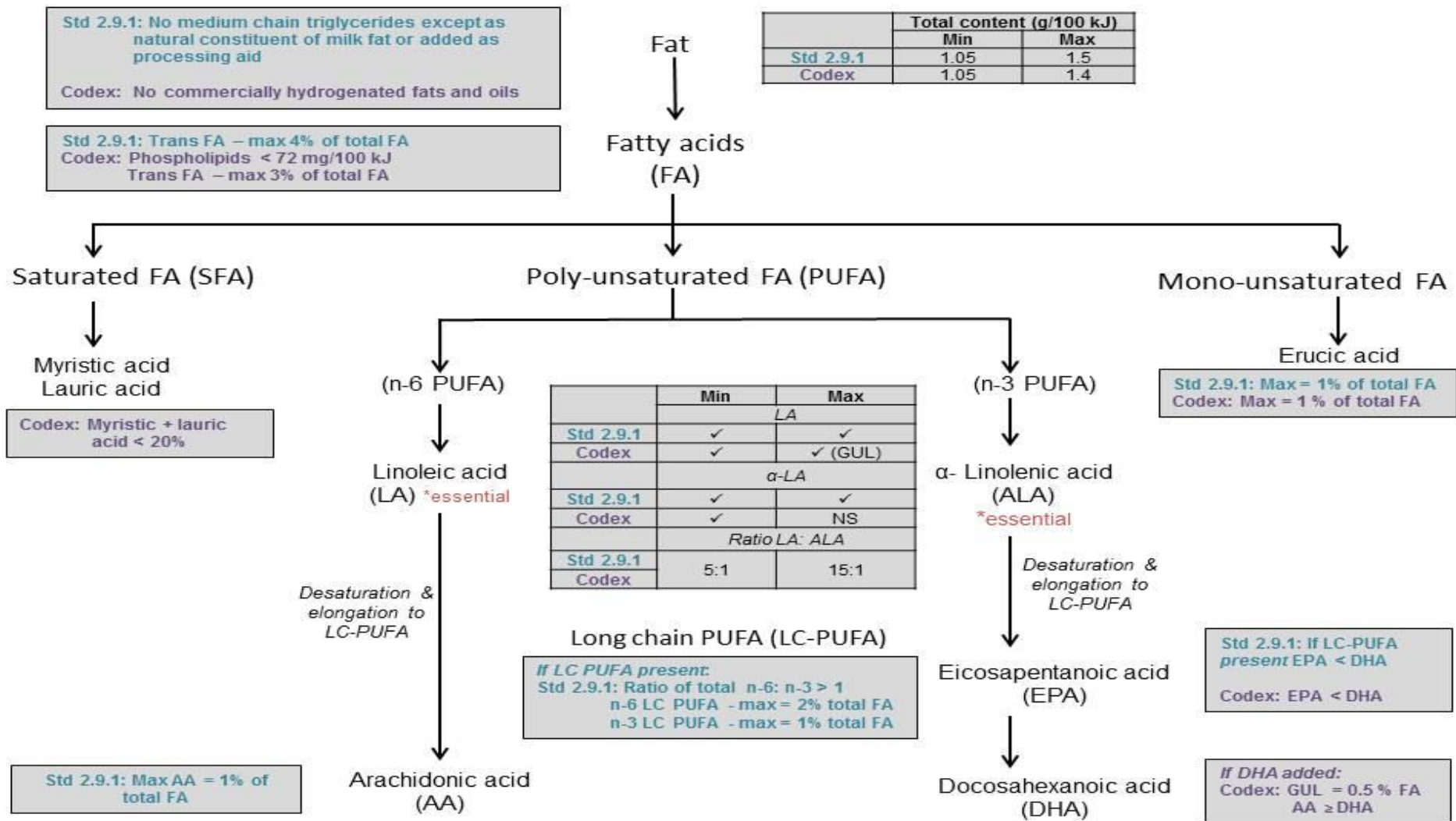


Figure 4.1: Overview of the fat composition provisions in Standard 2.9.1 and Codex STAN 72-1981

4.3 Fatty acid composition: linoleic acid and α-linolenic acid

Linoleic acid (LA 18:2, n-6) and α-linolenic acid (ALA, 18:2, n-3) are essential fatty acids because they cannot be synthesised endogenously. They are precursors of LC-PUFA.

As shown in Table 4.2, mandatory essential fatty acid requirements differ between the Code and Codex STAN 72-1981. In Standard 2.9.1, clause 23 and its accompanying table (section 2.9.1—11 and section S29—8 in the revised Code) set a minimum and maximum proportion of LA and ALA, and specify a ratio range for LA:ALA. Codex STAN 72-1981 specifies a minimum amount of LA and ALA, a guideline upper limit for LA, no maximum for ALA, and the same ratio range for LA:ALA. Standard 2.9.1 expresses all fatty acid requirements as a percentage of total fatty acids. Codex STAN 72-1981 expresses the *essential fatty acid* requirements as an amount per energy unit, whereas other fatty acids are expressed as a percentage of total fatty acids.

To compare the requirements of each standard, we converted the % total fatty acids of Standard 2.9.1 to mg/100 kJ in Table 4.2 using the minimum and maximum fat amounts in Standard 2.9.1 as appropriate and assuming 95% of fat is fatty acids (FA). When converted, the LA minimum in Standard 2.9.1 is higher than in Codex STAN 72-1981, whereas the ALA minimum is marginally different from Codex. Similarly, the LA maximum in Standard 2.9.1 is higher than in Codex STAN 72-1981, however, the Codex value is listed as a guidance upper level (GUL) rather than a maximum. Standard 2.9.1 prescribes a maximum proportion of ALA, whereas Codex STAN 72-1981 does not specify a maximum because it is indirectly controlled through the LA:ALA ratio range.

Table 4.2: Mandatory essential fatty acid requirements

| Fatty acid | Std 2.9.1 [^] Min–Max | Conversion Min–Max Code to Codex units* | Codex STAN 72-1981 Min–Max |
|--------------|-----------------------------------|--|-------------------------------|
| LA | 9–26% total FA | 90–371 mg/100 kJ | 70–330 (GUL) mg/100 kJ |
| ALA | 1.1–4% total FA | 11–57 mg/100 kJ | 12–NS mg/100 kJ |
| LA:ALA ratio | 5:1–15:1 | – | 5:1–15:1 |

[^](section S29—8 in the revised Code)

* see nutrition assessment for calculation assumptions

NS: not specified.

The endogenous conversions of LA to arachidonic acid (AA) and of ALA to docosahexaenoic acid (DHA) both utilise the same enzyme pathways, thus the LA and ALA content of infant formula must be suitably balanced to ensure an appropriate balance of AA and DHA. The nutrition assessment notes the current debate about infant requirements for essential fatty acids, and concludes that:

- No international consensus exists on the recommended amount of LA in infant formula.
- The evidence for the minimum LA does not support the lower Codex amount but is more consistent with the current Standard 2.9.1, and adoption of the minimum LA could potentially pose a risk to infant health.
- The continued use of the ALA minimum is unlikely to pose a risk to infant health.

- The basis for setting a maximum for LA in the Code is unclear. Recent reviews from EFSA (2014) have not recommended a mandatory maximum. There is no evidence of safety concerns with the current maximum in Standard 2.9.1, thus adoption of the slightly lower Codex maximum for LA as a GUL is unlikely to pose a risk to infant health.
- The maximum amount of ALA is controlled by the maximum ratio of LA to ALA of 15:1, thus removal of a maximum ALA is unlikely to pose an increased risk to infant health if the ratio is maintained.
- The current evidence suggests that the current LA:ALA ratio is unlikely to pose a risk to infant health. However, the ratio may need further consideration if DHA or other LC-PUFAs become mandated.

There were no specific comments on LA or ALA in submissions to the 2012 Consultation paper.

Overall, it is FSANZ's preliminary view that alignment with Codex STAN 72-1981 is appropriate and unlikely to pose a risk to infants for the following essential fatty acids provisions:

- maximum (GUL) for LA: although Codex GUL amount for LA is lower than the current maximum, depending on current manufacturing practice, reformulation of products may not be required as it is a guidance (advisory) level rather than a mandatory amount.
- minimum amount for ALA with no prescribed maximum for ALA
- LA:ALA ratio range.

However, as noted above, the Codex minimum LA amount needs further consideration and submitter input would be helpful.

Questions to submitters:

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

4.4 Long chain polyunsaturated fatty acids

LC-PUFAs are unsaturated fatty acids with more than one double bond in a cis-cis methylene pattern and a chain length greater than or equal to 20 carbon atoms, and include fatty acids with n-6 and n-3 chemical structures. They include:

- arachidonic acid (20:4, n-6) (AA) synthesised from LA
- eicosapentaenoic acid (20:5, n-3) (EPA) is a precursor to DHA.
- docosahexaenoic acid (22:6, n-3)(DHA) synthesised from ALA through EPA

As shown in Table 4.3, Standard 2.9.1 (section 2.9.1—11 and section S29—8 in the revised Code) prescribe limits on several LC-PUFA groups and the above three individual fatty acids when present in infant formula as optional additions. Codex STAN 72-1981 permits the voluntary addition of LC-PUFAs with differing maximum limits with the note that national authorities may deviate from the DHA, AA (and EPA) conditions as appropriate for nutritional needs. These fatty acids are generally present in infant formula through the use of specific oils in the formulation.

Table 4.3: Overview of differences in LC-PUFA composition provisions between the Code and Codex

| Standard | n-6 and n-3 LC-PUFA maximum | | | DHA, AA, EPA maximum | | | |
|-----------------------------|-----------------------------|-----------|-----------------------|----------------------|------------|-----|-----------|
| | % Total FA | | Ratio | % Total FA | | | Ratio |
| | n-6 LC-PUFA | 3 LC-PUFA | | AA | DHA | EPA | |
| Standard 2.9.1 [^] | 2% | 1% | n-6 ≥ n-3 | 1% | NS | NS | DHA ≥ EPA |
| Codex STAN 72-1981 | NS | NS | AA ≥ DHA DHA ≥ EPA | NS | 0.5% (GUL) | NS | NS |

[^]paragraphs 2.9.1—11(1)(c) & (d), and section S29—8 in the revised Code
NS: not specified

4.4.1 Sources of LC-PUFA

At the time Standard 2.9.1 was developed, three specific LC-PUFAs were identified in breast milk. Evidence of potential efficacy and some safety concerns about LC-PUFAs in infant formula was emerging. Also at that time, only the European Commission and the United Kingdom (UK) permitted the use of LC-PUFAs in infant formula as optional ingredients. The sources of LC-PUFA were certain edible oils (egg lipid, blackcurrant seed oil, fish oil) rather than purified fatty acids. During assessment of P93, ANZFA permitted two novel algal oils rich in DHA (as well as other fatty acids) for use in infant formula. However, there is currently no express permission in the Code for DHA to be used in infant formula. This lack of clarity on the use of oil ingredients that contribute the PUFA component has been raised by submitters previously. Also a number of submissions to the 2012 Consultation paper supported specifically recognising addition of DHA and AA to infant formula in the Code to align with the Codex standard.

4.4.2 EPA

Both Standard 2.9.1 (paragraph 2.9.1—11(1)(d) in the revised Code) and Codex STAN 72-1981 are generally aligned in relation to the approach for EPA. They specify that for any LC-PUFAs that are present, the EPA content must be no more than DHA content. Codex STAN 72-1981 also includes a note stating that national authorities may deviate from the DHA, AA (and EPA) conditions as appropriate for nutritional needs. The limit on EPA content in Standard 2.9.1 was introduced during P93 to manage the potential risk of EPA interfering with AA metabolism (ANZFA, 1999a). This restriction aligned with the European and UK regulations at the time.

The nutrition assessment concludes the Codex approach for EPA (which is aligned with Standard 2.9.1) would be unlikely to pose a risk to infant health. This is supported by the conclusions of the recent EFSA review of the evidence, which agreed that comparison with the relative concentration in breast milk was an appropriate approach (EFSA, 2014).

It is FSANZ's preliminary view that it is appropriate to maintain the requirement for EPA content to be no more than DHA content as this is already aligned with Codex.

4.4.3 DHA

The presence of DHA is optional in both Standard 2.9.1 (paragraph 2.9.1—11(1)(e) and section S29—8 in the revised Code) and Codex STAN 72-1981. The main difference between the standards is Codex STAN 72-1981 lists a DHA maximum as a GUL of 0.5% fatty acids whereas Standard 2.9.1 limits DHA as a component of the maximum 1% of long chain omega 3 series fatty acids.

DHA is an essential component of nerve and retinal cells and is involved in normal brain and visual function; and it accumulates in brain cells in the first two years of life. Over recent years there has been considerable debate about whether a mandatory minimum of DHA should be set for infant formula. Several submissions suggested that DHA should be made mandatory in infant formula. Reference was made to the FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition (FAO, 2010) and that EFSA had recognised the role of DHA in infant visual development to 12 months of age (EFSA, 2009).

The nutrition assessment examined several key reviews regarding the need for added DHA and concluded that the efficacy of DHA supplementation on infant growth and development has not been fully established. Furthermore, there is no evidence that voluntary DHA addition, as currently prescribed in both Standard 2.9.1 and Codex STAN 72-1981, poses a risk to infant health.

The current maximum proportion of 1% total n-3 LC-PUFA in Standard 2.9.1 (section S29—8 in the revised Code) consists of DHA and smaller proportions of EPA and other n-3 LC-PUFA. From a review of specifications for DHA oil in the Code (Standard 1.3.4 – Identity and Purity (Schedule 3 in the revised Code), it is possible that present formulations of infant formula contain slightly more DHA than the Codex GUL of 0.5% total fatty acids. However, FSANZ expects that there would be minor or no impact on current infant formula formulations if the maximum for all n-3 LC-PUFAs in the Code were replaced by a GUL for DHA (and other relevant ratios).

FSANZ's preliminary view is that a mandatory minimum DHA is not supported by the evidence and it is appropriate to control DHA when present with a guidance limit, by adopting the Codex GUL amount for DHA of 0.5% total fatty acids.

4.4.4 AA

The Table to clause 23 of Standard 2.9.1 (paragraph 2.9.1—11(1)(e) and section S29—8 in the revised Code) prescribes a maximum proportion of AA when present at no more than 1% total fatty acids. Codex STAN 72-1981 requires AA content of infant formula to reach at least the same content as DHA.

AA is present in cell membranes and is a precursor to a class of signalling compounds referred to as eicosanoids that are required for normal cell functions. Several submissions to the 2012 Consultation paper suggested that AA should also be considered as a mandatory fatty acid in infant formula. The nutrition assessment has reviewed recent reviews and notes that the EFSA (2014) opinion concludes that the addition of AA to infant formula is unnecessary even in the presence of added DHA. However, it also notes that the EFSA conclusion has been questioned in the literature as clinical trials have not been conducted that demonstrate the safety of added DHA without added AA.

FSANZ's preliminary view is that it is appropriate to maintain a maximum proportion of no more than 1% total fatty acids when AA is present.

