

## PROPOSAL P93 – REVIEW OF INFANT FORMULA

### ASSESSMENT OF ISSUES RAISED FOLLOWING PRELIMINARY INQUIRY (MAY 1999)

The issues, as listed below, were raised in submissions to the Inquiry of draft Standard 2.9.1 – Infant Formula Products during public consultation in May to June 1999.

An assessment of these issues was completed and changes to the draft standard recommended at Inquiry (Nov 1999). However Industry, namely the Infant Formula Manufacturers' Association of Australia (IFMAA) and the New Zealand Infant Formula Marketers' Association (NZIFMA), prior to formal adoption of the draft standard requested further consultation claiming some provisions in the standard would affect the affordability and availability of products on the local market. Industry provided a submission detailing a large number of issues with the draft standard as proposed at Inquiry (Nov 1999). The issues raised by Industry are indicated in the following list by **bolded** text.

ANZFA has now consolidated its assessment of all issues raised at Inquiry (June 1999 – February 2002) and makes recommendations on changes to the draft standard as proposed at Preliminary Inquiry (May 1999) and at Inquiry (Nov 1999).

### ISSUES

#### PART 1 – GENERAL PROVISIONS

##### Division 1 – Interpretation

##### 1. Definitions

- 1.1. Title of and inclusion of Follow on formula within the draft Standard
- 1.2. Infant formula product
- 1.3. Infant formula
- 1.4. Follow-on formula**
- 1.5. Infant
- 1.6. Lactose free and low lactose
- 1.7. Pre-term formula
- 1.8. Protein substitute
- 1.9. Soy protein formula
- 1.10. Fat modified.

##### 2. Division 2 – Calculations

- 2.1. Potential Renal Solute Load (PRSL)
- 2.2. Calculation of PRSL
- 2.3. Protein Quality – Amino acid reference profile**

3. Division 3 – General Composition Requirements
  - 3.1. Restrictions and prohibitions
  - 3.2. Permitted optional nutritive substances
    - 3.2.1. Error in drafting for carnitine, choline and inositol
    - 3.2.2. Carnitine
    - 3.2.3. Choline
  - 3.3. Nucleotides
  - 3.4. Food Additives
    - 3.4.1. Carrageenan
    - 3.4.2. Citric esters of mono– and di– glycerides of fatty acids
    - 3.4.3. Mono– and di–glycerides of fatty acids
    - 3.4.4. Diacetyl tartaric acid esters of mono– and di–glycerides (DATEM)
    - 3.4.5. Locust bean gum**
  - 3.5. Aluminium
  - 3.6. Composition of lactose free and low lactose formula
4. Division 4 – General labelling and packaging requirements
  - 4.1. General comments
  - 4.2. Clause 18 Requirement for a measuring scoop
  - 4.3. Clause 19 Required statements**
    - 4.3.1. Clause 19 (3) (a) and (b)
    - 4.3.2. Statement about additional foods**
    - 4.3.3. Clause 19 (1) Use of the term ‘very ill’
    - 4.3.4. Clause 19 Ready to drink formula
    - 4.3.5. Clause 19 Instructions on the preparation of bottle
  - 4.4. **Clause 20 Print and package size.**
  - 4.5. Clause 21 Declaration of nutrition information**
  - 4.6. Clause 22 Date marking and storage instructions
  - 4.7. Clause 23 Statement on the source of protein
  - 4.8. Clause 24 Statement on dental fluorosis
  - 4.9. Clause 25 Labelling of lactose free and low lactose formula
  - 4.10. Prohibited representations – ‘added iron’ claims**
- 5. Division 5 – General Microbiological Requirements**
6. PART 2 – INFANT FORMULA AND FOLLOW ON FORMULA
 

Composition

  - 6.1. Protein content
  - 6.2. Potential renal solute load (PRSL) of follow on formula (and special purpose formula)

## 6.3. Fat

### **6.3.1. Units of expression for linoleic (LA) and alpha-linolenic acid (ALA)**

### **6.3.2. ALA**

### 6.3.3. Trans fatty acids

### **6.3.4. Long chain polyunsaturated fatty acids (LCPUFA)**

#### **6.3.4.1. The regulation of LCPUFA**

#### 6.3.4.2. Levels of addition of series-6 fatty acids

#### 6.3.4.3. LCPUFA in follow-on formula

## 6.4 Vitamins and minerals

### 6.4.1 Policy for safety of vitamins and minerals

### 6.4.2 Specific Levels in the Table to Clause 31

#### 6.4.2.1 Selenium

#### 6.4.2.2 Copper

#### **6.4.2.3 Zinc to copper ratio**

#### **6.4.2.4 Chromium and molybdenum**

#### 6.4.2.5 Pyridoxine (Vitamin B6)

#### 6.4.2.6 Riboflavin (Vitamin B2)

#### **6.4.2.7 Iron**

#### **6.4.2.8 Phosphorus**

### 6.4.3 Schedule 1 – Permitted forms of nutrients

#### 6.4.3.1 General

#### 6.4.3.2 Cupric carbonate

#### 6.4.3.3 Nicotinic acid

#### 6.4.3.4 Selenium

#### 6.4.3.5 Choline and carnitine forms

## **7. PART 3 – INFANT FORMULA PRODUCTS FOR SPECIAL DIETARY USE**

### 7.1 Division 1 – Pre-term formula

#### 7.1.1 Fat content

#### 7.1.2 MCT content of pre-term formula

#### 7.1.3 Vitamin and mineral content of pre-term formula

#### 7.1.4 Use of pre-term formula

#### 7.1.5 Labelling statement on pre-term formula

### 7.2 Division 2 – Infant formula products formulated for metabolic and immunological conditions

#### 7.2.1 Scope

#### 7.2.2 Availability

#### **7.2.3 Claims on thickened formula**

#### **7.2.4 Composition and labelling of special purpose formula**

## 8. ISSUES NOT IN DRAFT STANDARD

- 8.1 Soy formula
- 8.2 Novel foods
- 8.3 Cadmium
- 8.4 Percentage labelling
- 8.5 Innovation**

### ASSESSMENT OF ISSUES

**NOTE: The clause numbers referred to in this assessment are those proposed at Preliminary Inquiry (May 1999) and may not coincide with the clause numbers in the draft Standard as proposed at Inquiry (Nov 1999) and Supplementary Final Assessment (Feb 2002). A summary of the changes (including clause numbering) to the draft standard as proposed at Preliminary Inquiry (May 1999) is included in the Supplementary Final Assessment (Inquiry – s.24) Report (Feb 2002) (see Section 5).**

### DIVISION 1 INTERPRETATION

#### 1. DEFINITIONS

##### 1.1 Title of, and inclusion of Follow-on Formula within, the draft Standard

Very few submissions addressed issues relating to the title of the draft Standard, or the proposed definitions of infant formula product, infant formula, and follow-on formula.

##### Proposed at Preliminary Inquiry

The title of the draft standard was proposed as “*Infant formula products*” and follow-on formula was included within the draft Standard.

##### Issue

**The New Zealand Infant Formula Marketers’ Association (NZIFMA)** objected to follow-on formula being included within the scope of the draft standard.

##### Assessment

The NZIFMA specifically, was concerned that the proposed title “*Infant formula products*” and scope of the draft Standard may potentially imply that *all* formula covered by this standard, including follow-on formula, should be considered within the category of infant formula (which is specifically defined as a breast-milk substitute in the WHO International Code of Marketing Breast-Milk Substitutes (WHO Code)). The NZIFMA was further concerned that this implied the need for follow-on formula to conform to the present definition of infant formula in the draft standard as the principal source of food/nourishment for infants. The NZIFMA based their objection on the articles of the WHO Code, which they contend, exclude follow-on formula unless it is presented as a breast-milk substitute.

[Ed note: It is not proposed to discuss in detail the interpretation of the WHO Code in this report other than to point out that the Code is interpreted and given effect differently in Australia and in New Zealand such that New Zealand manufacturers have agreed that advertising of follow-on formula could occur, but that Australian manufacturers have agreed not to advertise follow-on formula. The Authority reiterates its acceptance of the status quo in relation to the interpretation of the WHO Code in each country.]

## Recommendation

At Full Assessment (1995) the name of the standard was proposed as '*Human milk substitutes*'. This name was highly unpopular and '*infant formula*' as proposed at Preliminary Inquiry was much preferred. Therefore no change to the name of the standard is recommended. It is also proposed to maintain the inclusion of follow-on formula, but to amend the definition of follow-on formula (refer to Item 1.4 below).

### **1.2 Definition of infant formula product**

#### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was "*a product based on milk or other edible food constituents of animal or plant origin and which is intended to be, and is suitable for use as, the principal source of nourishment for infants*".

#### Issues

One manufacturer found the definition too prescriptive stating that it did not allow for any innovative modifications. Some support was given to the current and draft Codex definition for infant formula, especially the last part of the definition "*which has been proved for infant feeding*", partly as a means to ensure safety of products. A contrary view was that the latter part of the definition should read, "*which is intended as the principal source of food for infants who are not breastfed*". The **NZ Ministry of Health** pointed out that some formula categories within the draft standard would not necessarily be *the principal* source of food/nourishment.

#### Assessment

To address concerns and to include an explicit nutritional outcome, it is proposed to modify the definition to "*a product based on milk or other edible food constituents of animal or plant origin and which is **nutritionally adequate to serve as, the principal liquid** source of nourishment for infants*"

#### Recommendation

To modify the definition to "*a product based on milk or other edible food constituents of animal or plant origin and which is **nutritionally adequate to serve as, the principal liquid** source of nourishment for infants*"

### 1.3 Definition of infant formula

#### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was “*an infant formula product that is represented as being suitable as the principal source of food for infants*”.

#### Issues

Comments focused on criticising use of the term ‘suitable as’; on including reference to infants who are not breastfed; suggesting the latter part of the Codex definition for infant formula; and strengthening *principal* source to *sole* source for infants in the first 4 to 6 months of life.

#### Assessment

It is proposed to modify the definition consistent with the direction of the draft Codex standard for Infant Formula to become: “*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*”.

#### Recommendation

To modify the definition to: “*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*”.

### 1.4 Definition of follow-on formula

#### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was “*an infant formula product represented as being suitable as the principal source of food for infants aged over six months*”.

#### Issues

Most comments criticised the use of the term ‘the principal source’ as being inappropriate for infants from six months. There was general support for the Codex definition that refers to “liquid part of the weaning diet”. One contrary comment suggested “intended as a suitable source of food in conjunction with complementary foods, only for infants older than six months who are not being breast fed”.

#### Assessment

While not explicitly discussed at Preliminary Inquiry, it is reasonable to extend the applicability of follow-on formula to young children to align with current market practice (which sometimes provides guidance on the intake for children over 12 months), and the Codex standard for follow-on formula. However, it is not necessary to include specific provisions to do this, as there is no impediment to manufacturers providing additional information about a product, including information about ideal use and target population.

### Recommendation at Inquiry

It is proposed to modify the definition consistent with the direction of the Codex standard for Follow-up Formula to become: “an infant formula product represented as *either a breast-milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months*”.

### Industry issue at Inquiry

That follow-on formula be defined as being intended as ‘part of progressively diversified diet for an infant beyond six months of age’ and not as a breast milk substitute.

### Assessment

Health professionals advise that the Australian and New Zealand practice is different to that in Europe, since Australian and New Zealand mothers breastfeed their babies beyond the age of 6 months, whilst in Europe this is not common. It was noted that the current Codex standard is a European standard. Health professionals advise that locally ‘follow-on formula’ is perceived and used as a breast milk replacement for babies over 6 months of age. It was also noted that presentation of these products promotes their use as a replacement for infant formula, by use of:

- similar pack design;
- proprietary names that signify ‘second stage’;
- similar bottle preparation instructions; and
- adjacent placement on supermarket shelves.

### Recommendation at Supplementary Final Assessment.

The definition in the proposed standard be retained.

## **1.5 Definition of Infant**

### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was “*Infant means child under the age of 12 months*”.

### Issue

**Maureen Minchin (IBCLC)** suggests that a definition for infant should be included in the standard. She suggests the following definition.

*“An infant is a person under 12 months of age.”*

### Assessment

The standard already contains a definition of an infant in Clause 1. The definition in the standard has the same intent as the definition suggested by Maureen Minchin.

## Recommendation

The drafting should remain as proposed at Preliminary Inquiry.

### **1.6 Lactose Free and Low Lactose**

#### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was “‘*Lactose-free formula*’ and ‘*low lactose formula*’ mean infant formula products represented as being the principal source of food for lactose intolerant infants”.

#### Issue

**Maureen Minchin (IBCLC)** suggests that the definition for ‘lactose-free’ or ‘low lactose’ formula should highlight the temporary nature of the condition and the short-term nature of the formula use. ‘Lactose-free’ or ‘low lactose’ formula means infant formula products with reduced lactose content for short-term use by infants with medically diagnosed problems with lactose malabsorption.

#### Assessment

The reasoning **Maureen Minchin (IBCLC)** has given for inclusion of the temporary nature of lactose malabsorption in the definition of ‘lactose-free’ and ‘low lactose’ formula, is to educate consumers about the temporary nature of the condition. However, the definition of ‘lactose-free’ and ‘low lactose’ formula will not appear in the label of ‘lactose-free’ and ‘low lactose’ products. It only appears in the Food Standards Code in order for manufacturers and enforcement agencies to correctly name and identify the product. Therefore, there is no need for a statement on the temporary nature of lactose malabsorption in the definition of ‘lactose-free’ and ‘low lactose’ formula. Medical practitioners and/or health workers could supply this information to consumers.

Changes recommended for other definitions in this standard mean the definition for lactose free and low lactose formulas should also be amended for consistency.

## Recommendation

The definition of ‘lactose-free’ and ‘low lactose’ formula is amended to “*lactose free and low lactose formulas mean infant formula products which satisfy the needs of lactose intolerant infant*”.

### **1.7 Pre-term Formula**

#### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was “‘*Pre-term formula*’ means infant formula product represented as suitable, as the principal source of food, for infants of less than 37 weeks gestation”.



## Issues

**Bristol–Myers Squibb Australia Pty Ltd, Wyeth Australia Pty Ltd and Nestle Australia Ltd** state that in regard to ‘pre–term formula’ they recommend a more appropriate definition would be based upon the weight of the infant or at least include the weight of the infant. The amount of pre–term formula given to an infant is determined by the weight of the baby.