4.4.5 Ratios of DHA, AA and LC-PUFA

Standard 2.9.1 (paragraph 2.9.1—11(1)(c) in the revised Code) prescribes the minimum ratio of total n-6 to total n-3 to be ≥ 1 (or $n-6 \geq n-3$). The Codex STAN 72-1981 does not include any maximum or ratios for total n-3 and n-6 content. Instead a minimum AA:DHA ratio is included to manage any potential n-6 and n-3 imbalance.

Submissions to the 2012 Consultation paper proposed that the ratio of total n-6:n-3 LC-PUFA should be amended to a ratio of AA:DHA for greater clarity and consistency with Codex STAN 72-1981.

The total n-6:n-3 ratio was included in Standard 2.9.1 to manage any potential risk of imbalance of n-6 LC-PUFAs to n-3 LC-PUFAs, based on emerging evidence (at the time) suggesting that n-6 LC-PUFA may interfere with metabolism of n-3 LC-PUFA to varying extents. The total n-6:n-3 ratio was originally based on the ratio seen in breast milk and was subsequently amended after assessment in response to an application seeking to change the ratio of n-6 to n-3 LC PUFA from 2:1 to at least 1:1 (FSANZ, 2007).

The nutrition assessment notes that, as AA and DHA are metabolites of n-6 LC-PUFA and n-3 LC-PUFA respectively, setting a AA:DHA ratio instead of a n-6:n-3 ratio is appropriate to manage the potential imbalance. The nutrition assessment also refers to the EFSA (2014) opinion and various clinical trials, and concludes that, in the absence of more conclusive evidence on the appropriate ratios of DHA:AA, or n-6:n-3, adopting the relevant provisions in Codex STAN 72-1981 would be unlikely to pose a risk to infant health. Such a change could potentially reduce the amount of AA as it would no longer need to account for the presence of EPA as a component of long chain n-3 series fatty acids.

At this preliminary stage, our preliminary view is to replace the minimum ratio of total n-6 to total n-3 with the Codex minimum ratio of AA:DHA to avoid metabolic imbalance between n-3 LC-PUFAs and n-6 LC-PUFAs.

To assist stakeholders all of the preliminary considerations in section 4.4 are summarised in Table 4.4.

Table 4.4: LC-PUFA composition: preliminary view

| DHA, AA, EPA maximum | | | Ratio | n-6 and n-3 LC-PUFA maximum | | |
|----------------------|----|-----|---------------------------------|-----------------------------|-------------|-------|
| DHA | AA | EPA | | n-3 LC-PUFA | n-6 LC-PUFA | Ratio |
| % Total FA | | | % Total FA | | | |
| 0.5% (GUL) | 1% | NS | EPA \leq DHA AA \geq DHA | NS | NS | NS |

NS: not specified

4.5 Source of fat

Historically, dairy fat from the milk component of infant formula was the main source of fats in infant formula. However, dairy fat has a different fatty acid profile to breast milk fat, so fat formulations are now devised typically using a blend of vegetable oils to create the required fatty acid profile (McSweeney, O'Regan, and O'Callaghan, 2014). Supplementary fatty acids (i.e. DHA) for use in infant formula are specifically produced from different oils: fish oil, egg yolk lipid or oil isolated from specific algae or fungi.

Standard 2.9.1 does not specify or prohibit any particular sources of fat (or particular oils) used in infant formula. Instead clause 23 of Standard 2.9.1 (paragraph 2.9.1—11(1)(e) and section S29—8 in the revised Code) outlines compositional criteria for fatty acids in infant formula. Fatty acids which are considered harmful are restricted or limited to protect infants from adverse health consequences (ANZFA, 1999a) (refer to section 4.6). The general requirement of the Code, that an ingredient in infant formula must be safe and suitable for infant feeding also guards against the use of any potentially unsafe ingredients.

Codex STAN 72-1981 generally takes a similar approach on the source of fat (as the macronutrient component) in infant formula in that no specific sources are specified. Although the footnote to Part 3.1(b) specifies that commercially hydrogenated oils and fats should not be used. DHA is specifically listed as a permitted optional ingredient.

Some submissions to the 2012 Consultation paper commented that, as technology develops; more detail may be required in the Standard to specify which ingredients are permitted to make up the essential fat composition. Another submission noted there is no clear definition or differentiation between what is considered a lipid component versus a lipid ingredient incorporated for the macronutrient profile of the formula. This was considered to be particularly important for new technologies that are used to produce ingredients for infant formula, and for future-proofing the standard. These general issues are discussed in SD2 as part of the consideration of the pre-market assessment approach for novel and nutritive substances in infant formula.

During assessment of P93, it was not considered necessary to specifically prohibit any particular type of oil as a source of fat. The fatty acid composition limits mean that the restriction on commercially hydrogenated oils is not necessary. In addition the pre-assessment requirements of novel foods and novel sources of ingredients were considered sufficient to manage any potential risks of new ingredients, such as new sources of fats in infant formula. However FSANZ invites feedback from submitters on whether the current approach to the regulation for the source of fat is appropriate.

Question to submitters:

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.

4.6 Restrictions on certain fats

Table 4.5 summarises the maximum amounts of particular undesirable fatty acids in both Standard 2.9.1 (paragraphs 2.9.1—11(1)(a) and (e), and section S29—8 in the revised Code) and Codex STAN 72-1981.

Table 4.5: Maximum amounts of unfavourable fatty acids

| Fat | Unit | Standard 2.9.1 (section S29—8 in the revised Code) | Codex STAN 72-1981 |
|-----------------------------|------------|--|--------------------|
| Trans fatty acids | % total FA | 4 | 3 |
| Erucic acid | % total FA | 1 | 1 |
| Lauric acid + myristic acid | % total FA | — | 20 |

4.6.1 Medium chain triglycerides

A medium chain triglycerides (MCT) contains fatty acids of 6–12 carbon chains which include caprylic (C:8) and capric (C:10) acids. They occur naturally in many foods including dairy products, coconut and palm oils. Through subclause 23(a) (paragraph 2.9.1—11(1)(a) in revised Code), Standard 2.9.1 restricts the presence of MCTs in infant formula unless they are present as the result of their being:

- a natural constituent of a milk-based ingredient of a particular infant formula
- for a substance used as a processing aid in the preparation of a permitted fat soluble vitamin.

The original prohibition on MCTs in Standard 2.9.1 was based on potential safety concerns. This prohibition was retained by FSANZ in [Application A563 – Medium Chain Triglycerides in Infant Formula](#)⁶. The nutrition assessment notes that current expert recommendations support a prohibition on MCT in infant formula. Codex STAN 72-1981 does not include any statement about MCTs.

Our preliminary view is that the current limitations on MCTs in Standard 2.9.1 remain appropriate as they do not pose a risk to infants, and there is no apparent benefit from permitting MCTs in infant formula. However, this would not be consistent with Codex. Stakeholder feedback would be useful to inform the future assessment.

4.6.2 Trans fatty acids

Both Standard 2.9.1 and Codex STAN 72-1981 restrict the content of trans fatty acids (TFA) in infant formula with a prescribed maximum % total FA. Standard 2.9.1 (paragraph 2.9.1—11(1)(e) and section S29—8 in the revised Code) restricts the TFA content of infant formula to a maximum of 4% total FA. TFA are defined as the total of unsaturated fatty acids where one or more of the double bonds are in the *trans* configuration (refer to Table 2.3). With the transfer of the TFA definition from Standard 1.2.8 to Standard 1.1.2 in the revised Code, the definition of TFA now applies throughout the revised Code, including to Standard 2.9.1. Codex defines TFA as: “all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the *trans* configuration” (Guidelines on Nutrition Labelling CAC/GL 2-1985, 2015).

Codex STAN 72-1981 acknowledges that TFA are endogenous components of milk fat, and states in a footnote that the acceptance of up to 3% TFA is intended to allow for use of milk fat in infant formula.

Consumption of TFAs is shown to be associated with both short- and long-term adverse health effects. The nutrition assessment notes that partial hydrogenation of fats and oils can increase TFA. The nutrition assessment concludes that adoption of the lower Codex maximum level for TFA is unlikely to impact adversely on infant health.

FSANZ’s preliminary view is to lower the maximum proportion of TFA (as defined in the Code) to 3% total FA, to align with Codex STAN 72-1981.

⁶ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa563mediu3018.aspx>

4.6.3 Myristic and lauric acids

Myristic acid (C14:0) and lauric acid (C12:0) are saturated fatty acids. Standard 2.9.1 does not restrict the presence of either of these fatty acids. However, Codex STAN 72-1981 lists a combined limit for myristic and lauric acids of no greater than 20% total FA in infant formula.

The restriction on their presence is based on there being no demonstrated nutrition role; and potential negative effects on serum cholesterol and lipoprotein concentrations (Koletzko et al, 2005). The nutrition assessment notes that EFSA (2014) recently considered that there was no evidence to impose restrictions on levels of myristic and lauric acids.

Our preliminary view is to maintain no restriction on myristic and lauric acids in Standard 2.9.1, in line with the recent expert opinion although this differs from the Codex approach.

4.6.4 Erucic acid

Erucic acid (C:22, n-9) is a monounsaturated fatty acid. Both Standard 2.9.1 (paragraph 2.9.1—11(1)(e) and section S29—8 in the revised Code) and Codex specify the proportion of erucic acid to be no more than 1% total FA due to its presence in relatively high concentrations in vegetable oils and its potential adverse health effects.

The nutrition assessment notes EFSA (2014) concluded that infant formula made from vegetable oils containing erucic acid is safe from a toxicological point of view, and there is no additional indication that this restriction should be removed.

As Standard 2.9.1 is currently aligned with Codex, our preliminary view is to retain the limit on erucic acid.

4.6.5 Phospholipids

Phospholipids are a class of lipids that are a major component of all cell membranes. They occur in both breast milk and bovine milk (Thompkinson and Kharb, 2007). They are sold and used as an alternative source (to triacylglycerol sources) of LC-PUFA in infant formula e.g. from egg phospholipids (Makrides et al., 2005, EFSA 2014, Kent 2014). Phospholipids include inositol and are also one of the components of lecithin (up to about 50% phospholipids) which have a technological use as a food additive (emulsifier) in infant formula.

Standard 2.9.1 does not restrict the class of phospholipids in infant formula; however, Codex STAN 72-1981 specifies a maximum amount (72 mg/100 kJ) of phospholipids as part of the total fat conditions. Both Standard 1.3.1 (Schedule 15 in the revised Code) and Codex STAN 72-1981 permit the use of lecithin phospholipid as an emulsifier in infant formula up to a combined emulsifier maximum level of 0.5 g/100 mL of product ready for consumption.

There is increasing interest in potential nutritional benefits of addition of phospholipids for a nutritive purpose. The nutrition assessment reviewed this evidence, which mostly stems from the use of the milk fat globule membrane. The assessment comments that trial results are too preliminary to indicate addition of phospholipids is nutritionally safe or beneficial. Recently, EFSA (2014) also considered the evidence of benefit from addition of phospholipids as a source of LC-PUFA, and concluded evidence was insufficient.

The nutrition assessment concludes that the amount of phospholipids in infant formula should not exceed the amount that naturally occurs in breast or cow's milk (i.e. approximately 250 mg/L). The limit in Codex STAN 72-1981 (72 mg/100 kJ) would be equivalent to approximately 2 g/L, which is higher than cow's or breast milk content.

FSANZ's preliminary view is that total phospholipids should be restricted but that more information is needed before a maximum such as 250 mg/L could be established. Also, that the evidence does not support alignment with the higher Codex maximum. Any final maximum amount needs to take account of the level of lecithin in infant formula.

Question to submitters:

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

5 Carbohydrate

Regulating carbohydrate in infant formula requires consideration of the definition, the total content, the type and source of carbohydrate and calculation of carbohydrate content. The Code does not currently prescribe the total content or the type and source of carbohydrate that may be used in infant formula.

Industry submitters generally support harmonisation with international standards including Codex. However, carbohydrate was not specifically addressed in the 2012 Consultation paper, and no clarity or safety issues were raised by submitters in relation to carbohydrate content or source.

5.1 Definitions and calculations relevant to identity of carbohydrate

Classification and terminology of carbohydrates varies across the literature and different regulations. Several definitions related to carbohydrate and its components are listed in the Code (shown in Table 2.3). These are located in Standard 1.2.8 or Standard 1.1.1 in the current Code (Standard 1.1.2 in the revised Code).

The definition of carbohydrate differs between the current Code and the revised Code. The complicated definition of carbohydrate in Standard 1.2.8 in the current Code (see Table 2.3) refers to available carbohydrate and carbohydrate by difference and also to their respective methods of calculation. The simpler definition of carbohydrate in Standard 1.1.2 in the revised Code refers to the definitions of: 'available carbohydrate' and 'available carbohydrate by difference', which are themselves defined in that Standard. The definitions of 'carbohydrate', 'available carbohydrate' and 'carbohydrate by difference' now apply throughout the revised Code. Their respective methods of calculation are now set out in Schedule 11 in section S11—3, instead of being contained within the definition. Standard 1.1.2 also includes a definition of dietary fibre. Schedule 11 includes methods of analysis for dietary fibre (S11—4), which do not apply across the whole Code.

Although the *requirements* of Standard 1.2.8 (section 1.2.8—3 in the revised Code) do not apply to infant formula (as Standard 2.9.1 contains its own labelling provisions); the *definitions* in Standard 1.2.8 were specifically applied to infant formula as they were considered appropriate for the compositional requirements of infant formula (through clause 1 of Standard 2.9.1 in the current Code). FSANZ acknowledges this has caused confusion and anticipates that transfer of the definitions to Standard 1.1.2 in the revised Code has resolved that confusion.

Standard 2.9.1 also permits optional addition of ITF and galacto-oligosaccharides (refer to Table 2.3). Previous FSANZ assessments ([Proposal P306](#)⁷ and [Application A1055](#)⁸)

⁷ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp306addition3639.aspx>

commented that oligosaccharides in infant formula are *largely* undigested in the small intestine and undergo colonic fermentation by microorganisms to yield short chain fatty acids. According to this description, these oligosaccharides (and possibly other carbohydrates such as dried glucose syrup and maltodextrins) may comprise both unavailable and available carbohydrates. The Code does not define unavailable carbohydrate however several carbohydrates are allocated lower energy factors than available carbohydrate in the Code. Some of these such as D-tagatose do not have prescribed methods of analysis for dietary fibre and may contain unavailable carbohydrate components. Unavailable carbohydrate is relevant to calculation of energy and of [available] carbohydrate by difference. However in both the calculation of available carbohydrate and energy, dietary fibre is identified as a component of unavailable carbohydrate.