Suggested categorisation:

- extremely low birth weight infant (ELBW) as less than 1000 g; and
- pre–term as 1000 g – 1750 g in weight.

**InforMed Systems Ltd** suggest the definition of a pre term formula should be for infants less than 38 weeks gestation, since 38 – 42 completed weeks is defined as a term infant.

**Maureen Minchin (IBCLC)** states pre–term formula means infant formula products specially modified / intended for use by infants of less than 36 weeks gestation.

## Assessment

The type and amount of infant formula product given to a pre–term baby is determined by the weight of the baby and biomedical parameters rather than the gestational age. The pre–term category was intended to provide for infants with special needs due to prematurity or low birth weight whilst providing scope for a range of formulations.

Weight for height tables for normal infants start at 2500 g for the 5<sup>th</sup> percentile weight at birth. Therefore, it seems reasonable to define a low birth weight infant as an infant below 2500g at birth. However for the purposes of setting a food standard category for infants born prematurely or who are of low birth weight where the choice of formula is decided by medical specialists, it is not necessary to include specifics about age or weight in the definition. Manufacturers would also be in the best position to state the most appropriate use for the formula. Therefore it is recommended that the definition be amended to refer in a general way to prematurity and birth weight.

## Recommendation

Amend the drafting to define the age and weight in general terms such as “*a pre–term formula means an infant formula product specially formulated to satisfy particular needs of infants born prematurely or of low birthweight*”.

### **1.8 Protein substitute**

#### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was “ ‘*Protein substitute*’ means *L–amino acids and / or the hydrolysate of one or more of the proteins on which infant formula product are normally based*”.

## Issue

**Abbott Australasia Pty Ltd** suggest the use of specific terms such as hydrolysates or amino acids instead of the proposed term protein substitutes.

## Assessment

The term 'protein substitutes' covers a range of protein extracts. It would be difficult to list them all. Using the class name is the best option for use in the standard.

## Recommendation

The drafting remain as proposed at Preliminary Inquiry.

### **1.9 Soy-based Formula**

#### Proposed at Preliminary Inquiry

The definition given at Preliminary Inquiry was “ ‘*Soy-based formula*’ means infant formula product in which soy protein isolate is the sole source of protein”.

## Issue

**Maureen Minchin (IBCLC)** suggests that it may limit the definition of soy protein formula if it only mentions soy protein isolate.

## Assessment

Soy protein isolate is the only fraction of soy that is permitted in soy formula.

## Recommendation

The drafting remain as proposed at Preliminary Inquiry.

### **1.10 Fat Modified**

#### Proposed at Preliminary Inquiry

A definition of 'fat modified' was not included in the draft standard at Preliminary Inquiry.

## Issues

**The International Formula Council** expressed concern about the term ‘fat modified’ and wish to clarify that this term has been dropped.

**Abbott Australasia Pty Ltd** indicate that they believe the definition ‘fat-modified’ is still inappropriate due to the fact the there are other means of modifying the lipid component than through the use of medium chain triglycerides.

## Assessment

The term ‘fat modified’ is no longer used in the standard.

## **2. DIVISION 2 – CALCULATIONS**

### **2.1 Potential Renal Solute Load (PRSL)**

#### Proposed at Preliminary Inquiry

It was proposed at Preliminary Inquiry to control the PRSL of formula instead of prescribing the ‘osmolality’. PRSL is a more suitable parameter of formula to indicate risk to infants for dehydration illness in certain relatively common adverse circumstances to which infants are prone. Submissions were received about the prescribed calculation method, the PRSL values and also the justification for the prescription of the PRSL given it is not prescribed by the Codex standard (see also Item 6.3).

### **2.2 Calculation of Potential Renal Solute Load**

#### Proposed at Preliminary Inquiry

5. *The potential renal solute load must be calculated as follows:*

$$\begin{aligned} & \text{Potential renal solute load in mOsm/100 kJ} \\ & = [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [P(mg/100 kJ)/31] \\ & + [protein (mg/100 kJ)/175]. \end{aligned}$$

#### Issue

The calculation for estimating the PRSL provides for total phosphorus content. Fomon and Ziegler (1999), the original authors of this calculation, have recently revised it to exclude ‘unavailable phosphorus’<sup>1</sup>.

## Assessment

Unavailable phosphorus is that part of the phosphorus content of an infant formula likely to be bound to phytate. Phytate–phosphorus is excreted in the faeces rather than absorbed into the blood supply and thus does not contribute to the renal excretion load.

Fomon and Ziegler (1999) have estimated that one third of the total phosphate content of a soy–based formula is likely to be bound to phytate and hence unavailable for metabolic use. Therefore they claim 1/3 of the total phosphorus of a soy–based formula will not contribute to renal excretion load. Phytate is present in cereals, legumes and some nuts. These foods could be potential ingredients for infant formula and therefore may also impact on available phosphorus content.

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<sup>1</sup> Fomon AJ and Ziegler EE (1999) Renal solute load and potential renal solute load in infancy. J Pediatr 134: 11–4.

Currently these foods are not significant ingredients of infant formula and hence will not be factored into the estimation of 'unavailable phosphorus' for the calculation of PRSL at this time. It is accepted that the unavailable phosphorus content of formula should be excluded from the estimation of PRSL for infant formula products.

The Fomon and Ziegler calculation uses nitrogen rather than protein. The protein value was included at Preliminary Inquiry as it was thought to be easier for manufacturers but it seems nitrogen is the more useful for analytical purposes. Therefore, it is recommended that the nitrogen value be included in the calculation instead of the protein value.

### Recommendation

That the equation for calculation of PRSL be amended to exclude the unavailable phosphorus content of infant formula products and to substitute nitrogen for protein. The calculation recommended is

$$\text{Potential renal solute load in mOsm/100 kJ} \\ = [\text{Na (mg/100 kJ) /23}] + [\text{Cl (mg/100 kJ) /35}] + [\text{K (mg/100 kJ) /39}] + [\text{P}_{\text{avail}} \text{ (mg/100 kJ)/31}] \\ + [\text{N (mg/100 kJ)/28}].$$

Where  $P_{\text{avail}}$  is P of milk-based formulas + 2/3 P of soy-based formulas.

## **2.3 Protein Quality**

### Proposed at Inquiry

At Full Assessment (1995) it was proposed that the protein in infant formula be the same quality as that in human milk. Human milk amino acid levels were referenced in the draft standard for use in complying with this requirement. The values proposed were those recommended by the FAO/WHO in 1985 and again in the 1991 report on Protein Quality Evaluation<sup>2</sup>. These protein quality values are reported in the standard way as 'g amino acid per 100g protein' (g/100g).

The FAO/WHO reference values summed the values for cysteine and methionine as well as for phenylalanine and tyrosine, however submissions from health professionals indicated it was necessary to include a minimum value for cysteine as this amino acid is considered essential for very young infants. At Preliminary Inquiry (May 1999), in response to this advised potential health need for cysteine, ANZFA included values for these four individual amino acids as reported by Sarwar et al<sup>3</sup>. In addition, an amino acid score of 0.8 was proposed, as it was believed this would allow manufacturers to meet the recommended protein quality levels within the minimum protein content. This approach was consistently maintained and was included in the draft standard as proposed at Inquiry (Nov 1999).

### Issues at Preliminary Inquiry

**Wyeth Australia Pty Ltd** submit that they would need to reformulate to meet the amino acids levels which are set in the standard and that these levels are unsubstantiated.

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<sup>2</sup> Protein Quality Evaluation (1991) Report of the Joint FAO/WHO Expert Consultation. FAO Rome

<sup>3</sup> Sarwar G et al (1996) Use of amino acid profiles of pre-term and term human milks in evaluating scoring patterns for routine protein quality assessment of infant formulas. J AOAC Int 79 N 2 p 498.

**Abbott Australasia Pty Ltd** submitted that the valine content of 5.5 g/100 g of protein is still much higher than the reference cited by the European Union (4.5 g /100 kJ).

### Industry issue at Inquiry

Industry argued that to allow for manufacturing practicalities the amino acid reference values should be expressed per 100 kJ of energy rather than per 100g protein. In addition, industry disagreed with the proposed amino acid profile specified (i.e. FAO/WHO 1991), particularly the values for cysteine, histidine, phenylalanine, tryptophan and tyrosine. Industry suggested that the amino acid profile from the European Commission (EC) Directive (91/321/EEC), including being able to sum cysteine and methionine, be used in Standard 2.9.1.

### Assessment

The issue of protein quality has been the most contentious and difficult to resolve. Industry has argued strongly against the proposed breast milk reference values for a number of reasons namely, inconsistency with international regulations, significant reformulation of current products required to meet the proposed values and the lack of evidence to support the safety of the proposed values versus the current regulations that have a history of promoting normal growth and development in formula fed infants.

Industry commissioned Makrides et al <sup>4</sup> to conduct *inter alia* a review of amino acid profiles, which in addition to favouring a lower reference value for cysteine, concluded that '*the standard of clinical trials in the area of protein quality and growth is poor and offers little guidance for recommendations for infant diets*'.

This lack of clear scientific evidence is an inherent difficulty in resolving this issue as health professionals have indicated support for the expression of protein as g/100g protein because of concerns of the potential health risks associated with higher levels of poorer quality protein in infant formula.

### *Reference Amino Acid Profile*

The amino acid profile of human milk has been studied by a number of researchers in the last 30 years. In 1991 the FAO/WHO commissioned an Expert Consultation on Protein Quality Evaluation. This consultation reaffirmed the amino acid profile for breast-milk as determined by FAO/WHO in 1985. ANZFA recommended this profile as expressed as g/100g protein (Schedule 1) for inclusion in the draft standard at Full Assessment.

The EC has also used human milk protein quality (expressed in mg/100 kJ) as the basis for its Directive but set the levels using data from the 1970s. The 1991 FAO/WHO Expert Consultation noted that the review of a 1970 FAO publication on amino acid content of foods revealed considerable shortcomings in the FAO data especially for cysteine, tryptophan and methionine and concluded these earlier recommendations needed revision.

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<sup>4</sup> Makrides M et al (2000) Report to the Infant Formula Manufacturers Association of Australia – “Review of amino acid profiles, zinc to copper ratios and essential fatty acid composition of infant formulas

Additionally Dr Sarwar Gilani<sup>5</sup> recently compared literature reports on the amino acid composition of human milk with the amino acid values reported by FAO/WHO (1991) and EC (1991). This comparison indicated that the literature supports the use of the FAO/WHO values for assessing protein quality in foods for infants less than one year of age.

These values were considered by a range of stakeholders at a forum to consider industry issues in May 2000 and again by members of the ANZFA External Team in June 2000. Schedule 1 from the Full Assessment was re-tabled at the External Team meeting. This schedule which uses the values recommended by the WHO in 1991 summed cysteine and methionine and also summed phenylalanine and tyrosine. It was agreed that this Schedule would be recommended for re-inclusion in the standard.

### *Cysteine needs of infants*

The enzyme cystathionase facilitates the conversion of methionine to cysteine. Many researchers report that cystathionase activity is insufficient in premature infants and some term infants. Atkinson and Lonnerdal<sup>6</sup> note that cystathionase levels appear to reach mature levels when infants are about 3 months of age. Therefore, cysteine is considered to be 'essential' for some infants such as premature or low birth weight infants. Therefore it is important to ensure a cysteine content of formula, especially those prepared for very young or premature infants as the need for cysteine may not be as crucial for full term infants.

### *Cysteine level in human milk for the setting of a reference value*

A minimum cysteine level, based upon the level in human milk, is proposed for the standard to ensure infant formula products meet the needs of very young infants.

The WHO/FAO recommendations provide for cysteine in combination with methionine and therefore do not provide an individual recommendation for cysteine. The level of cysteine proposed at Preliminary Inquiry (2.45g cysteine /100g protein) was that reported by Sarwar to be the level in transitional human milk i.e. milk from mothers who had given birth in the previous few weeks. Industry challenged this value on the basis that it was from transitional milk rather than from mature milk for older infants. Given the public health interest in relation to very young babies for whom cysteine may well be considered an 'essential' nutrient, this choice was justified.

Industry submitted an assessment of literature reports on the cysteine value of human milk and claimed the mean value from that literature review was 1.7 g /100g protein<sup>7</sup>. However this report failed to report on key papers which assessed human milk amino acid content such as the Sarwar paper (cysteine of  $2.45 \pm 0.15$  g/100g protein for transitional milk,  $2.51 \pm 0.42$  for pre-term milk g/100g protein), the Darragh and Moughan<sup>8</sup> paper (8. g protein/L and 310 mg cysteine /L) and Davis TA et al<sup>9</sup> (cysteine of  $20.2 \pm 2.6$  mg/g total amino acid).

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<sup>5</sup> Dr Sarwar, personal communication, 2001

<sup>6</sup> Atkinson SA and Lonnerdal B. (1989) Protein and non-protein nitrogen in human milk. CRC Press Inc Boca Raton, Florida, USA

<sup>7</sup> Makrides M et al (2000) Report to the Infant Formula Manufacturers Association of Australia – "Review of amino acid profiles, zinc to copper ratios and essential fatty acid composition of infant formulas.

<sup>8</sup> Darragh AJ and Moughan PJ. (1998) The amino acid composition of human milk corrected for amino acid digestibility. Br J Nutr 80: 25–34.

<sup>9</sup> Davis et al Amino acid composition of human milk is not unique. (1994) J Nutr 124: 1126–1132

These recent papers generally had assessed the cysteine content to be higher than the mean derived by the Makrides team for the submission by industry.

Darragh and Moughan analysed human milk from New Zealand women in their 10–14th weeks of lactation. They found the cysteine content to be 20% higher than previously reported values and attributed this higher level to the correction for losses due to acid hydrolysis before the amino acid analysis. The Darragh and Moughan values when calculated to g/100g protein show cysteine content of the order of 3.5 g/100g protein or higher than the Sarwar transitional milk values from Canadian women. It is not proposed to incorporate the Darragh and Moughan values into the standard but they indicate that Sarwar values are not ‘outliers’ as claimed by industry.