Codex STAN 72-1981 does not contain definitions for carbohydrate, available carbohydrate or unavailable carbohydrate or dietary fibre. However the Codex *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) includes a definition of dietary fibre (see Box 2). Although the Codex guidelines apply to the nutrition labelling of all foods, there are also some labelling provisions included in Codex STAN 72-1981 as well. There is an inconsistency between these two Codex texts as Part 9.3 of Codex STAN 72-1981 states that nutrition information declared on infant formula should include "... the number of grammes of protein, carbohydrate and fat per 100 grammes...". While the CAC/GL 2-1985 states that energy shall be determined using "...available carbohydrate (i.e. dietary carbohydrate excluding dietary fibre), fat, saturated fat, sodium and total sugars...". Codex STAN 72-1981 has no specific provisions for the addition of oligosaccharides other than through the permissions for optional ingredients; and does not include any energy factors. However, CAC/GL 2-1985 lists the energy factors, only listing carbohydrate energy factor (17 kJ). Thus it is unclear if the carbohydrate in Codex STAN 72-1981 refers to 'dietary carbohydrate excluding dietary fibre' or total carbohydrate.

Box 2: Definition of dietary fibre in Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)

Dietary fibre means carbohydrate polymers² with ten or more monomeric units³, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

Footnotes:

² When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds associated with polysaccharides in the plant cell walls. These compounds also may be measured by certain analytical method(s) for dietary fibre. However, such compounds are not included in the definition of dietary fibre if extracted and re-introduced into a food.

³ Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

⁸ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1055shor4991.aspx>

FSANZ's preliminary view is that definitions and the method of calculation relevant to carbohydrate identity in the revised Code are appropriate for infant formula. We also consider that the classification of carbohydrates as available or unavailable is best left to manufacturers. Whether the concept of dietary fibre or its prescribed methods of analysis are relevant to infant formula is an open question. FSANZ notes that fructo-oligosaccharide is permitted in infant formula and, although not currently applicable to infant formula, has a prescribed method of analysis when identified as a dietary fibre.

Question to submitters:

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

5.2 Introduction of a maximum and minimum content

Standard 2.9.1 does not directly specify a minimum or maximum content of total carbohydrate for infant formula as the carbohydrate content of infant formula is indirectly controlled by the provisions for protein, fat and energy content. The determination of carbohydrate content by this procedure was consistent with Codex regulations at the time of the preceding review of Standard 2.9.1 (ANZFA 1999b).

Codex STAN 72-1981 does list a minimum and maximum amount of 2.2-3.3 g/100 kJ for carbohydrate. The amount of carbohydrate permitted in Standard 2.9.1 after energy, fat and protein requirements are taken into account is slightly lower than Codex STAN 72-1981. This is due to the higher maximum fat amount in Standard 2.9.1.

The nutrition assessment notes that the minimum and maximum amounts of carbohydrate in Codex STAN 72-1981 are effectively aligned⁹ with Standard 2.9.1. Indeed, these limits are simply the result of numerical calculations relating to the mandatory limits on energy, protein and fat, and so are unnecessary.

FSANZ's survey of label information on products in the market place indicates that the labelled carbohydrate content lies within the Codex minimum – maximum range.

FSANZ's preliminary view is to retain the current approach by not specifying a minimum and maximum amount for carbohydrate, noting this is in effect aligned with the Codex range.

5.3 Carbohydrate source

Lactose is the main source of carbohydrate in breast milk. Lactose, maltose, glucose, dried glucose syrup, sucrose, maltodextrins, and pre-cooked starch and gelatinised starch (gluten free) are the main carbohydrates used in infant formula. Their use in infant formula varies depending on the type of protein upon which the formula is based, although this is more relevant to formulas for specific dietary use. For example sucrose is used in formulas made from protein hydrolysates to mask the bitter taste.

Standard 2.9.1 does not include any provisions relating to the source of carbohydrate in infant formula. Codex STAN 72-1981 includes guidance on the types of digestible carbohydrate to be used (e.g. 'preferred' sources of carbohydrate and that sucrose and fructose "should be avoided"), but this is not mandatory.

⁹ calculated using the carbohydrate conversion factors: 1 g carbohydrate = 17 kJ for Codex STAN 72-1981

The P93 assessment considered the suitability of carbohydrate sources and determined that:

- maltodextrin could be permitted for use in all infant formula products
- sucrose could be permitted for use in formula except pre-term formula, in amounts up to 20%
- high fructose corn syrup should not be permitted in infant formula products
- glucose syrup and dried glucose syrup could be permitted in pre-term formula
- the origin of starch must be declared in the ingredient list.

Submitter comments at the time recommended that the source of carbohydrate in infant formula should be controlled and that lactose should be the preferred carbohydrate in formulas that are not for a special purpose. However at that time, the Codex standard and draft revised Codex standard did not specify carbohydrate sources. Therefore, FSANZ decided not to prescribe the source in Standard 2.9.1 on the basis that doing so may have created a trade barrier.

The nutrition assessment notes that Codex guidance for source of carbohydrate in infant formula is in line with current expert opinion. The use of 'prebiotic' carbohydrates (non-digestible carbohydrates) is an area of current research. As mentioned above, ITF and galacto-oligosaccharides are permitted in Standard 2.9.1 whereas Codex has no specific provisions for the addition of oligosaccharides other than through the permission for optional ingredients.

As evidence is not strong for mandatory restrictions on the source of carbohydrate in infant formula, FSANZ's preliminary view is to maintain the current provisions in Standard 2.9.1. We recognise this will not align with Codex STAN 72-1981. As carbohydrate was not addressed in the 2012 Consultation paper, submitter views would be useful.

Question to submitters:

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.

6 Energy

6.1 Energy content

To ensure infant formula provides sufficient but not excess energy, Standard 2.9.1 prescribes a range for energy density of 2500–3150 kJ/L. This range was based on the evidence and alignment with the Codex provisions at the time of the previous review (ANZFA 1999b). Since then, the permitted range in Codex STAN 72-1981 has been narrowed to 2500–2950 kJ/L by lowering the maximum density.

The nutrition assessment concludes that there are no public health indicators to suggest that this small decrease is unlikely to adversely affect normal growth and development. Therefore, adoption of the lower maximum energy amount is unlikely to pose a risk to infant health.

In response to FSANZ's 2012 Consultation paper, all submissions supported aligning the minimum and maximum energy requirements for infant formula with the current Codex

levels. FSANZ's label survey indicated that the average energy content range, as labelled, was within the Codex minimum/maximum range.

FSANZ's preliminary view is to lower the maximum energy density to 2950 kJ/L as in Codex STAN 72-1981. The minimum energy density is already aligned.

6.2 Calculation of energy density

Clause 3 of Standard 2.9.1 (paragraph 2.9.1—4(2)(a) in the revised Code) specifies that the energy density of infant formula must be calculated using only the energy contributions from fat, protein and carbohydrate ingredients (*components* in section S29—2 in the revised Code), using the equation and energy factors specified for nutrition labelling provided in clause 2 of Standard 1.2.8 (section S11—2 in the revised Code).

During development of Standard 2.9.1, it was considered that the energy factors listed in Standard 1.2.8 were appropriate for calculating the energy density of infant formula (ANZFA, 2002) including adoption of the energy factor 8 kJ/g for unavailable carbohydrate. Nevertheless, Standard 1.2.8 includes a statement that the Standard does not apply to Standard 2.9.1. FSANZ acknowledges that the apparent conflict between the two standards (and Schedule 11 in the revised Code) in the Code has caused some confusion for stakeholders. but expects that the relevant modifications in the revised Code have resolved that confusion.

Codex STAN 72-1981 does not list energy factors or refer to the Codex *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) which lists energy factors for labelling.

As shown in Table 6.1, the energy factors in the Code potentially relevant to labelling of infant formula include a factor for both available (defined with method of calculation) and unavailable carbohydrate (not defined).

Table 6.1: Energy factors for labelling of energy density

| Food Component | Standard 1.2.8/ Section S11—2 Energy factor (kJ/g) | Codex GL 2-1985 energy factor (kJ/g)* |
|--|---|--|
| Carbohydrate (excluding unavailable carbohydrate) | 17 | 17 |
| Unavailable carbohydrate (including dietary fibre) | 8 | |
| Fat | 37 | 37 |
| Protein | 17 | 17 |

*The draft revised Codex Standard for Follow-up Formula has modified the term 'carbohydrate' to 'available carbohydrate' (Appendix III, REP16/NFSDU).

Our preliminary view is to maintain application of energy factors for calculating the energy density of infant formula. Furthermore, the Code's factors outlined in Table 6.1 should continue to apply to infant formula including both energy factors for available and unavailable carbohydrate.

7 Micronutrient composition

Infant formula is required to contain 25 vitamins, minerals and electrolytes. Standard 2.9.1 (sections S29—9 and S29—10 in the revised Code) contains several provisions for each of these micronutrients including a prescribed minimum amount, and either a maximum amount or a guideline level (recommended maximum amount) in Standard 2.9.1 in the revised Code). The micronutrient range is prescribed to ensure the formula provides for the nutritional needs of infants, at all stages of growth and development during infancy. In addition, there are specific minimum ratios for certain nutrients e.g. vitamin E per gram of polyunsaturated fatty acids; calcium and phosphorus.

The micronutrient provisions in Standard 2.9.1 were developed as part of P93. The assessment took into consideration the recommendations of the 1998 Life Sciences Research Office (LSRO) report, as well as alignment with the European infant formula standard and draft revised Codex Infant Formula Standard at the time. Overall, the approach for setting micronutrient amounts in the Code is similar to Codex STAN 72-1981.

The following assessment specifically compares the current provisions for each micronutrient in Standard 2.9.1 with Codex STAN 72-1981, and considers whether or not Standard 2.9.1 could be amended to align with the Codex standards for consistency and harmonisation. Where appropriate, this assessment considers the nutritional safety, potential impact on the manufacture of infant formula, and submitter comments. FSANZ's preliminary views are provided and specific questions are included for submitters in some cases. The use of recommended maximum amounts, the permitted range of vitamins, minerals and electrolytes are discussed in the following sections.

7.1 Approach to setting guidelines or maximum amounts

In Standard 2.9.1 (section S29—9 in the revised Code) all nutrients have either a maximum amount or a recommended guideline maximum amount. Absolute maximum amounts are only prescribed for those vitamins and minerals considered to pose a significant risk to infants if consumed in excess. Standard 2.9.1 (section S29—10 in the revised Code) also lists recommended maximum amounts (hereafter referred to as GULs) for 14 micronutrients in infant formula, as the risk posed by the nutrient was “not of significance on the basis of current scientific knowledge” (ANZFA, 1999a). These GULs are not binding and serve as guidance for industry in designing formulations.

Codex STAN 72-1981 uses a similar approach, with either maximum amounts or GULs for most nutrients (not iron). There are some differences as GULs are assigned to 20 micronutrients in the Standard. Annex II of the Codex standard sets out the *General Principles for establishing minimum and maximum values for essential composition of infant formula*. GULs have been assigned where there was insufficient information about adverse effects from excessive intakes for a science-based risk assessment to set a mandatory limit.

A 2009 audit of the legal efficacy of the Code noted that any substantive material in the Code should be captured in a clause within the Code¹⁰, rather than as guidance. As the standards in the Code are legal instruments, it was queried whether the use of advisory maximum guidance in the guideline is appropriate. The guidance is included in the revised Code as the consideration of the approach is being undertaken in this Proposal. Thus we are considering whether the GULs should be formally incorporated into Standard 2.9.1.

¹⁰ Details can be found at <http://www.foodstandards.gov.au/code/code-revision/Pages/default.aspx> and <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

The 2012 Consultation paper contained two questions on the advisory maximum approach for micronutrients. We sought information on how the guidance levels are used by manufacturers; and submitter views on whether it would be appropriate to change from advisory levels to legally binding maximum limits in Standard 2.9.1. Table 7.1 outlines the feedback from submitters, which generally supported retaining the advisory approach to maximum amounts where appropriate. Submissions also supported alignment with relevant Codex GULs.

Table 7.1: Summary of submitter comments on guideline maximum amounts

| Comment | Submitter |
|---|------------------------------|
| Topic: Do not support mandating GULs | |
| This would not be on the basis of safety issues, there has been no evidence of harm or of market failure to date, and this would not align with the minimal effective regulation objective of both the Australian and New Zealand government. | Multiple industry submitters |
| Topic: Support mandating GULs | |
| Mandate the levels to ensure action can be taken for any breaches; and assist in maintaining uniform standard among manufacturers. | Consumers |
| Support the inclusion of GULs into the legally binding document to enable enforceability, given the vulnerability of the population, and maintain similar levels to breast milk. | Government submitters |
| Support retaining GULs to accompany the Standard | |
| If the GULs are not included in the Code, suggest a reference in the standard to the GULs, which could be provided in a separate user guide. | Government |
| Supports the use of GULs in association with the Standard but further consideration required. | Government |
| Topic: Use of GULs | |
| GULs are useful as they provide guidance for recipe design for the manufacture of infant formula. | Industry |
| Many of these vitamins and minerals do not have an Upper Level of Intake in the Australia and New Zealand NRVs, but a GUL for these nutrients minimises any adverse interactions with other vitamins, minerals and electrolytes. | Government |
| When an upper level cannot be clearly established for a nutrient, composition based on a guidance level provides confidence in the safety and suitability of a product. | Industry |
| The principle of 'Good Manufacturing Practice' (GMP) is applied to the addition of nutrients in the manufacture of infant formula. Thus a number of factors limit the addition of nutrients to formula: <ul style="list-style-type: none"> • The average nutrient requirement per serve or % of product • The need to ensure that under recommended storage conditions the average quantity declared on the label is achieved through the life of the product • The cost of the nutrient compound used to provide a given nutrient value • The method of addition of a particular nutrient to a food and how effectively it can be distributed throughout the food. | Industry |
| Topic: Other issues | |
| The prime consideration should be the vulnerability and best interests of infants. | Consumers |
| FSANZ should consider which nutrients (with a GUL) require a maximum level so as not to place a metabolic or physiological burden on the infant. Should be reviewed for any new evidence regarding the safety. | Government and consumers |

| Comment | Submitter |
|---|-----------|
| The margin of safety is not the same for all nutrients thus a change to mandatory levels would require a full scientific assessment of each nutrient to justify any change. | Industry |

7.1.1 How guideline amounts (GULs) are used for micronutrients

Industry submitters indicated that the GULs are useful in guiding recipe design for the manufacture of infant formula. Submissions noted that there are several factors which limit addition of nutrients, also that the good manufacturing practice (GMP) principle applies for nutrient compounds as it does for food additives and processing aids.

Several submissions noted that the current limits align with NRVs as there are no upper levels set for these vitamins and minerals. Industry submissions noted that GULs are based on the same premise as ULs i.e. when a UL cannot be clearly established for a nutrient, formula composition based on a guidance level provides confidence in the safety and suitability of a product. Several submitters also note the margin of safety is not the same for all nutrients. There was no support from industry submitters to include the GULs as part of the legally binding standard although there was support from some government and consumer submitters for this.

During 2013 and 2014, FSANZ also undertook targeted consultation with jurisdictions and industry to consider potential options for the location of the advisory maximums e.g. as a separate guidance document outside the Code. This approach was not generally supported because retention of all requirements and recommendations in one document was considered more convenient.

The following 9 vitamins: vitamin K, thiamin, riboflavin, niacin, vitamin B₁₂, pantothenic acid, folic acid, vitamin C, and biotin all have GULs designated in both Standard 2.9.1 and Codex STAN 72-1981. However, calcium is the only mineral with a GUL in both Standards. The individual limits are discussed later in the SD.