#### Methods of analysis for cysteine

Industry claim that the values considered above are reported from non–standard methods of analysis. The method of analysis used to estimate cysteine content has been fairly standard for about 15 years (personal communication with Mr C Rayner, Agriculture Victoria). This method requires pre–oxidation, hydrolysis and measurement of free amino acid (cysteine) using HPLC. Whilst as with all analytical methods there will be variation in results reported from laboratory to laboratory, the method is sufficiently well used for there to be no need to prescribe a method of analysis in the Food Standards Code for cysteine.

#### Cysteine level in current formulations

The level of cysteine proposed at Preliminary Inquiry (2.45g cysteine /100g protein) was able to be met by some manufacturers of Spanish infant formulas<sup>10</sup> and was therefore considered achievable as some formula are currently complying with the proposed level.

Industry did not provide ANZFA with data about the amino acid content of formula on the Australian or New Zealand market, so ANZFA was not able to assess the real extent of the problem for industry. Therefore ANZFA requested a Professor of Biochemistry from the External Advisory Group to review the amino acid content of the source ingredients (whey and casein) using amino acid sequence data and data supplied by industry on whey:casein ratios and total protein content of various products. This assessment indicated formula prepared to 60:40 whey: casein ratios met the minimum proposed amino acid content for all prescribed amino acids, including cysteine. The high casein based products, such as follow–on–formula varieties met the proposed minimum amino acid contents for all amino acids, except cysteine. Cysteine is not considered to be an essential amino acid for infants 6 months and over.

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<sup>10</sup> Alegria A et al (1999) Amino acid contents of infant formulas. J Food Comp Anal 12: 137–146.

### Cysteine level for the reference value in the standard

The 1998 Life Sciences Research Office (LSRO)<sup>11</sup> report commissioned by the US Food and Drug Administration, stated that although they made recommendation that the sulphur containing amino acids (i.e. cysteine and methionine) could be summed, *'it should be noted that in no case should the requirement be met with only one of the respective constituents. Because the ratio of each of these combinations of amino acids is approximately 1:1 in human milk, ratios that exceed 2:1 or 1:2 are probably unbalanced and should not be used without appropriate testing for adequacy'*.

The ANZFA External Advisory Group agreed that a minimum level of 1.9 g cysteine per 100g protein be provided for infants under 6 months. This would adjust to a reference value for human milk of 2.4g cysteine per 100g protein (using an amino acid score of 0.8) if one should be included. This level is consistent with the recommendations of the LSRO report in relation to the ratio of sulphur containing amino acids as given the reference value for the sulphur containing amino acids (i.e. sum of cysteine and methionine) of 4.2g/100g protein the minimum ratio would be 1.2.

At a further meeting with industry in August 2000, evidence was presented that the Zlotkins group<sup>12</sup> showed that pre-term infants given parenteral nutrition lacking in cysteine grew well and that the addition of cysteine to the infants' regimen did not improve growth or nitrogen retention. Attention was also drawn to the LSRO report's recommendation on combining the cysteine and methionine values and the recommended ratio. The stakeholders considered, on the basis of industry data, that by adopting this additional parameter, it might be possible to retain the current form of protein expression and not shift to expression of amino acids/100 kJ.

Therefore, new industry data and previously provided average values for formula products were re-examined to test the ratio approach. This was shown not to be feasible unless the ratio was lowered to 1:4, cysteine to methionine. Rather than introduce a new approach, the absolute minimum value for cysteine was reduced to 1.1 mg /100g protein to apply to infant formula products suitable from birth. On the basis of submitted industry data, this level does not require manufacturers to add cysteine but provides infants with a source of cysteine.

### *Units of expression*

The protein content permissions proposed for the draft standard are consistent with those of Codex, that is, a protein range of 0.45– 0.7 g protein/100 kJ for formulas prepared for the youngest infants and 0.45– 1.3 g protein/100 kJ for infants over 6 months of age.

Protein content and protein quality are interrelated in determining the biological use of a food protein source. Whilst the amino acid components are utilised for growth and maintenance of tissues, any excess is required to be partially metabolised and excreted. Therefore, the protein content and protein quality of an infant formula contributes to the load on the infant's kidneys.

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<sup>11</sup> Raitrn DJ et al (1998) Assessment of nutrient requirements for infant formulas. J Nutr Supplement Vol 128 no 15–Report prepared for the Centre for Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services, Washington DC

<sup>12</sup> Zlotkin SH et al (1981) Cysteine supplementation to cysteine – free intravenous feeding regimes in new born infants. Am J Clin Nutr 34: 914–923



Protein quality is traditionally expressed in units of amino acids per total protein content i.e. g/100g protein and Schedule 1 from Full Assessment is expressed in this way and allows for the summation of cysteine and methionine, and phenylalanine and tyrosine levels.

Expression as g amino acids per 100 g protein was accompanied by a requirement that all of the protein in the formula be at least 80% of the quality of the reference human milk profile (i.e. Schedule 1). ANZFA maintained the opinion that the needs of formula fed infants were best served by a protein profile expressed in g/100g protein that closely follows that of human milk.

Industry however stated that to meet these values, free amino acids would need to be added to some lower quality formula, which would potentially incur risks if not first subjected to clinical trial. ANZFA disputed this generalised claim. The current Standard R7 and the international standard (Codex), and most international regulations permit the addition of L–amino acids to improve the quality of the protein in the formula. Safety is determined by the quality and amounts of amino acids added and Industry are expected to use only amino acids in safe forms. It was noted that free amino acids are already used in special purpose formulas and these are apparently safe in that context.

However in acknowledging that this approach was different to existing international standards, ANZFA sought the assistance of Dr Sarwar Gilani (Health Canada). Dr Sarwar, having expertise in the area of protein quality and infant formula, was chairing one of the FAO/WHO/UNU Working groups on reviewing protein and energy requirements in Rome in July 2001. Dr Sarwar kindly agreed to raise the issue of infant formula and the expression of protein quality at the working group meetings as a means of establishing a consensus from working group participants.

Following the meetings, Dr Sarwar reported that discussions, albeit limited, provided no conclusive evidence to support the expression of protein quality by grams amino acid / 100 grams of protein (g/100g protein) over the more common expression by energy value (mg amino acid / 100 kJ) for regulatory purposes.

Consequently, due to the apparent lack of conclusive evidence to favour the expression of protein quality as g amino acid / 100 grams protein and the lack of precedent for this requirement in other international regulations, ANZFA believes it is no longer able to maintain its position on the expression of protein quality. It is therefore recommended that the amino acid reference values as proposed at Full Assessment (Schedule 1) be expressed as mg / 100 kJ and including the summation of cysteine and methionine and phenylalanine and tyrosine.

Following the decision to change the expression of protein quality to milligrams amino acid/100 kJ, a minimum level of cysteine was still considered important. Based on the conversion of the proposed level of 1.1g/100g protein to 4.95 mg /100 kJ, ANZFA is proposing a minimum level of cysteine of 6 mg/100 kJ, which corresponds to the level required by the EC and equates to an approximate minimum ratio of cysteine to methionine of 1:2 in line with LSRO.

## Recommendation at Supplementary Final Assessment

It is recommended that:

1. the values proposed at Full Assessment, i.e. Schedule 1 that provide reference values for human milk, be expressed as mg amino acid/100 kJ and be reinstated in the draft standard;
2. the standard no longer permits deviation from reference values as per an amino acid score because an absolute minimum has been set instead; and
3. in allowing the summation of cysteine and methionine, and phenylalanine and tyrosine, infant formula products should provide a minimum cysteine content (6 mg/100 kJ) and a minimum level for phenylalanine (17 mg/100 kJ).