7.1.2 No change from GUL to maximum amount

The nutrition assessment did not identify any advisory maximum amounts for vitamins and minerals that should be amended to a maximum amount. Our preliminary view is that none of the current GULs for vitamins and minerals in Standard 2.9.1 need to be amended to a prescribed maximum amount.

7.1.3 Change from maximum to guideline amounts

Nine vitamins and minerals that are prescribed legally binding maximum amounts in the Code have GULs applied in Codex STAN 72-1981. FSANZ's nutrition assessment considered the need for a prescribed maximum amount or a GUL for these nine vitamins and minerals.

For some nutrients, data related to adverse effects from excessive intakes in infants are relatively well documented; for others the data are inconsistent. This creates a number of uncertainties and makes it difficult to establish science-based upper nutrient levels (MacClean et al 2010). In Standard 2.9.1 the GULs were assigned to nutrients after a risk assessment determined that there were no known reports of toxicity, and no other safety concerns at high intakes in infants (ANZFA, 1999b). Prior to this, several nutrients had no maximum amount listed in either the previous Australian Standard R7 or New Zealand Food Regulations.

FSANZ is aware that managing tight specifications for a large number of nutrients in each batch of formula can be a major challenge for infant formula companies. The GUL approach taken in both Standard 2.9.1 and Codex STAN 72-1981 provides flexibility.

The use of GULs minimises any potential risk of adverse health effects from consumption of vitamins, minerals that exceed an infant's requirements. The approach is based on several principles:

- breast milk has a self-limiting level for all vitamins and minerals and the setting of maximum amounts in infant formula mimic this natural protective factor
- an excessive supply of dietary components which could potentially burden an infant's metabolic functions (Koletzko et al., 2012)
- although not all vitamins and minerals are toxic in excessive quantities, an excess of one nutrient can interact adversely with others
- it is expected that the levels serve as guidance for manufacturers and will be used according to Good Manufacturing Practice (GMP)
- take into account an established history of safe use.

In setting the Codex maximum levels and GULs, analytical data on nutrient levels in cow's milk- and soy protein-based formulas from manufacturers around the world was compiled (MacLean et al., 2010). Although not a fully representative sample for each nutrient, the data assisted in consideration of technological issues that can influence the nutrient levels. This included information on:

- the form of the product (liquid vs. powder product)
- inherent levels of vitamins and minerals in formula ingredients used to supply macronutrients (e.g. riboflavin in ingredients supplying milk protein and lactose)
- the source of protein
- significant nutrient instability (defined as 25% loss over shelf life)
- known problems with analytical variability (defined as 10% relative standard deviation in the same laboratory and/or 20% variability between different laboratories)
- aspects which may affect stability of nutrients such as packaging, container material or container size and effects of processing.

Thus the inclusion of GULs in Codex STAN 72-1981 was based on knowledge of nutrient requirements of infants, technological and manufacturing considerations, known variability in current formulas and a history of apparent safe use in infant formulas. The rationale and approach used for both Standard 2.9.1 and Codex STAN 72-1981 align.

As shown in Table 7.2, the nutrition assessment identified no evidence to indicate that a GUL would pose a risk to infant health for vitamin E, vitamin B₆, phosphorus, magnesium, manganese, iodine, selenium, copper or zinc.

Table 7.2: Basis for amending Code maximum amounts to GULs consistent with Codex STAN 72-1981

| Micronutrient | Nutrition assessment conclusion | Preliminary view |
|------------------------|--|---|
| Vitamin E | No basis for this difference could be determined. Based on the long history of safe use at this level and no new evidence of vitamin E toxicity in infants, it is reasonable to conclude that a GUL would be unlikely to pose a risk to infant health. | Propose to change from a maximum amount to a GUL |
| Vitamin B ₆ | There is no evidence indicating excessive vitamin B ₆ intakes in formula-fed infants. A GUL would be unlikely to pose a risk to infant health | Propose to change from a maximum amount to a GUL |
| Magnesium | Use of a GUL would be unlikely to pose a risk to infant health | Propose to change from a maximum amount to a GUL |
| Manganese | Use a GUL would be unlikely to pose a risk to infant health. | Propose to change from a maximum amount to a GUL |
| Iodine | Use of a GUL would be unlikely to pose a risk to infant health. | Propose to change from a maximum amount to a GUL |
| Copper | Use of a GUL would be unlikely to pose a risk to infant health. | Propose to change from a maximum amount to a GUL |
| Zinc | No evidence was identified to support the mandatory maximum amount currently set in Standard 2.9.1. | Propose to change from a maximum amount to a GUL |
| Folate | No evidence was identified to support the mandatory maximum amount currently set in Standard 2.9.1. | Propose to change from a maximum amount to a GUL |
| Phosphorus | <p>Although excess phosphorus intake may induce hypocalcaemia, use of a GUL would be unlikely to pose a risk to infant health because there is no recent evidence indicating that older infants (>14 days) consuming infant formula develop hypercalcemia due to excess phosphorus intakes.</p> <p>No additional studies were found suggesting adverse effects linked to high phosphorus intakes in formula-fed infants. Therefore, the Codex GUL amount for phosphorus did not meet the assessment criteria but further analysis indicated that use of this voluntary maximum would be unlikely to pose a risk to infant health.</p> <p>Hypocalcaemia due to excess phosphorus in formula-fed infants is prevented by limiting the calcium phosphorus ratio.</p> | <p>Codex STAN 72-1981 includes a footnote that this “GUL should accommodate higher needs with soy formula”</p> <p>Needs to be considered in relation to the calcium: phosphorus ratio.</p> <p>Seeking further information to inform future assessment</p> <p>Refer to section 7.3.2.2</p> |

| Micronutrient | Nutrition assessment conclusion | Preliminary view |
|---------------|---|--|
| Selenium | <p>The higher Codex GUL amount represents a less restrictive maximum and potentially allows exceedance of the UL.</p> <p>However, there is no international consensus on an appropriate maximum. In the absence of data indicating that the Codex maximum amount is unsafe, it is concluded that its use is unlikely to pose a risk to infant health.</p> | <p>Seeking further information to inform future assessment</p> <p>Refer to section 7.3.3.3</p> |

FSANZ’s preliminary view is that it is appropriate for some nutrients to retain a GUL in Standard 2.9.1, and for others to be amended from a prescribed maximum to a GUL to align with Codex (as summarised in Table 7.2). Folate, phosphorus and selenium require further information and are considered in sections below. Further discussion on the amounts for each nutrient is found in sections 7.3.

7.2 Vitamin dietary equivalents and conversion factors

Although most vitamins are families of chemically related compounds, differences exist in the physiological utilisation of different forms, and therefore there are different ways of determining and reporting the vitamin activity from food. Codex STAN 72-1981 and Standard 2.9.1 differ in the way in which vitamin equivalents for vitamins A and E and niacin are managed and expressed. Also, neither of them applies Dietary Folate Equivalents (DFE) to folates.

7.2.1 Vitamin A

Vitamin A is the general term that covers all-trans retinol (also called retinol), which refers to the family of naturally occurring compounds associated with the biological activity of retinol (such as retinal, retinoic acid, retinyl esters), and provitamin A carotenoids that are dietary precursors to retinol. Dietary sources of vitamin A are either preformed vitamin A obtained from animal sources; or provitamin A carotenoids (e.g. β -carotene) obtained from plant sources. The permitted forms of vitamin A are discussed in section 8.1 of this paper.

Three systems/units of expression have been used to report the vitamin A activity in food: international units (IU), retinol equivalents (RE) and retinol activity equivalents.

Standard 2.9.1 (section S29—9 in the revised Code) lists the vitamin A requirements for infant formula as vitamin A without reference to units of retinol equivalents (RE) or applicable conversion factors. (The vitamin A requirements were expressed as RE in the previous infant formula standards in the Code (Standard R7, transitional Standard 1.1A.1) however, it is not clear why RE was removed in Standard 2.9.1). Standard 2.9.1 also lists β -carotene as a permitted form of vitamin A in infant formula and the Code also permits various chemical forms of β -carotene for use in infant formula as a colour.

However, the revised Code sets out in paragraph 1.1.2—14(3)(a) that vitamin A should be calculated in terms of RE (for all foods including infant formula) and, for provitamin A forms of vitamin A, calculated using the RE conversion factors in section S1—4. β -carotene is listed as provitamin A in infant formula in section S29—7; and elsewhere in the revised Code it is listed for use as a colour in infant formula. Thus, if β -carotene is added, regardless of whether it is for colouring or nutritional purposes, the revised Code requires that β -carotene should be counted as contributing to the vitamin A content of infant formula.

Codex STAN 72-1981 lists the vitamin A amounts as RE but also includes a footnote which states “retinol contents shall be provided by preformed retinol whereas any carotenoid content should not be included in the calculation and declaration of Vitamin A activity”. The following conversion factors are listed in the footnote:

| |
|--|
| $1 \mu\text{g RE} = 3.33 \text{ IU Vitamin A} = 1 \mu\text{g all-trans retinol}$ |
|--|

Several submissions noted there are inconsistencies in the Code as some standards set vitamin A requirements in units of $\mu\text{g RE}$ whereas they are listed as μg alone for infant formula which is inconsistent with international regulation. This was particularly confusing as β -carotene is listed as a permitted form of vitamin A for use in infant formula in Standard 2.9.1 (S29—7 in the revised Code). Submissions sought clarification on both the contribution of β -carotene to total vitamin A, and also the expression as retinol equivalents (RE).

FSANZ’s nutrition assessment notes that the bioavailability of β -carotene from infant formula is less certain than from breast milk. It also noted that the NRVs for vitamin A are not expressed in RE units for infants aged 0–6 months (NHMRC & MoH, 2006). Recent reviews continue to exclude carotenoid forms on the basis of lack of knowledge on the bioconversion of carotenoids in infants. Thus the nutrition assessment concludes that limiting vitamin A content of infant formula only to that derived from preformed vitamin A is unlikely to pose a risk to infant health.

FSANZ’s preliminary view is to exclude β -carotene from the total amount of vitamin A in infant formula in light of uncertainty around its bioavailability, and also to support expressing of vitamin A requirements in units of μg alone (rather than RE), as this clarifies that β -carotene should not contribute to the vitamin A content. The Code would then align with Codex and other international regulations in relation to β -carotene contribution to vitamin A content but will differ in relation to the vitamin A units.

7.2.2 Folate

Folate refers to the form that occurs naturally in food such as green leafy vegetables; folic acid is the synthetic form of folate added to food and supplements. Upon absorption, folic acid is converted to the biologically functional form folate which is present in the body’s circulation, and in breast milk. Folic acid is essentially 100% bioavailable whereas folate from foods (and presumably breast milk, although this has not been determined) is 50-60% bioavailable. Dietary Folate Equivalents (DFE) is the unit that accounts for differences in the absorption efficiency of folates.

Neither Standard 2.9.1 (section S29—9 in the revised Code) nor Codex STAN 72-1981 sets requirements for infant formula as DFE. The Codex minimum amount is expressed as folic acid, whereas the requirement in Standard 2.9.1 is listed as folate. Although the bioavailability of folic acid from formula consumed by infants has not been specifically assessed, recent EFSA (2014) recommendations on the composition of infant formula have proposed the use of DFE, using the Institute of Medicine (IoM) conversions.

Milk and milk powder have naturally occurring levels of folate, thus infant formula generally contains a mixture of naturally occurring folate and added folic acid. Setting the minimum folate requirement as folic acid (as in the Codex standard) would exclude the contribution of naturally occurring folate. According to MacLean et al (2010), up to 40% of the folate in finished product is inherent in the ingredients used to produce infant formula.

Although DFE were first introduced as the units for the folate nutrient reference values in 2006, they have not yet been incorporated into the Code. Currently the Code treats folic acid

and folate as having equivalent bioavailability with values for folate and folic acid considered equal (FSANZ, 2005). Previously, FSANZ proposed that introducing the term DFE into the Code would be considered when reviewing all vitamin and mineral reference amounts in the Code (FSANZ, 2005). In 2010, FSANZ considered revising the [regulatory NRVs¹¹](#) (rNRVs) in the Code with a preferred approach to update the rNRV to DFE (FSANZ, 2010). This was generally supported by submitters. However, revision of the rNRVs is not yet under active consideration.

Use of DFE in Standard 2.9.1 would require the appropriate conversion to be specified. As discussed in the nutrition assessment, DFE have been defined by IOM (1998) as:

1 DFE = 1 µg food folate = 0.6 µg folic acid from fortified food or as a supplement consumed with food = 0.5 µg of a folic acid supplement taken on an empty stomach.

As neither Codex STAN 72-1981 nor Standard 2.9.1 currently use DFE to express the folate content of infant formula, our preliminary view is to retain the nutrient name as folate rather than folic acid although this differs with Codex STAN 72-1981, and retain units of µg folate. It is unclear whether allowing for natural folate but not adopting the DFE units would make any difference. We are seeking further information from stakeholders to inform future assessment.

Question to submitters:

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

7.2.3 Vitamin E

Vitamin E refers to a group of compounds that include naturally occurring tocopherols and tocotrienols and several synthetic homologues. Recent evidence suggests that naturally occurring d-α-tocopherol (or RRR-α-tocopherol) is considered to be the only form that contributes towards meeting the vitamin E requirements because the other naturally occurring forms are “recognized poorly by the α-tocopherol transfer protein” in the liver (IOM, 2000)¹². Synthetic alpha-tocopherol used in fortified foods and supplements provides half the vitamin E activity as the natural form of alpha-tocopherol. Vitamin E activity is either identified as alpha-tocopherol only or alpha-Tocopherol Equivalents (α-TE).

Standard 2.9.1 (section S29—9 in the revised Code) lists the vitamin E units as mg vitamin E referring to α-tocopherol; all permitted forms of added vitamin E are synthetic or natural forms of α-tocopherol. Codex STAN 72-1981 lists units of vitamin E as α-TE although a note specifies that 1 mg α-TE = 1 mg d-α-tocopherol.

No submitter comments were received on this issue.

¹¹ <http://www.foodstandards.gov.au/science/monitoringnutrients/Pages/nutrientreferenceval5831.aspx>

¹² Previously total alpha-tocopherol was used as the measure of vitamin E activity and was determined from alpha-, beta-, gamma-, and delta-tocopherols. Currently vitamin E (total α-tocopherol) is defined as limited to the following forms of alpha-tocopherol:

- RRR-alpha-tocopherol, the form of α-tocopherol that occurs naturally in food, and
- 2-R-stereoisomeric forms of α-tocopherol that occur in fortified foods and supplements

It is FSANZ's preliminary view that mg α -TE should be adopted as the units for vitamin E to indicate the relative activities of natural and synthetic forms of alpha-tocopherol. The revised Code specifies conversion factors in section S1—5 for some of the synthetic forms of vitamin E permitted in infant formula and this list could be completed as part of this Proposal if relevant to infant metabolism.

7.2.3.1 Vitamin E content relative to polyunsaturated fatty acids

Vitamin E prevents oxidation of PUFA, including LC-PUFA, thus the amount required is influenced by the unsaturated fatty acid content of infant formula. Both Standard 2.9.1 (subsection 2.9.1—12(3) in the revised Code) and Codex STAN 72-1981 specify a minimum amount of vitamin E per g of PUFA. Standard 2.9.1 sets a minimum amount of 0.5 mg vitamin E per g of any PUFA whereas Codex STAN 72-1981 also lists 'factors of equivalence' from 0.5 mg/g for LA and increasing in increments of 0.25 mg/g to 1.5 mg/g for DHA according to the number of fatty acid double bonds in individual PUFAs in an infant formula. These factors are applied to determine the minimum amount of vitamin E for a particular PUFA mixture in infant formula.

The nutrition assessment notes recent research suggesting vitamin E content should be increased in formula supplemented with PUFA, although further studies are required. The nutrition assessment examined the difference between calculating vitamin E using the different approaches in the two Standards, by estimating the minimum amount of vitamin E required in an infant formula taking account of the range of fatty acid profiles in infant formula and using their maximum requirements in Standard 2.9.1. Applying the more complex Codex equation generally gave higher vitamin E, although there are very small differences. The greatest difference calculated to be 0.04 mg/100 kJ at the maximum fat content, using soybean oil as source, with maximum addition of DHA (refer to appendix 4 of the nutrition assessment for more detail). The nutrition assessment concludes that application of the Codex STAN 72-1981 conversions for vitamin E equivalents makes only a marginal difference in the amount of vitamin E needed to be present compared to application of the approach currently used in Standard 2.9.1. There is limited evidence to indicate that the use of different factors depending on the number of PUFA double bonds is warranted.

Applying the more complex Codex equation to maximum LC-PUFA content in a theoretical infant formula composition gives a total vitamin E difference of 0.018 mg/100 kJ, which is a marginal difference given that the prescribed range of vitamin E is 0.012–1.2 mg/100 kJ in Codex STAN 72-1981. On this basis, and without evidence of harm of the current approach, not applying the specific Codex 'factors of equivalence' for α -TE to PUFA would be unlikely to pose a risk to infant health.

FSANZ's preliminary view is that the current approach to vitamin E requirements relating to the PUFA content of infant formula is retained. It is not considered necessary to adopt the 'factors of equivalence' for α -TE to individual PUFA outlined in Codex STAN 72-1981.

7.2.4 Niacin

Preformed niacin is the term used to refer to the niacin present in foods. In humans, niacin can be synthesised from tryptophan. Niacin requirements are therefore commonly expressed as niacin equivalents (NE) which take account of the niacin in the diet as well as the conversion of tryptophan to niacin. However, both Standard 2.9.1 (section S29—9 in the revised Code) and Codex STAN 72-1981 list the niacin requirements as preformed niacin. Infant formula therefore contains sufficient niacin to meet infant requirements without the need for metabolic conversion from the amino acid.

Our preliminary view is that it is appropriate to retain the requirement for niacin amount in infant formula to be limited to the contribution from preformed niacin.

7.3 Permitted range for micronutrients: minimum and maximum amounts

A permitted range is established for each of the 25 vitamins, minerals and electrolytes required in infant formula. The table to subclause 24(1) in Standard 2.9.1 (subsection 2.9.1—12(1) and section S29—9 in the revised Code) lists the minimum amounts for every listed micronutrient, and maximum amounts only where necessary. GULs for the other micronutrients are located in the guidelines to the Standard (section S29—10 in the revised Code). In Codex STAN 72-1981, section 3.1 (d) and (e) set out minimum amounts and maximum amounts or GULs for vitamins and minerals. The approach adopted in the two standards is similar, with both setting minimum amounts and either a maximum amount or a GUL for the same range of micronutrients although the actual minimum and maximum amounts may vary.

This section discusses the suitability of aligning the permitted ranges with Codex STAN 72-1981. The conclusions of the nutrition assessment are taken into consideration along with submitter comments, and potential implications on trade. The discussion is organised by the potential changes to the minimum–maximum range in Standard 2.9.1 for the micronutrients:

- where the permitted range already aligns with Codex STAN 72-1981
- where the permitted range could be aligned
- for which there is some uncertainty whether alignment is appropriate.

Previous FSANZ submissions generally supported alignment of the vitamin, mineral and electrolyte permitted ranges with the Codex Standard. Table 7.3 provides a summary of the general comments. Further specific points raised by submitters are noted under the relevant nutrients.

Table 7.3: Summary of submitter comments on alignment of micronutrient permissions with Codex STAN 72-1981

| Comment | Submitter |
|--|---------------------|
| Topic: Rationale for supporting alignment with Codex STAN 72-1981 | |
| Alignment promotes consistency with international standards, supports trade, and allows for future innovation and reformulation. | Multiple submitters |
| The permitted ranges recommended in Codex Stan 72-1981 have been evaluated for nutritional adequacy and safety, and reflect recent scientific opinion. | Multiple submitters |
| Export infant formula products are a significant commodity for New Zealand and facilitation of production should be a high priority – removing trade barriers is very important. | Government |
| Generally there should be alignment for maximums and minimums with commonly agreed scientific principles. Enforceable maximums and minimums depend on target values, test methods and other relevant factors for each country. To assist trade alignment with Codex is preferable. | Industry |
| Supports alignment with Codex to the greatest extent possible, and also consider local requirements. Would support variation from Codex if supported by evidence. | Government |
| In general support alignment with Codex as it is large international credible body with evidence sourced from ESPGHAN. | |

| Comment | Submitter |
|--|---------------------|
| Alignment is beneficial as it would mean the amounts are similar to those specified in the EU Regulations for standard infant formula. For certain critical nutrients e.g. iron, products will have to have a level that meets the nutritional needs for the broad age range of 0–12 months | Industry submitters |
| Topic: Specific alignment requests | |
| For 0–6 months support alignment with Codex particularly for copper, potassium, selenium, chloride. | Industry submitters |
| For vitamins: a small increase in riboflavin. For minerals: decreases for copper, potassium and selenium, and increases for chloride. Also, replace maximums with GULs for potassium, copper and selenium. | Industry submitters |
| Topic: Considerations required | |
| Must meet the needs of the full infant age range i.e. 0–<12 months | |
| Minimum and maximum for vitamins, minerals and electrolytes should take into account safe preparation with water >70°C. | Individual |
| There should be transparency in the compositional differences between Codex and the Code | Government |

7.3.1 Vitamins, minerals and electrolytes aligned with Codex

The minimum and maximum amounts for both vitamin A and vitamin D are already aligned with Codex STAN 72-1981 as shown in Table 7.4.

Table 7.4: Micronutrient amounts permitted in Standard 2.9.1 and Codex STAN 72-1981

| Vitamin or mineral | Units | Std 2.9.1 (section S29—9 in the revised Code) | | Codex STAN 72-1981 | | Range of average content in products on the market |
|--------------------|-----------|---|------|--------------------|---------|--|
| | | Min | Max | Min | Max | |
| Vitamin A | µg/100 kJ | 14 | 43 | 14 (RE) | 43 (RE) | 18.52–33.08 |
| Vitamin D | µg/100 kJ | 0.25 | 0.63 | 0.25 | 0.6 | 0.25–0.45 |

7.3.1.1 Vitamin D

Submissions noted that US Dietary Reference Values (DRVs) for vitamin D have been reviewed recently resulting in increased recommended infant requirements. Further consideration was given to vitamin D based on this recent revision in the USA.

The nutrition assessment notes that international expert panels have recently updated recommended intakes for vitamin D for infants 0–6 months old to 10 µg/day, assuming minimal sun exposure. The nutrition assessment considered the recent evidence and concludes that the current minimum requirement for vitamin D, as in both Standard 2.9.1 and Codex STAN 72-1981, is unlikely to pose a risk to infant health.

Amending Standard 2.9.1 in line with recent recommended requirements would result in inconsistency with Codex STAN 72-1981. As the current requirement is unlikely to pose a risk and is currently achievable for industry, thus not impacting on the manufacture of infant formula, our preliminary view is that it is appropriate to maintain existing provisions.

7.3.2 Vitamins, minerals and electrolytes that could be aligned

For the 18 vitamins, minerals and electrolytes listed in Table 7.5, either the minimum and/or maximum amount differs between the Code and Codex STAN 72-1981.

Table 7.5: Vitamins, minerals and electrolytes that could be aligned

| Vitamin or mineral | Units | Standard 2.9.1 (section S29—9 in the revised Code) | | Codex Stan 72-1981 | | Range of average content in products on the market |
|------------------------|-----------|--|---------------|--------------------|----------------------|---|
| | | Min | Max | Min | Max | |
| Vitamins | | | | | | |
| Vitamin B ₆ | µg/100 kJ | 9 | 36 | 8.5 | 45 (GUL)* | 12.55–30.66 |
| Vitamin B12 | µg/100 kJ | 0.025 | 0.17 (GUL) | 0.025 | 0.36 (GUL)* | 0.04–0.16 |
| Pantothenic Acid | µg/100 kJ | 70 | 360 (GUL) | 96 | 478 (GUL)* | 84.04–227.3 |
| Riboflavin | µg/100 kJ | 14 | 86 (GUL) | 19 | 119 (GUL)* | 24.01–71.68 |
| Thiamin | µg/100 kJ | 10 | 48 (GUL) | 14 | 72 (GUL)* | 15.25–62.02 |
| Folate | µg/100 kJ | 2 | 8 (GUL) | 2.5 | 12 (GUL)* | 2.78–5.56 |
| Niacin (preformed) | µg/100 kJ | 130 | 480 (GUL) | 70 | 360 (GUL)* | 130.1–272.7 |
| Vitamin E | mg/100 kJ | 0.11 | 1.1 | 0.12 (α-TE) | 1.2 (GUL)* (α-TE) | 0.26–0.58 |
| Vitamin K | µg/100 kJ | 1 | 5.0 (GUL) | 1 | 6.5 (GUL)* | 1.21–2.93 |
| Biotin | µg/100 kJ | 0.36 | 2.7 | 0.4 | 2.4 | 0.50–1.29 |
| Minerals | | | | | | |
| Calcium | mg/100 kJ | 12 | 33 (GUL) | 12 | 35 (GUL)* | 15.38–23.57 |
| Manganese | µg/100 kJ | 0.24 | 24 | 0.25 | 24 (GUL)* | 1.53–18.71 |
| Magnesium | mg/100 kJ | 1.2 | 4.0 | 1.2 | 3.6 (GUL)* | 1.65–2.52 |
| Copper | µg/100 kJ | 14 | 43 | 8.5 | 29 (GUL)* | 14.01–20.64 |
| Phosphorus | mg/100 kJ | 6 | 25 | 6 | 24 (GUL)* | 8.57–16.22 |
| Electrolytes | | | | | | |
| Potassium | mg/100 kJ | 20 | 50 | 14 | 43 | 20.79–31.65 |
| Chloride | mg/100 kJ | 12 | 35 | 12 | 38 | 14.39–25 |
| Sodium | mg/100 kJ | 5 | 15 | 5 | 14 | 5.71–11.47 |

*Change to GUL is discussed in section 7.2

For vitamin K, thiamin, riboflavin, pantothenic acid, vitamin B₁₂, biotin, magnesium, chloride and sodium: the range set in the Codex standard met all of the nutrition assessment criteria as discussed in Attachment 1; and no new evidence emerged to indicate that Standard 2.9.1 should not align. Therefore, the nutrition assessment concludes that alignment with the minimum and maximum (as maximum amounts or GULs) specified in Codex STAN 72-1981 is unlikely to pose a risk to infant health.

For vitamin E, vitamin B₆, niacin, folate, potassium, calcium, phosphorus, zinc, copper, manganese, chromium, molybdenum: the range set in the Codex STAN 72-1981 did not meet all of the nutrition assessment criteria. However, further examination, as detailed in the nutrition assessment, indicated that the range in the Codex standard was supported by the current scientific evidence base. Therefore, for these micronutrients, it was also concluded that alignment with the range specified in the Codex STAN 72-1981 is unlikely to pose a risk to infant health.

Some submissions to the 2012 Consultation paper specifically requested alignment with Codex STAN 72-1981 for riboflavin, copper, potassium and chloride. As shown in Table 7.5, the label survey of infant formula found that the labelled amount of all these vitamins, mineral and electrolytes falls within the range listed in Codex STAN 72-1981.

Our preliminary view is to align the minimum and maximum amounts for the vitamins, minerals and electrolytes listed in Table 7.5 with Codex STAN 72-1981, with the exception of phosphorus which requires further consideration (see section 7.1.3 and below).

7.3.2.1 Phosphorus and the calcium: phosphorus ratio range

Standard 2.9.1 and Codex STAN 72-1981 are generally aligned for the minimum and maximum amounts of calcium and phosphorus. Both standards (subsection 2.9.1—12(4) in the revised Code) also prescribe a ratio range of calcium to phosphorus (Ca:P), although they differ slightly. The ratio is to minimise the risk to infants from potential hypocalcaemia if formulas were to contain maximum amounts of phosphorus, combined with minimum calcium content. It also allows for the natural variation of raw materials used in manufacture of infant formula.

The current Codex STAN 72-1981 minimum Ca:P ratio is 1:1 whereas the minimum ratio in Standard 2.9.1 is 1.2:1 which was the previous Codex requirement. The Codex and Standard 2.9.1 maximum ratio is the same at 2:1. Further discussion on the interaction of copper and phosphorus with other minerals is included in section 7.3.3.

As noted in section 7.1.3, Codex STAN lists a GUL rather than maximum amount to accommodate the higher phosphorus levels in isolated soy protein formula. Our label survey only looked at three isolated soy protein based formulas although the labelled amount fell into the current range in Codex Stan 72-1981.

Submitters previously supported the Codex ratio. The nutrition assessment notes that if an infant formula contained the minimum calcium content (12 mg/100 kJ) and the maximum phosphorus content (24 mg/100 kJ), this would result in a Ca:P ratio of 0.5. It is also noted that there is no scientific evidence to indicate that the maximum Ca:P ratio is inappropriate. Thus it is concluded that the marginally lower minimum ratio would be unlikely to pose a risk to infant health.

FSANZ's preliminary view is that it is appropriate to change the current maximum (25 mg/100 kJ) in Standard 2.9.1 to a GUL of 24 mg/100 kJ in alignment with Codex. We also propose to adjust Standard 2.9.1 to align with the minimum Ca:P ratio of 1:1 as the nutrition

assessment indicates that such a change would be unlikely to pose a risk to infant health, and the shift required to align is small.

Question to submitters:

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.

7.3.3 Vitamins, minerals and electrolytes for which alignment may not be appropriate

For the vitamins and minerals listed in Table 7.6, the minimum, maximum, or both require some further assessment. Each discussed in the sections that follow.