## The future

Refinement to regulations for protein quality will be desirable in the future to capture the evolving knowledge about the protein profile of human milk, the bioavailabilities of amino acids from these human milk proteins and the technological advances in the development of the proteins that mimic the bioactivity of the human milk proteins.

It is anticipated that ANZFA will review the issue of protein quality following the outcomes of the joint FAO/WHO Expert Consultation on Human Protein Requirements scheduled to take place in April 2002 and developments in the Codex draft standard for infant formula.

## **3. DIVISION 3 – GENERAL COMPOSITIONAL REQUIREMENTS**

### **3.1 Restrictions and prohibitions – Clause 7**

#### Proposed at Preliminary Inquiry

*A vitamin, mineral, food additive or nutritional substance must not be added to infant formula unless:*

- (a) expressly permitted by this standard; or*
- (b) it is included in the infant formula as naturally present in an ingredient of the infant formula product.*

*An infant formula product must not contain any detectable gluten.*

#### Issues

**InforMed Systems Ltd** queried if the proposed list of ‘additives’ at Clause 7 to be permitted in infant formula was more restrictive than Codex, as Codex does not specify precise forms of additives in their draft standard.

## Assessment

This issue was addressed at Preliminary Inquiry. Specification of forms of vitamins, minerals, food additives and nutritive substances is intended to ensure substances other than ‘foods’ which are added to formula are safe and suitable.

This clause also controls the use of potential novel ingredients by ensuring independent safety assessments are carried out before these substances are used in formula sold in Australia and New Zealand (refer to Item 8.2 – Novel Foods).

## Recommendation

Clause 7 be retained as prepared at Preliminary Inquiry.

### **3.2 Permitted optional nutritive substances – Clause 8**

The term ‘*nutritive substance*’ has been defined in the Preliminary Provisions (Standard 1.1.1) of the joint Food Standards Code (Volume 2), therefore the term ‘*nutritional substance*’ used at Preliminary Inquiry has been changed at Inquiry to ‘*nutritive substance*’.

#### Proposed at Preliminary Inquiry

The draft standard provides for certain nutritive substances to be added to infant formula, in one or more of the forms specified, on a voluntary basis. Maximum permitted amounts of these nutritive substances are provided and a minimum specified level, which must be met in order to make a claim.

#### **3.2.1 Error in draft standard for Carnitine, Choline and Inositol.**

The maximum level included in the table to Clause 8 for carnitine, choline and inositol were incorrect as the values set at Full Assessment were included in the draft standard rather than the revised levels agreed at Preliminary Inquiry. Therefore, the following correct recommended maximum levels as reflected in the Preliminary Inquiry report are recommended for the standard.

	Maximum permitted amount per 100 kJ
Choline	7.1 mg per 100 kJ
Carnitine	0.8 mg per 100 kJ
Inositol	9.5 mg per 100 kJ

#### **3.2.2 Carnitine**

##### Proposed at Preliminary Inquiry

The range of carnitine permitted to be added to an infant formula product is 0.21–0.42 mg per 100 kJ.

## Issues

The **Dairy Goat Co–Operative (NZ) Ltd** submitted that the maximum level should be deleted or raised to accommodate the innate carnitine level of goat milk. **Nestlé Australia Ltd** also submitted that the range for carnitine is too narrow to provide for the innate carnitine levels of the base milk ingredients.

## Assessment

The draft standard only regulates carnitine in the circumstance when carnitine is 'added' as an ingredient to the formula. In that case, the regulation provides for 'total carnitine'. The regulation is intended to provide for the addition of carnitine to formula such as soy–based or amino acid based which do not have innate carnitine levels. As there is no need and hence no justification for adding carnitine to a milk–based formula, this provision should not apply to formula based upon either cow or goat milk.

## Recommendation

An editorial note be included in the relevant clause to the effect that *“it is not the intent of the standard to regulate the maximum nutritive substance level of formula in the case when the nutritive substance is not added as an ingredient to the formula”*.

### **3.2.3 Choline**

#### Proposed at Preliminary Inquiry

The range of choline permitted to be added to an infant formula product is 1.7–5.4 mg per 100 kJ.

#### Issue

**InforMed Systems Ltd** submits that choline is classified as an essential nutrient and therefore should be listed under 'vitamins'.

#### Assessment

This issue was addressed at Preliminary Inquiry where it was noted that the dietary use for choline is still inconclusive and as it has not been declared an essential nutrient would be regulated as an optional ingredient.

#### Recommendation

It is recommended choline continue to be regulated as an optional ingredient.

### 3.3 Nucleotides – Clauses 8 and 9

#### Proposed at Preliminary Inquiry

The draft standard provides for 5 nucleotides not previously permitted in infant formula to be added on a voluntary basis. Maximum total and individual levels of nucleotides are provided and a minimum specified level must be met in order to make a claim.

#### Issues

A lack of standardised methodologies for the analysis of nucleotides has resulted in wide ranges of values being reported for the individual nucleotide content of human milk.

**Bristol Myers Squibb Australia Pty Ltd** commented that the permissions to add nucleotides should be included in the additive standard and cross-referenced for use in infant formula. This includes any necessary purity standards. **Wyeth Australia Pty Ltd** commented that the moisture specification and bacteriological profile might be redundant, as they are included under Division 5–General Microbiological Requirements. **Abbott Laboratories (NZ) Ltd** and **Abbott Australasia Pty Ltd** asked that the specifications for the 5 nucleotides be increased to those proposed in the most recent LSRO report. The **Nursing Mothers' Association of Australia** commented that the safety of all optional ingredients should be established before being permitted in infant formula.

#### Assessment

The levels of nucleotides permitted in the draft standard have been based on the European Commission (EC) Directive. However more recent research would seem to support that the levels in the EC Directive actually underestimate the levels of nucleotides in breast milk. The recent LSRO report recommended a maximum content of [nucleotides and nucleotide precursors] of 16 mg/100 kcal (3.8 mg/100 kJ), a value similar to the upper level reported for human milk. The current draft standard permits up to a maximum total nucleotide level of 1.2 mg /100 kJ.

There are currently believed to be 13 different nucleotides present in human breast milk. At Preliminary Inquiry it was suggested that until further evidence of safety and efficacy was available, only 5 of the 13 nucleotides be permitted for use in infant formula. Therefore it is recommended that the level proposed at Full Assessment and at Preliminary Inquiry for the 5 specified nucleotides be retained. The maximum total nucleotide content could be raised to the level the LSRO of 3.8 mg/100 kJ.

It was commented that nucleotide specifications should not be contained in an infant formula products standard. It was never intended that these specifications would be in the infant formula standard. As outlined at Preliminary Inquiry, these specifications for nucleotides will be included in Standard 1.3.4 – Identity and Purity. In addition, the microbiological specifications will be deleted from this standard, as these are incorporated under general microbiological requirements (Standard 1.6.1) with which infant formula must comply.

#### Recommendation

That the proposed maximum permitted total nucleotide content in infant formula be increased to 3.8 mg/100 kJ as recommended by the LSRO report.