Table 7.6: Vitamins, minerals and electrolytes that require further consideration

| Vitamin or mineral | Units | Standard 2.9.1 (section S29—9 in the revised Code) | | Codex Stan 72-1981 | | Range of average content in products on the market |
|--------------------|-----------|--|-----------|--------------------|------------|--|
| | | Min | Max | Min | Max | |
| Vitamin C | mg/100 kJ | 1.7 | 5.4 (GUL) | 2.5 | 17 (GUL) | 1.83–6.81 |
| Chromium | µg/100 kJ | - | 2.0 (GUL) | – | – | – |
| Molybdenum | µg/100 kJ | - | 3.0 (GUL) | – | – | – |
| Iodine | µg/100 kJ | 1.2 | 10 | 2.5 | 14 (GUL) | 2.10–5.92 |
| Zinc | mg/100 kJ | 0.12 | 0.43 | 0.12 | 0.36 (GUL) | 0.14–0.25 |
| Iron | mg/100 kJ | 0.2 | 0.5 | 0.1 | NS | 0.20–0.32 |
| Selenium | µg/100 kJ | 0.25 | 1.19 | 0.24 | 2.2 (GUL) | 0.29–0.96 |

NS: Not specified

7.3.3.1 Vitamin C

Standard 2.9.1 sets a minimum of 1.7 mg/100 kJ whereas the minimum in the Codex STAN 72-1981 is 2.5 mg/100 kJ. The nutrition assessment concludes the higher minimum is unlikely to pose a risk to infant health.

The maximums in both standards are GULs, however the GUL in Codex STAN 72-1981 is 17 mg/100 kJ, whereas the GUL in Standard 2.9.1 is much lower at 5.4 mg/100 kJ. The higher Codex GUL takes into account possible high losses and includes a footnote stating “this GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper limits should be aimed for”. The nutrition assessment concludes that the increased maximum is unlikely to pose a risk to infant health.

FSANZ’s label survey indicated that the lowest labelled vitamin C content in the sample was 1.8 mg/100 kJ, which is less than the Codex STAN 72-1981 minimum amount (2.5 mg/100 kJ). Therefore, if adopted, some manufacturers may need to adjust formulations to comply with the higher Codex minimum amount. The highest labelled content was 6.8 mg/100 kJ, mainly in powdered products as few liquid products are available on the Australian and New Zealand market.

Vitamin C is chemically labile which can create technological issues for manufacturing. Large losses may occur over shelf life since vitamin C degrades rapidly when exposed to air and water (MacLean et al, 2010). Losses ranging from 30–75% have been reported in liquid products (MacLean et al, 2010). As few liquid products are available, further consideration is required on the need to align with the higher GUL amount (17 mg/100kJ). Further information from submissions will assist this consideration.

Question to submitters:

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

7.3.3.2 Iron

The minimum for iron listed in Codex STAN 72-1981 (0.1 mg/100 kJ) is half the minimum prescribed in Standard 2.9.1 (Schedule 29 in the revised Code) (0.2 mg/100 kJ).

It is noted that there is no international consensus on the appropriate minimum amount of iron in infant formula. Formula-fed infants have a lower risk of ID or IDA than breastfed infants but there is evidence for inadequate iron status in some population groups of older infants. The Codex STAN 72-1981 minimum is lower than Standard 2.9.1 so presumably the risk of ID would increase using the Codex STAN 72-1981 amount thus is concluded that it could pose a risk to infant health.

The adequacy NRV for iron is an Adequate Intake (AI) for younger infants (0–6 months) whereas an Estimated Average Requirement (EAR) is established for older infants (7–12 months). New Zealand infants with intakes below the EAR had an increased risk of iron deficiency compared to those with intakes meeting or exceeding the EAR, thus FSANZ considers that use of the lower Codex minimum could potentially pose a risk to infant health although the extent of risk is uncertain.

A maximum amount of iron is prescribed in Standard 2.9.1 (0.5 mg/100 kJ) whereas Codex STAN 72-1981 notes instead that national authorities may determine their own amount. The maximum specified in Standard 2.9.1 is higher than current international recommendations however the nutrition assessment estimated that intakes based on that amount would not exceed the UL. Therefore, the current maximum in Standard 2.9.1 is unlikely to pose a risk to infant health.

FSANZ's label survey of infant formula found the iron content of all formula was within both the Codex and Standard 2.9.1 minimum – maximum provisions. Therefore, it is anticipated that retaining the current Code requirements would not have adverse impacts on industry or trade.

However, iron requirements for ISP-based infant formula may need further consideration. There are no special or additional requirements for iron with soy protein sources in Codex STAN 72-1981 or Standard 2.9.1 but the need for a higher minimum has been raised as a potential issue by some expert bodies (EC SCF, 2003). Previously it has been recommended that setting minimum amounts for certain minerals in soy-based infant formula should consider the phytic acid content of soy proteins and the potential for reduced availability of minerals. The literature suggests it is technologically possible to remove phytic acid from soy-based formula. Recently EFSA (2014) noted that studies show that reduction of phytic acid content completely or even by around half in ready-to-feed formula improves iron absorption but to a lesser extent than zinc.

Our preliminary view is to retain the higher iron minimum and current maximum of Standard 2.9.1. Retaining the Standard 2.9.1 maximum is appropriate, and in line with the Codex note that individual authorities may choose to set their own maximum. However, further information provided through consultation will assist future assessment.

Question to submitters:

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

7.3.3.3 Selenium

Standard 2.9.1 and Codex STAN 72-1981 have very similar minimum selenium amounts (0.25 µg/100 kJ and 0.24 µg/100 kJ, respectively). Standard 2.9.1 (Schedule 29 in the revised Code) prescribes a maximum of 1.19 µg/100 kJ whereas Codex lists a GUL of 2.2 µg/100 kJ.

There are significant geographical variations in the selenium content of soil and food crops in many countries including Australia and New Zealand (FSANZ, 2008). The nutrition assessment notes that studies indicate lower breast milk selenium concentrations in Australian and New Zealand mothers. Research has also reported a lower selenium status of Australian infants relative to other international studies, although this has not been associated with any clinical or adverse health outcomes. Intake estimates using the current minimum do not meet the current Australian and New Zealand AI, thus could pose a risk to infant health. The assessment also notes that recent studies indicate the minimum amount in infant formula should be increased. The nutrition assessment further notes that Codex STAN 72-1981 nearly doubles the upper amount of Standard 2.9.1 and also sets it as a GUL rather than a maximum amount. The Codex approach potentially allows exceedance of the UL. However, there is no international consensus on an appropriate maximum. In the absence of data indicating that the Codex GUL for selenium is unsafe, the nutrition assessment concludes that use of the Codex GUL is unlikely to pose a risk to infant health.

FSANZ's label survey indicates the lowest selenium content of the infant formula was 0.43 µg/100 kJ in New Zealand samples and 0.29 µg/100 kJ in Australian products.

FSANZ's preliminary view is that increasing the minimum requirement for selenium in Standard 2.9.1 may be appropriate for the Australian and New Zealand context. However this would not align with Codex STAN 72-1981 and may require reformulation of some products. If the minimum requirement was raised and the Codex higher GUL also adopted, the range may remain similar. Further input from submitters on the impact of potential changes to the selenium requirements in Standard 2.9.1 will help inform the final approach.

Questions to submitters:

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

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

7.3.3.4 Iodine

The minimum iodine amounts in Standard 2.9.1 and Codex STAN 72-1981 differ considerably in that Codex is 2.5 µg/100 kJ which is more than double the minimum in Standard 2.9.1 of 1.2 µg/100 kJ (Schedule 29 in the revised Code).

The nutrition assessment estimates that intakes based on either a minimum iodine of 1.2 µg/100 kJ (Standard 2.9.1) or 2.5 µg/100 kJ (Codex STAN 72-1981) do not meet the AI for younger or older infants. Raising the minimum iodine content may increase iodine intakes in formula-fed infants who would be then more likely to meet the AI. However, it is also noted that studies in the period after mandatory-iodine fortification suggest that Australian and New Zealand infants are not iodine deficient.

For the maximum, Codex STAN 72-1981 lists a GUL (14 µg/100 kJ) which is higher than the maximum set in Standard 2.9.1 (10 µg/100 kJ). The nutrition assessment notes that there is no iodine UL for infants in Australia and New Zealand, and concludes that a higher maximum of 14 µg/100 kJ would be unlikely to adversely pose a risk to infant health.

Submissions to the 2012 Consultation paper recommended that the range of iodine required in infant formula be reassessed so that the minimum amount would ensure that a young infant's intake could achieve the AI. Submissions noted that at the current minimum, it is possible that a substantial proportion of infants (especially younger infants) would not achieve an adequate iodine intake, thus consideration of a higher minimum should be undertaken.

FSANZ's label survey showed that the range of iodine content as 2.10–5.92 µg/100 kJ. FSANZ's preliminary view is that alignment with the higher Codex minimum and maximum (GUL) amount for iodine may be appropriate for Australian and New Zealand infants. We are seeking information on whether this is likely to require reformulation by manufacturers.

Question to submitters:

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

7.3.3.5 Chromium

Neither Codex nor Standard 2.9.1 set a minimum amount for chromium. In relation to a maximum, Standard 2.9.1 sets a GUL; to allow for the natural chromium in dairy products. Codex STAN 72-1981 does not include a maximum amount or a GUL. Thus there is no permission for the addition of chromium in either standard.

When Standard 2.9.1 was developed, the assessment concluded that there was no reliable biological or nutritional data to specify infant requirements or recommended intakes. Since then, an AI has been set for chromium for both younger (0–6 months) and older (7–12 months) infants (NHMRC and MoH, 2006).

The nutrition assessment notes that EFSA recently concluded that there is insufficient evidence to consider chromium an essential nutrient, thus addition of chromium in infant formula was not necessary and did not recommend a minimum amount (EFSA 2014). No evidence has emerged indicating that formula fed infants are at risk of chromium deficiency or low intakes. Therefore, the absence of a minimum amount as set in both Standard 2.9.1 and Codex STAN 72-1981 was determined to be unlikely to pose a risk to infant health.

The nutrition assessment also notes there is no Australian and New Zealand UL set for chromium, as there are no known adverse effects associated with high intakes of chromium from food. Based on this the nutrition assessment concludes that removal of the guidance level from Standard 2.9.1 to align with Codex STAN 72-1982 is unlikely to impact on infant health.

To consider how chromium may need to be regulated in infant formula, we are interested in considering the amounts of chromium that occur in ingredients used to manufacture infant formula, and thus the amount in finished infant formula. The Australian food composition database NUTTAB 2010¹³ lists amounts in milk ranging from 0.3–1.1 µg/100 mL (FSANZ, 2015). The 22nd Australian Total Diet Survey (ATDS) measured the chromium in six composite samples of prepared infant formula. One sample contained 110 mg/kg chromium; the other five had levels below 0.01 mg/kg, while the tap water had levels below the analytical level of detection (FSANZ 2008). Based on these analytical values, the theoretical infant diet estimated mean intakes of 17.6 µg/day and intakes at the 95th percentile of 43.4 µg/day for nine month old infants. These intakes are both above the AI of 5.5 µg/day.

At this preliminary stage, we are seeking further information to consider whether there is a need to set a minimum requirement for chromium and to retain the current GUL.

Question to submitters:

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.

7.3.3.6 Molybdenum

Neither Codex nor Standard 2.9.1 set a minimum for molybdenum, or permit the addition of molybdenum to infant formula. However, molybdenum naturally occurs in dairy products and thus is present in infant formula. Standard 2.9.1 sets a GUL but Codex STAN 72-1981 does not include a maximum amount or a GUL.

When Standard 2.9.1 and Codex STAN 72-1981 were developed, the assessment concluded that there was no reliable biological or nutritional data to specify infant requirements or recommended intakes. Since then, an AI has been set for molybdenum for both younger and older infants (NHMRC and NZ MoH, 2006). However, because no minimum amounts have been defined in either standard, the nutrition assessment has not estimated a minimum intake compared with the AI. The nutrition assessment notes that the recent EFSA scientific opinion proposed a minimum of 0.1 µg/100 kJ; intakes at this minimum would meet the AI for both infant age groups. However as no evidence has emerged indicating that formula-fed infants are at risk of low intakes leading to molybdenum deficiency, the absence of a minimum amount is unlikely to pose a risk to infant health. The assessment also notes there is no UL set for infants and concludes that removing the GUL would be unlikely to pose a risk to infant health.

To consider whether a minimum amount of molybdenum may need to be specified for infant formula, we are interested in considering the amounts of molybdenum that are inherent in the ingredients used to manufacture infant formula. The Australian food composition

¹³NUTTAB (NUTrient TABLEs for use in Australia) is Australia's reference nutrient database. It contains a wide range of foods and nutrients. The nutrients reported in NUTTAB will vary between foods, according to the data we currently have available. <http://www.foodstandards.gov.au/science/monitoringnutrients/Pages/default.aspx>

database NUTTAB 2010¹⁴ lists molybdenum levels in cow's milk ranging from 2.9 to 4.4 µg/100mL and 4.2 µg/100mL in soy beverages (FSANZ, 2015). The 22nd Australian Total Diet Survey (ATDS) measured the molybdenum in six composite samples of prepared infant formula. Four samples contained molybdenum at levels ranging from 0.01–2010 mg/kg; two samples had levels below 0.01 mg/kg, the tap water used to prepare infant formula had levels of molybdenum below the analytical level of reporting. The theoretical infant diet estimated intakes of molybdenum of 22 µg/day based on these analytical values, well above the AI (FSANZ, 2008).

We are seeking further information from submitters to inform consideration of a need to set a minimum and whether there is need to retain the current GUL.

Question to submitters:

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.

7.3.3.7 Copper

Both the Standard 2.9.1 minimum and maximum amount for copper are higher than the Codex STAN 72-1981 minimum amount and GUL respectively. The Codex minimum is based on average breast milk content.

The nutrition assessment indicates that estimated copper intakes of infants using the minimum amount specified in Codex STAN 72-1981 would not meet the AI for copper for older or younger infants. However, powdered infant formula is typically mixed with tap water. Codex STAN 72-1981 includes a footnote: "adjustments may be needed in these levels for infant formula made in regions with a high content of copper in the water supply". Thus if the intake assessment is revised to account for the copper from tap water in Australia, the estimated combined intake of copper from infant formula is likely to meet the AI for both younger and older infants. Therefore, alignment with the lower minimum in Codex STAN 72-1981 would be unlikely to pose a risk to infant health.

Standard 2.9.1 sets a maximum for copper whereas Codex provides a lower GUL. FSANZ has not found a clear basis for these levels in any literature. There is no UL set for copper for infants. Copper toxicity is not known to occur in full-term breastfed or formula-fed infants and the nutrition assessment identified no recent studies suggesting adverse effects related to high copper intakes of formula-fed infants. The nutrition assessment concludes that adopting the GUL at the lower amount would be unlikely to adversely affect infant health.

FSANZ's label survey indicated that the copper content of infant formula lies within the minimum to maximum range specified in Codex STAN 72-1981.

FSANZ's preliminary view is that alignment with Codex STAN 72-1981 minimum amount and GUL amount is appropriate. However this needs to be considered in the context of the zinc copper ratio.

¹⁴ <http://www.foodstandards.gov.au/science/monitoringnutrients/Pages/default.aspx>

7.3.3.8 Zinc

Standard 2.9.1 and Codex STAN 72-1981 are aligned for the minimum amount of zinc (0.12 mg/100 kJ). However, the maximum in Standard 2.9.1 (0.43 mg/100 kJ) is higher than the GUL in Codex STAN 72-1981 (0.36 mg/100 kJ). Standard 2.9.1 also prescribes a ratio of zinc to copper (Zn:Cu) of maximum 15:1, whereas Codex STAN 72-1981 does not specify a ratio.

The higher maximum amount in Standard 2.9.1 allowed for lower absorption of zinc from soy-based formula due to the presence of phytates, which can bind with zinc. The zinc copper ratio was included to manage the potential impact of zinc intakes on copper bioavailability (ANZFA, 1999b). In 2005, the draft Codex GUL was reduced from the previous (2003) level on the basis that high intakes of zinc may interfere with the absorption and metabolism of other micronutrients, such as copper. At the time of gazettal of Standard 2.9.1, the Zn:Cu ratio was a new concept in infant nutrition and was considered a separate issue from the minimum and maximum limits of zinc and copper (ANZFA, 2002). A cautious approach was taken and the ratio was included in the Standard for several reasons:

- the Zn:Cu ratio of breast milk is 10:1 but there were no studies in infants to indicate the appropriate or optimal Zn:Cu ratio for formula
- infants have immature systems (absorption, metabolism, excretion)
- when infant formula is the sole source of nutrition, infants are at a stage of development characterised by intense growth (which may make infants more vulnerable to factors such as copper deficiency)
- data on adverse effects are limited.

The nutrition assessment notes that intake estimates at both the maximum in Standard 2.9.1 and the lower GUL in Codex STAN 72-1981 potentially exceed the UL but concludes that there is no evidence of a risk to infant health from such intakes. FSANZ previously assessed the UL as conservative (FSANZ 2011). No evidence was identified to support retaining the maximum amount in Standard 2.9.1. Thus alignment with the Codex GUL amount would be unlikely to pose a risk to infant health.

The nutrition assessment notes limited evidence to support the need for a Zn:Cu ratio in formula even though the Zn:Cu ratio in breast milk is about 10:1. Since FSANZ's previous assessment, no further evidence of zinc-induced micronutrient deficiencies occurring in healthy term formula-fed infants has emerged. Thus the nutrition assessment concludes that deleting the Zn:Cu ratio from Standard 2.9.1 would have minimal impact on micronutrient status of healthy term infants.

FSANZ's label survey suggests that zinc content lies within the Codex minimum – maximum range, as all were all below the Codex GUL amount. Other label information indicates that soy-based formula can contain higher amounts of zinc than standard formula. Previously it has been recommended that setting minimum amounts for certain minerals in infant formula in soy-based infant formula should consider the phytic acid content of soy proteins and the potential for reduced availability of minerals. The literature suggests it is technologically possible to remove phytic acid from soy-based formula. Recently EFSA (2014) noted that studies show that reduction of phytic acid content completely or even by around half in ready-to-feed formula improves zinc absorption.

Consideration of the maximum amount must also include the composition of soy-based infant formula and the Zn:Cu ratio. We are seeking further information from submitters to inform the future assessment.

Questions to submitters:

- Q1.19 What information can you provide on the phytic acid content of soy-based infant formula?
- Q1.20 Are there any technical issues if the lower Codex minimum and maximum levels for copper were to be incorporated into the Code?
- Q1.21 Should a Zn:Cu ratio be retained. If so, what should it be and why? If not, what is your rationale?

8 Permitted forms of vitamins, minerals and electrolytes

This section discusses FSANZ's comparison of the permitted forms of vitamins, minerals and electrolytes in Standard 2.9.1 with Codex GL 10-1979 which lists the forms of vitamins, minerals and electrolytes for use in infant formula.

Schedule 1 to Standard 2.9.1 (section S29—7 in the revised Code) lists the permitted forms for the vitamins, minerals and electrolytes intended for use as a nutrient when added to infant formula. Standard 1.3.4 – Identity and Purity (Schedule 3 in the revised Code) includes a list of acceptable sources of specifications e.g. FAO JECFA Monographs, Food Chemicals Codex (FCC), European Pharmacopoeia (refer to Table 8.1). The current list of permitted forms in the Code was developed during P93 to align with the 1991 European Commission Infant Formula Directive (91/321/EEC) and the previous version of Codex GL 10-1979. The substances on these lists were assessed as part of the toxicology and risk assessment during assessment of P93.

The Codex GL 10-1979 list for infant formula was comprehensively reviewed by CCNFSDU around the time of the review of Codex STAN 72-1981. A set of criteria was devised to ensure that any permitted nutrient form would be safe and appropriate for use in products for infants (Box 1). In addition, the CCNFSDU agreed that to ensure safety, permitted forms of nutrients must comply with certain specifications. The specifications outline the information on the substance including the identity, origin, production and acceptable level of purity.

Box 2: Criteria for inclusion and deletion from Codex GL 10-1979

Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

- a. they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children
- b. it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available
- c. the purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognised specification. If there is no internationally recognised specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered
- d. the stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated
- e. the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.

Source: Codex GL 10-1979, section 2.1

Table 8.1 lists the particular forms of vitamins, minerals and electrolytes that are permitted by Codex but which are not permitted for use in infant formula in the Code. Column 3 indicates whether each form has a specification source listed in Standard 1.3.4. (Schedule 3 in the revised Code?)

Submissions to the 2012 Consultation paper generally supported aligning the permitted forms of nutrients in Standard 2.9.1 with Codex GL 10-1979 on the basis that these forms have been evaluated by Codex for nutritional adequacy and safety in infant formula. Some submissions noted that alignment should only be considered where there is evidence of safety, function and availability for any forms in Codex that are not in Standard 2.9.1. Submitters did not support the removal of any currently permitted nutrient forms from Standard 2.9.1.

Industry submissions noted that, while there were no current barriers related to the range of permitted forms of vitamins and minerals for infant formula, problems may arise in the future if these are not aligned because such alignment would provide consistency, and benefit innovation and reformulation. Particular requests were to clarify the permitted forms of niacin and vitamin A, and to consider additional permitted forms for niacin, pantothenic acid, copper, iron, magnesium, potassium and zinc, however no justification for these forms was provided. Some of these submissions suggested FSANZ also consider including any nutrient forms listed in other international regulations such as the European legislation (Commission Directive 2006/141/EC) to avoid potential significant trade implications for infant formula from Europe. However, FSANZ is not aware of any specific issues for nutrient forms and will focus on alignment with Codex.

The individual vitamins and minerals are discussed in the following sections.

Table 8.1: Differences in nutrients forms for use in infant formula in Codex GL 10-1979 and Standard 2.9.1

| Nutrient | Forms permitted by Codex <u>not</u> permitted in Standard 2.9.1 | Forms permitted in Standard 2.9.1 <u>not</u> permitted in Codex | For Codex permitted forms: where is the Specification listed? |
|------------------|---|--|---|
| Vitamins | | | |
| Niacin | Nicotinic acid | | FCC, USP, BP, Ph Eur |
| Pantothenic acid | Sodium D-pantothenate | | JFS |
| | DL-Panthenol | | FCC, USP, Ph Eur |
| Vitamin A | | Retinyl propionate | Not Applicable |
| Vitamin D | | Cholecalciferol-cholesterol | Not Applicable |
| Vitamin E | | d- α -tocopheryl acid succinate dl- α -tocopheryl succinate Tocopherols concentrate, mixed | Not Applicable |
| Vitamin K | | Phytylmenquinone | Not Applicable |
| Minerals | | | |
| Chromium | | Chromium sulphate | Not Applicable |
| Copper | Cupric carbonate | | MI |
| Iron | Ferric citrate | | FCC |
| | Ferrous bisglycinate | | JECFA |
| | Ferrous sulphate | | JECFA, FCC, USP |
| Magnesium | Magnesium hydroxide carbonate | | JECFA, USP, BP |
| | Magnesium hydroxide | | JECFA, USP, BP, Ph Eur |
| | Magnesium salts of citric acid | | USP |
| Potassium | Potassium L-lactate | Potassium glycerophosphate | JECFA, FCC, USP |
| Selenium | | Seleno methionine | Not Applicable |
| Zinc | Zinc lactate | | FCC |
| | Zinc citrate (either zinc citrate dihydrate or zinc citrate trihydrate) | | USP |

Abbreviations used in table:

| | | | |
|-------|---|--------|------------------------|
| JECFA | Joint Expert Committee on Food Additives | FCC | Food Chemicals Codex |
| USP | United States Pharmacopeia | MI | Merck Index |
| BP | British Pharmacopoeia | Ph Eur | European Pharmacopoeia |
| JFS | Japan's Specifications and Standards for Food Additives | | |

8.1 Vitamins

8.1.1 Vitamin A

The Code permits four retinol forms (retinol, retinyl acetate, retinyl palmitate, and retinyl propionate) and β -carotene for use in infant formula. Several submissions noted there is confusion as to whether β -carotene should count as vitamin A. The revised Code has clarified that β -carotene is permitted as a provitamin A form, rather than as a carotenoid form of vitamin A.

Codex GL 10-1979 lists three forms of vitamin A (all-trans retinol, retinyl acetate, and retinyl palmitate) and lists β -carotene as a form of provitamin A but does not allow including β -carotene in the calculation of vitamin A content of food. It is not clear why β -carotene is listed as a nutrient compound in Codex when it cannot contribute to vitamin A content.

FSANZ has suggested above that β -carotene should not contribute to the calculated vitamin A activity (see section 7.2.1). Submissions to the 2012 Consultation paper supported retaining the β -carotene permission in the Code as a nutrient compound, although no rationale for this was provided.

FSANZ's preliminary view is to retain the current permitted forms of vitamin A. Thus there is now alignment between the standards (see section 7.2.1). However, we are seeking further information on the justification to retain β -carotene as a provitamin A form in Standard 2.9.1.

Questions to submitters:

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

8.1.2 Vitamin D

The Code currently permits both vitamin D₃ (cholecalciferol) and vitamin D₂ (ergocalciferol) in infant formula. Codex GL 10-1979 permits only cholecalciferol (D₃) based on uncertainty of the bioavailability of vitamin D₂ in infants.

The nutrition assessment concludes that both forms are equally effective in raising serum 25OHD concentration and use of vitamin D₂ is unlikely to pose a risk to infant health. A review of the labelled ingredient lists on products shows that both forms are currently used. Thus restricting the form of Vitamin D to the D₃ form to align with Codex may impact on the manufacture of infant formula. Recent evidence supports the suitability of the use of both forms in infant formula.

FSANZ's preliminary view is to retain the two permitted forms.

8.1.3 Pantothenic acid

The Code lists dexpanthenol as the only permitted form of pantothenic acid. Codex GL 10-1979 lists D-panthenol, DL-panthenol, calcium D-pantothenate, and sodium D-pantothenate as forms suitable for use in infant formula.

D-panthenol is a synonym for dexpanthenol, where D stands for dextrorotatory (abbreviated to Dex); it is the optical isomer of the alcohol analogue of pantothenic acid thus these forms are aligned. DL-panthenol is the racemic mixture of the two D and L optical isomers. Calcium and sodium D-pantothenate are the calcium and sodium salts of pantothenic acid, respectively and are commonly used in supplements.

Panthenol is converted to pantothenic acid in the body, the D-form is biologically active while the L-form of panthenol is not, thus the physiological activity of the DL form is half of the D-isomer. Specifications for DL-panthenol are given in FCC, the United States Pharmacopoeia and the European Pharmacopoeia. However, the DL form is not permitted for use in infant formula other regulations around the world. No specific permission for DL-pantothenic acid has been sought by submitters.

Thus, our preliminary view is that it is not appropriate to permit DL-panthenol acid for use in infant formula. We are seeking further information and technological justification for calcium D-pantothenate and sodium D-pantothenate as forms suitable for use in infant formula.

8.1.4 Niacin

Niacin describes two related compounds, nicotinic acid and nicotinamide, which function in the same way (NHMRC and MoH, 2006). Submissions noted confusion around permissions for forms for niacin, particularly the forms considered to be pre-formed niacin. As discussed in section 7.2.4, both Standard 2.9.1 and Codex STAN 72-1981 set niacin requirements as preformed niacin, meaning only natural forms of preformed niacin and the amount of niacinamide (nicotinamide) or nicotinic acid (if permitted) in infant formula can contribute.

The Codex GL 10-1979 lists both niacinamide (nicotinamide) and nicotinic acid. The rationale for inclusion of nicotinic acid in the Codex list could not be determined. Nicotinic acid was previously excluded from Standard 2.9.1 because it was uncertain whether the adverse effects observed in adults with high doses of nicotinic acid were relevant to infants.

The nutrition assessment notes that nicotinic acid does not have the same safety profile as nicotinamide. While there is no evidence to indicate that infant formula containing nicotinic acid has caused adverse effects in infants, nicotinamide is less toxic than nicotinic acid and serves the same biological function. Therefore, it is concluded that use of nicotinic acid may pose a risk to infant health.

FSANZ's preliminary view is not to permit nicotinic acid for use in infant formula.

8.2 Minerals and electrolytes

The Code permits some mineral compounds as food additives and also as nutrient compounds. For example, magnesium carbonates (INS 504) are permitted food additives whereas magnesium carbonate (INS 504(i)) and magnesium hydroxyl carbonate (INS 504(ii)) are permitted as separate sources of magnesium in foods for special medical purposes, which reflects the approach in Codex GL 10-1979 for infant formula. To provide clarity and the greatest measure of specificity for these nutrient forms in special purpose foods, FSANZ's preliminary view is to list related nutrient compounds separately.

8.2.1 Copper

Standard 2.9.1 lists three permitted forms, whereas Codex GL 10-1979 lists four. Cupric carbonate is the additional form listed in Codex GL 10-1979. In 2012, submitters requested this form be included, although no technological justification was provided to support the request. Standard 1.3.4 includes a source containing a relevant specification. Cupric carbonate was also requested by submitters during P93, however, at that time, it was not included in the Codex list for use in infant formula at Codex.

At this preliminary stage, FSANZ is seeking further information on the technological justification for the addition of these particular forms to inform future assessment.

8.2.2 Magnesium

Standard 2.9.1 lists seven forms of magnesium for use in infant formula whereas Codex lists ten. The additional forms listed in Codex GL 10-1979 all have specifications in sources referenced in Standard 1.3.4. Submitters have previously requested that FSANZ consider magnesium hydroxide and magnesium salts of citric acid, but not magnesium hydroxide carbonate.

At this preliminary stage, we are seeking further information on the technological justification for the addition of these particular forms to inform further assessment.

8.2.3 Potassium

Standard 2.9.1 lists 10 permitted forms of potassium, as does Codex GL 10-1979. However, two differences exist: the Code lists potassium glycerophosphate as suitable for use in infant formula whereas this permission is limited to infant formula for special medical purposes in Codex GL 10-1979. Codex lists potassium L-lactate, as suitable for use in infant formula. Submitters have not previously indicated support for the inclusion of potassium L-lactate in Standard 2.9.1.

At this preliminary stage, we are seeking further information on the technological justification for the use of potassium L-lactate in infant formula to inform further assessment.