### 3.4 Food Additives

#### Proposed at Preliminary Inquiry

At Preliminary Inquiry, ANZFA proposed to include the Codex provisions for food additive use in infant formula, with adjustment for the recommendations by the European Commission's Scientific Committee on Food (SCF).

#### 3.4.1 Carrageenan

##### Issues

**The Victorian Food Safety Council Food Standards Sub-committee and the NZ Ministry of Health** expressed some concerns regarding the safety of the food additive carrageenan. Both submissions requested that further consideration be given, especially as the additive is still under review internationally.

The **International Formula Council** supported the proposal. **InforMed Systems Ltd** suggested that the proposed levels of carrageenan in hydrolysed and amino acid based formula were more restrictive than Codex; and that the standard for infant formula should align with Codex recommendations.

##### Assessment

Carrageenan is currently permitted in infant formula in New Zealand, with no maximum limit prescribed. Under the current standard R7, infant formula may contain not more than 0.3g per litre (0.03%) of carrageenan, in the case of liquid milk-based and soy-based varieties, and not more than 1.0 g per litre of carrageenan in the case of liquid hydrolysed protein-based and amino acid-based types.

At Full Assessment, ANZFA proposed not to permit the addition of carrageenan in infant formula. At Preliminary Inquiry, ANZFA undertook an assessment of carrageenan. Since the Preliminary Inquiry report was written, no new evidence has been presented. As concluded at Preliminary Inquiry, there is not considered to be sufficient evidence of potential adverse effects of carrageenan to restrict its use in infant formula.

ANZFA proposes to permit no more than 0.03g of carrageenan per 100 mL of liquid infant formula product, and no more than 0.1g of carrageenan per 100 mL of infant formula product based upon protein substitutes for a specific dietary use.

##### Recommendation

The provisions proposed at Preliminary Inquiry be retained.

##### *Permission to add carrageenan*

##### Issue

**Nestle Australia Ltd** commented that the drafting at Clause 11(3) does not give permission for the addition of carrageenan.

## Assessment

ANZFA has amended the drafting to ‘... *may contain not more than* ...’ to ensure permission for addition of carrageenan to infant formula is provided.

## Recommendation

The permission for the use of carrageenan in liquid infant formula products should remain as proposed at Preliminary Inquiry. However, the words ‘must not contain more than’ in Clause 11 Subclause 3 should be amended to ‘*may contain not more than*’.

### **3.4.2 Citric esters of mono- and di-glycerides of fatty acids (E472c)**

#### Issue

**Nestle Australia Ltd** requested the inclusion of the food additive citric esters of mono- and di-glycerides of fatty acids for the preparation of formula based on extensively hydrolysed protein, as this was included in the European Commission (EC) Directive for Infant Formula in November 1998.

#### Assessment

The Scientific Committee on Food (SCF) of the European Commission considered citric acid esters of mono- and di-glycerides of fatty acids (E472c) to be safe for use in infant formula based on extensively hydrolysed protein at a level of 0.9 g/100 mL.

#### Recommendation

Therefore it is recommended that citric acid esters of mono- and di-glycerides of fatty acids (E472c) be permitted up to a level of 0.9 g/100 mL in formula based on extensively hydrolysed protein.

### **3.4.3 Mono- and di-glycerides of fatty acids (E471)**

The names of the mono- and di- glycerides listed in the Tables at Clauses 11 and 42 are class names rather than the specific food additives included under INS number 471. The appropriate food additives numbers have been added to the table for clarification.

### **3.4.4 Diacetyl tartaric acid esters of mono and diglycerides (DATEM) (E472e)**

The value for DATEM in the Table to Clause 42 proposed at Preliminary Inquiry included a typographical error that created an error of a factor of 10 in the table. The figure in the table was to be that recommended by the SCF for infant formula based upon protein substitutes. The SCF recommended 0.4 g/L, which should have been included in the Table as 0.04 g/100 mL.

#### Recommendation:

The correct figure of 0.04 g/100 mL for DATEM be included in the Table to Clause 42. The food additive number E472e should also be included in the Table to Clause 42.

### 3.4.5 Locust bean gum

#### Proposed at Preliminary Inquiry and Inquiry

Permission to use locust bean gum to a maximum level of 0.1 g/100 mL.

#### Industry issue

Industry proposes the maximum locust bean gum level be increased from 0.1 to 0.7 g/100 mL.

#### Assessment

ANZFA has relied on reports from the Scientific Committee on Food (SCF) of the European Commission for its assessment of food additives. The term of reference for this committee is:

*'To consider the safety-in-use of certain additives in infant formulae, follow-on formulae and weaning foods for infants and young children in good health and in foods for special medical purposes (FSMP) for infants and young children.'*

#### *Locust bean gum (E410)*

In respect of the use of locust bean gum, the SCF<sup>13</sup> reported that locust bean gum, also called carob bean gum, is refined from the endosperm of the carob tree, *Ceratonia siliqua*. It contains tannins and the carbohydrate component is a galactomannan polymer consisting of linked D-mannose units with side chains of D-galactose. It is used as a stabiliser and thickening agent

Locust bean gum was evaluated by JECFA in 1981. An Acceptable Daily Intake was not specified due to lack of toxicity known. However, in considering a request to increase the permission for locust bean gum in infant formula products from 0.1 to 1 g/100 mL, the SCF considered:

- there are indications of growth depression in animals fed locust bean gum, although these are equivocal;
- bean gum preparations are fermented in the colon, providing a small energetic gain. They can cause abdominal pain and diarrhoea;
- absorption of minerals and trace elements may be reduced by dietary fibre and tannins. Although a study on adults ingesting locust bean gum has shown no evidence of impaired absorption of minerals and trace elements, it is not always appropriate to use results from adults when evaluating health effects in infants in cases where growth may be affected. In rapidly growing healthy infants, even minor effects on gastro-intestinal absorption of trace elements and minerals may have growth retarding effects; and
- studies on growth in healthy infants chronically exposed to locust bean gum are lacking.

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<sup>13</sup> Opinion on certain additives for use in foods for infants and young children and in foods for special medical purposes- adopted 106<sup>th</sup> meeting of SCF (March 1997).



The SCF concluded it was not persuaded that it is necessary to give thickened infant formula to infants in good health. It therefore recommended that the use of locust bean gum is not acceptable, at the doses requested, for use in infant formula and follow-on formula intended for infants in good health.

#### *Gastro-oesophageal reflux (GOR).*

The SCF noted ‘*that some medical specialists recommend that thickening of foods is useful in the treatment of GOR, and that in cases of uncomplicated GOR, treatment with thickening agents may be started without complementary investigations.*’

Clinical observations have shown that the clinical efficacy is best when locust bean gum is added to infant formula in the concentration range 4–10 g/L. However, there are few controlled studies of the efficacy of use of thickened infant formula in reducing GOR. It is believed that the increased viscosity of thickened feed will reduce the episodes of reflux, but it has been shown that the effects are unpredictable. Thickeners added to infant formula may reduce the number of reflux episodes, but may also prolong the duration of remaining episodes. Increased coughing in infants after thickened feedings compared with after unthickened feedings has also been reported.

Nonetheless the SCF accepted that the use in food for special medical purposes up to 10g/L is acceptable.