8.2.4 Zinc

Zinc lactate is not permitted in Standard 2.9.1 but is a listed form of zinc in Codex GL 10-1979. Industry submitters noted that there is a FCC specification for this compound. However, a search of the current version (i.e. 9th edition referenced in Standard 1.3.4) found no such specification. It is possible that there may have been a previous specification at some time. To permit this form in Standard 2.9.1 a specification source needs to be included from one of the references in Standard 1.3.4. FSANZ is also aware that last year Codex approved the inclusion of zinc citrate i.e. zinc citrate dihydrate or zinc citrate trihydrate in Codex GL 10-1979.

At this preliminary stage, we are seeking further information on the technological justification for the addition of these particular forms to inform further assessment.

8.2.5 Iron

Standard 2.9.1 permits eight different forms of iron for addition to infant formula. However it does not permit ferric citrate or ferrous bisglycinate, which are forms listed in Codex GL 10-1979. Submissions requested that the Codex forms be considered for alignment. As noted in table 8.2, ferrous bisglycinate has specifications in the Code from JECFA and FCC. Ferric citrate has FCC specifications.

At this preliminary stage, we are seeking further information on the technological justification for the addition of these particular forms to inform further assessment.

8.3 Summary of new permitted forms of vitamins and minerals proposed for infant formula

For the following micronutrients, further information is needed on: the technological justification for the addition of particular forms and a recognised specification, before a safety assessment of the particular form is undertaken.

Table 8.2: Summary of the nutrient forms that require further information

| Nutrient | Form |
|------------------|--|
| Vitamin | |
| Pantothenic acid | Sodium D-pantothenate |
| Mineral | |
| Copper | Cupric carbonate |
| Iron | Ferric citrate |
| | Ferrous bisglycinate |
| | Ferrous sulphate |
| Magnesium | Magnesium hydroxide carbonate |
| | Magnesium hydroxide |
| | Magnesium salts of citric acid |
| Potassium | Potassium L-lactate |
| Zinc | Zinc lactate |
| | zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate) |

Question to submitters:

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?

9 Other optional substances

In Standard 2.9.1, the Table to clause 7 (section S29—5 in the revised Code) lists substances permitted for use as nutritive substances in infant formula and their permitted forms. In addition, Standard 1.3.4 (Schedule 3 in the revised Code) includes a list of acceptable sources of specifications e.g. FAO, JECFA Monographs, FCC, European Pharmacopoeia.

Codex GL 10-1979 also lists forms for some optional ingredients. Section 3 of that Guideline notes that not all permitted optional ingredients are listed in Codex standards; however any optional ingredients should meet the same criteria for nutrient compounds as shown in Box 1 above.

Codex STAN 72-1981 prescribes the mandatory addition of three substances to infant formula which are considered optional in the Code: choline, L-carnitine, and inositol. Many infant formulas contain these substances and no adverse effects in infants consuming these formulas have been reported. Thus, the prescribed optional amounts have an extended history of safe use both in Australia, New Zealand and overseas and the safety of infant

formula supplemented with these nutrients has not been further examined. Consideration of the regulation of these three nutritive substances is discussed in the sections below.

9.1 Choline

Standard 2.9.1 currently permits optional addition of choline in the range of 1.7–7.1 mg/100 kJ whereas the mandatory range in Codex STAN 72-1981 is 1.7–12 mg/100 kJ with the higher upper amount as a GUL.

Since 2006, choline has been classed as an essential nutrient in the NRVs. Submissions to the 2012 Consultation paper also noted this and supported mandating choline in Standard 2.9.1.

The nutrition assessment notes some uncertainty in the evidence for setting an appropriate minimum amount of choline. However, in the absence of evidence of choline insufficiency in the population, it concludes that the mandatory inclusion of choline in the range in Codex STAN 72-1981 is unlikely to pose a risk to infant health. Moreover, the higher GUL amount in Codex STAN 72-1981 is also concluded to be unlikely to pose a risk to infant health. However, based on the uncertainty of the safety of excess intakes, the nutrition assessment concludes the choline should have a maximum amount rather than a GUL.

The label survey found many products had listed choline in the ingredient list and/or the nutrition information statement and declared the content within the range in Codex STAN 72-1981.

Choline in milk is present in several forms: free choline, phosphocholine, glycerophosphocholine, phosphatidyl choline, and sphingomyelin. The amounts of these forms vary considerably (Holmes-McNary et al. 1996). As shown in Table 9.1, Codex GL 10-1979 lists three forms of choline that are not permitted in Standard 2.9.1. Two of these forms: choline citrate and choline bitartrate do not have a specification source listed in Standard 1.3.4, Submitters have previously requested these two forms be added to the Standard.

Table 9.1: Comparison of permitted forms of choline

| Permitted form | Std 2.9.1 | Codex GL 10-1979 | Specification reference listed in Standard 1.3.4 [^] |
|---------------------------|-----------|------------------|---|
| Choline chloride | ✓ | ✓ | ✓FCC |
| Choline bitartrate | ✓ | ✓ | ✓FCC |
| Choline | ✗ | ✓ | ✓ FCC, USP |
| Choline citrate | ✗ | ✓ | ✗ |
| Choline hydrogen tartrate | ✗ | ✓ | ✗ |

[^]Schedule 3 in the revised Code
 FCC Food Chemicals Codex
 USP United States Pharmacopeia

Our preliminary view is that choline should be listed as a mandatory substance in infant formula with a mandatory range of 1.7–12 mg/100 kJ. To consider additional forms of choline, we require further information on the technological justification for their use in infant formula, evidence to demonstrate safety and a reference to a specification source.

Questions to submitters:

- Q.1.24 Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.
- Q1.25 What is the technological justification can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?
- 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)?
 - (b) evidence to demonstrate safety can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?

9.2 L-carnitine

Standard 2.9.1 permits L-carnitine to be added as an optional substance in the range of 0.21–0.8 mg/100 kJ. However, Codex STAN 72-1981 has set a mandatory higher minimum amount of 0.3 mg/100 kJ, but has set no maximum amount.

Carnitine is considered as conditionally essential for infants mainly because they may lack the developmental maturity for endogenous synthesis ¹⁵.

Based on the evidence, the nutrition assessment considers that the mandatory inclusion of L-carnitine at the amount prescribed by Codex is unlikely to pose a risk to infant health. Although no adverse effects in infants consuming L-carnitine-supplemented formulas have been reported; recent research indicates uncertainty in the safety of excess L-carnitine consumption. Thus, it is concluded that lack of a maximum amount may pose a risk to infant health.

Some industry submitters on the 2012 Consultation paper supported setting L-carnitine requirements as mandatory with several government submitters suggesting that FSANZ give consideration to the evidence for listing these as essential.

The milk of all mammals contains L-carnitine but mainly in the amine form and, the concentration may be decreased during fractionation and dilution of milk protein in manufacturing. The minimum and maximum amounts in Standard 2.9.1 and Codex STAN 72-1981 refer to the total amount including any naturally occurring amounts present in source ingredients (i.e. cow's milk). Many of the products examined in our label survey listed L-carnitine in the ingredient list and nutrition information statement.

As shown in Table 9.2, Codex lists two forms of L-carnitine that are not permitted for addition to infant formula in Standard 2.9.1. Both of these already have a specification reference in the Code.

¹⁵ Carnitine is the term for several compounds including L-carnitine and its acetyl and propionyl esters. L-carnitine is the biologically active enantiomer, while D-carnitine is essentially biologically inactive (Combs, 2008).

Table 9.2: Comparison of permitted forms of L-carnitine

| Permitted form | Std 2.9.1 | Codex GL 10-1979 | Specification reference listed in Standard 1.3.4 [^] |
|---------------------------|-----------|------------------|---|
| L-carnitine | ✓ | ✓ | FCC, USP |
| L-carnitine hydrochloride | ✗ | ✓ | FCC |
| L-carnitine tartrate | ✗ | ✓ | FCC |

[^]Schedule 3 in the revised Code

FCC Food Chemicals Codex

USP United States Pharmacopeia

Our preliminary view is that L-carnitine should be listed as a mandatory substance in infant formula with a mandatory range of 0.3–0.8 mg/100 kJ. A technological justification for additional forms of L-carnitine and evidence to demonstrate safety of these forms in infant formula is needed to inform future assessment.

Questions to submitters:

- Q1.27 Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.
- Q.1.28 What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?
- Q.1.29 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?

9.3 Inositol

Standard 2.9.1 and Codex STAN 72-1981 permit the same range 1.0–9.5 mg/100 kJ, although Codex lists inositol as a mandatory inclusion with a GUL. Inositol was originally permitted as an optional substance in the Code to allow for infant formula based on ISP and to align with levels in breast milk (ANZFA, 1999b).

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

The nutrition assessment notes the evidence supporting the mandatory addition includes presence in breast milk, low serum concentrations and physiological or biochemical outcomes suggesting inadequacy in infants fed un-supplemented formulas. On the basis of this evidence, mandatory inclusion of inositol at the minimum amount in Codex STAN 72-1981 is unlikely to pose a risk to infant health. The nutrition assessment notes recent reviews on infant formula composition have not set a mandatory maximum, and suggested that the upper level should be around that reported for breast milk (9.6 mg/100 kJ) (EFSA 2014). The nutrition assessment also notes no safety data or negative health effects related to inositol in infants or children have been reported. Thus alignment by setting a GUL instead of maximum amount is unlikely to pose a risk to infant health.

There was some support from submitters on the 2012 Consultation paper to consider inositol as a mandatory nutrient in infant formula. Almost all products surveyed by FSANZ were labelled as inositol, with amounts within the current Codex recommended range.

Codex GL 10–1979 lists myo-inositol (previously referred to as meso-inositol) as the only permitted form of the inositols. The specification listed in Food Chemicals Codex (as referenced in Codex GL 10–1979 and Standard 2.9.1) lists three alternative names for the inositol: i-Inositol, meso-Inositol, myo-Inositol. In the literature inositol can also be used as the common name to refer to several compounds. Thus the permitted forms currently align, however the use of multiple names does create some potential for confusion.

Table 9.3: Comparison of permitted forms of inositol

| Permitted form | Std 2.9.1 | Codex GL 10-1979 | Specification reference listed in Standard 1.3.4^ |
|----------------|-----------|------------------|---|
| Inositol | ✓ | ✓ | FCC |
| Myo-inositol | ✓ | ✓ | FCC |

^Schedule 3 in the revised Code
FCC Food Chemicals Codex

Our preliminary view is that it is appropriate to prescribe the mandatory inclusion of inositol in infant formula at the current minimum amount (which already aligns with Codex STAN 72-1981) and list a GUL of 9.5 mg/100 kJ. We also consider listing the permitted form of inositol as myo-inositol will provide clarity.

Questions to submitters:

- Q1.30 Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.
- Q1.31 Do you supporting listing the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex?

9.4 Nucleotides

Standard 2.9.1 permits the optional addition of five specific nucleotides to infant formula through clause 7(1) and the Table to clause 7 (section S29—5 in the revised Code). Standard 2.9.1 outlines a minimum and maximum for each of the permitted nucleotides. Clause 8 (paragraph 2.9.1—8(b) in the revised Code) also states that “infant formula product must contain no more than 3.8 mg/100 kJ of nucleotide 5’ monophosphates”. Codex STAN 72-1981 permits the addition of nucleotides at the discretion of national authorities. Comparison of the permitted forms of nucleotides in each standard shows they are already aligned.

FSANZ is aware that there has been confusion amongst submitters between the prescribed maximum amount for individual nucleotides, and the combined total limit of nucleotides. The revised Code clarifies that the combined total nucleotide content is intended to include naturally occurring nucleotides which means that not all individual nucleotides can be present infant formula at their individual maximum amounts from addition alone. The prescribed maximum for each nucleotide 5’ monophosphate sums to 0.76 mg/100 kJ.

FSANZ's preliminary view is to retain the current permission and maximum combined total limit of nucleotides. We are seeking feedback on the clarity of the drafting in the revised Code.

Question to submitters:

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

10 Other composition issues raised by submitters

| Issue | Raised by | FSANZ response |
|--|-----------------------|--|
| Future proofing the standard | | |
| <p>With improved research into the nutritional requirements of infants and the nutritional qualities of breast milk it is likely in the future that some of these optional nutritive substances may become essential ingredients. Suggest it would be important to include a clause in Standard 2.9.1 that requires a review of the essential composition across all infant formula products within a specified time period. This will allow infant formula products to more closely align with international standards in addition to enabling some optional ingredients to progress to essential ingredients. This will ultimately improve the nutritional outcomes for all infants where infant formula is their sole or principal source of nutrition.</p> | Government | <p>FSANZ is unable to determine the timeframe for review at this point and a review period is not currently set for any Standards in the Code.</p> |
| <p>A time period for future compositional review should be included within Standard 2.9.1.</p> | Government & industry | |
| <p>Need to have provisions that define and clearly differentiate between components or ingredients, i.e. incorporated to align the macronutrient profile of the formula with breast milk; and nutritive substances added to fortify or enhance the formula to achieve functional or health enhancing purposes beyond that of the basic macronutrient composition.</p> | Industry | See SD2. |
| Definitions | | |
| <p>Suggest that definitions should be included for anti-reflux and hypoallergenic formulas.</p> | Government | <p>These comments will be considered at a later stage when special purpose infant formulas are considered.</p> |

| Issue | Raised by | FSANZ response |
|---|----------------------------------|--|
| <p>The definitions in the revised Code are included in Standard 1.1.2 and in Standard 2.9.1. Those in Standard 2.9.1 have been re-ordered and arranged alphabetically.</p> <p>Submitters supported retaining the non-alphabetical order by noting an alphabetical sequence would be both confusing and illogical given the definition for infant formula product is the overarching term.</p> | Multiple submitters | This is outside the scope of this Proposal as this has been considered and addressed through Proposal P1025. |
| Scope of composition assessment | | |
| Suggests scope is wider than Codex STAN 72-1981. There are other international regulations which have significant trade implications for infant formula. | Industry | FSANZ has considered a range of factors when determining alignment with Codex. There is a need to contain the scope of Proposal P1028 but other regulations may be considered when appropriate, on a case-by-case basis. |
| As a principle; where FSANZ has already considered an application for change to Standard 2.9.1, conducted a risk assessment and amended the standard as a result, these provisions should be retained in Standard 2.9.1 even if they do not align with Codex e.g. the Standard 2.9.1 provisions for inulin derived substances, galacto-oligosaccharides, and lutein should be retained. | Government | Noted |
| Specific substances | | |
| Notes lutein is a nutritive substance in Standard 2.9.1. Elsewhere in the Code it is designated and permitted as a food additive. Therefore suggests lutein be removed from table to clause 7 and be included as a separate clause. | Industry | Lutein was previously assessed as a nutritive substance in infant formula under an Application. In infant formula it has a different purpose to its use as a food additive. |
| If an optional ingredient is deemed to be of benefit then it should be included in mandatory compositional requirement. E.g. choline, PUFAs, ARA and DHA. | Industry & government submitters | FSANZ has considered latest science, as well as Codex, as noted in the above SD and attachment case-by-case. |

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