ANZFA has already stated its concerns about the use of claims about physiological conditions. ANZFA has requested, but not been provided with data to show that the marketing of products with these claims does not reduce breastfeeding rates (see Item 7.2.3). Therefore the standard does not provide for claims about physiological conditions such as ‘anti-reflux’, and there is no provision for ‘anti-reflux’ formula in Division 3 of the standard.

The SCF raised a number of concerns about the efficacy of these formulations. Therefore it is considered appropriate that an increase in the use of a food additive, which has the potential to impact adversely on the health of infants, be subjected to a full assessment as required under the food standard setting process.

#### Recommendation:

The proposed provisions for locust bean gum be retained.

#### **Summary of recommendations for Section 3.4**

Clause 11 should be varied at Subclause (3) to read “liquid infant formula product may contain not more than 0.03 g carrageenan per 100 mL”.

The Table to Clause 42 be amended to include permission for the use of citric acid esters of mono- and di-glycerides of fatty acids (E472c) up to level of 0.9 g/100 mL in formula based on extensively hydrolysed protein.

The entry for mono- and di- glycerides listed in the Tables at Clauses 11 and 42 be amended to mono- and di-glycerides of fatty acids (E471).

Permission to use locust bean gum to a maximum level of 0.1 g/100 mL is retained.

### **3.5 Clause 13 – Limit on aluminium**

#### Proposed at Preliminary Inquiry

- (1) *Infant formula product, other than a soy-based formula product or pre-term formula, must not contain more than 0.05 mg of aluminium per 100 mL.*
- (2) *Pre-term formula must not contain more than 0.02 mg of aluminium per 100 mL.*
- (3) *Soy-based formula must not contain more than 0.1 mg of aluminium per 100 mL.*

#### Issues

Several industry groups supported this proposal although the **NZ Dairy Marketing and Customer Services** submitted additional costs would be incurred by this provision. The **NZ Ministry of Health** submitted that the toxicological assessment does not provide a robust argument demonstrating safety at this level; **Maureen Minchin (IBCLC)** submitted that the lower level should be universal, not the higher. **Nestle Australia Ltd** submitted that the prescription of a level is consistent with international regulations but submit that there should only one limit, which should be a guideline level to meet WTO obligations and if there is no health or safety issue with the level of aluminium in soy-based infant formula, then this level should apply to all formula.

#### Assessment

At Full Assessment, ANZFA consulted experts on the levels that would be adequate to protect public health and safety. Available data at that time on aluminium levels in infant formula, from the Australian Market Basket Survey and from industry, showed that in general the levels in soy-based products were higher than those in milk-based products.

Consequently, the levels at Preliminary Inquiry were proposed not only to protect public health and safety but also from the advice received at levels which were also achievable from sound manufacturing processes. No new evidence was provided about the safety of aluminium levels in infant formula, therefore the level proposed at Preliminary Inquiry should be retained.

#### Recommendation

Retain levels proposed at Preliminary Inquiry.

### **3.6 Composition of lactose free and low lactose formula**

#### Proposed at Preliminary Inquiry and Inquiry

An infant formula product that makes a claim that it is 'low lactose' must not contain more than 0.24 g lactose per 100 mL.

## Issue

The lactose content of low lactose infant formula product was specified before the provisions were set for low lactose foods. The level set for a claim for a low lactose food (general purpose) is not more than 0.3g per 100g of the food (Standard 1.2.8 (14)). An infant formula product that makes a claim that it is 'low lactose' must not contain more than 0.24 g lactose per 100 mL.

## Assessment

At Preliminary Inquiry and Inquiry, it was proposed to revise the provisions for low lactose formula such that low lactose formula regardless of base ingredient should not contain more than 2.4 g/L but it was noted this maximum level might be revised when Standard R1 (5) is reviewed in the Review of Food Standards to ensure consistency.

Given the Nutrition Information Table will provide information on the lactose content of a low lactose formula, it is considered that increasing the maximum permission to 0.3g per 100g will not create problems for lactose intolerant infants.

## Recommendation at Supplementary Final Assessment

Drafting is revised to specify that low lactose formula must contain no more than 0.3 g lactose per 100 mL infant formula product.

## **4. DIVISION 4 – GENERAL LABELLING AND PACKAGING REQUIREMENTS**

### **4.1 General Comments**

## Issues

**The Victorian Food Safety Council Food Standards Sub-Committee** suggest that there should be specific education material to inform health professionals and users of the product about the rationale for the content of the new standard.

**Nestlé Australia Ltd** states that the required statements specified are listed in the labelling requirements of the International Code of Marketing of Breast-milk Substitutes that Australia has agreed to comply with. The inclusion of specific statements for the labelling these products will create a difficulty for our WTO obligations with respect to the importation of infant formula.

## Assessment

The WHO International Code of Marketing of Breast milk Substitutes is a voluntary Code. Inclusion of requirements for specific labelling statements in the Food Standards Code is essential to ensure compliance and enforcement. Only those sections of the WHO Code essential to protect public health and safety are included in the standard.

## Recommendation.

No changes to the drafting are required. A communication / education strategy will be developed to inform health professionals and consumers of the changes to the standard for infant formula.

### **4.2 Clause 18 – Requirement for a measuring scoop**

#### Proposed at Preliminary Inquiry

A package, other than a single serve sachet, containing infant formula product in a powdered form, must contain a scoop, which facilitates the use of the infant formula product in accordance with the directions contained in the label on the package.

#### Issues

**Wyeth Australia Pty Ltd** suggest that Clause 18 should read “A package, other than a single serve sachet or a package containing single serve sachets, must contain a scoop which facilitates the use of the infant formula product in accordance with directions contained in the label on the package.”

**InforMed Systems Ltd** states that Codex has no statement on scoops.

**The Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition** state that in regard to the measuring scoop it would have been preferable to have a standard scoop for measuring infant formula, e.g. 1 scoop to 30 mL or 1 scoop to 60 mL. This would reduce consumer confusion when changing brands.

#### Assessment

No information has been presented in submissions concerning the need for a statement about the ‘scoop’ that was not discussed at Preliminary Inquiry. The wording should be amended to take into account the suggestion of Wyeth Australia Pty Ltd.

#### Recommendation

The drafting will now read “*A package, other than a single serve sachet or a package containing single serve sachets, must contain a scoop which facilitates the use of the infant formula product in accordance with directions contained in the label on the package.*”

### **4.3 Clause 19 – Required statements**

#### Proposed at Preliminary Inquiry

Several mandatory advisory statements and one mandatory warning statement were proposed to be required in the label of infant formula products.

### 4.3.1 Clause 19 (3)(a) and (b)

#### Proposed at Preliminary Inquiry

Statements are required to indicate that:

- breast feeding is superior to the use of infant formula product in the feeding of infants; and
- infant formula products should only be used on the advice of a medical practitioner or health worker as to the need for its use and proper method of use.

#### Issues

There is concern from consumers and public health organisations that the proposed information to be provided in the label of infant formula is not sufficient to advise consumers that breastfeeding is the best method of feeding for infants. Some submissions commented that consumers should be warned that infant formula might be dangerous to infants and mothers.

Consumers and Public Health representatives submitted that they felt there should be stronger warning statements. Comments made included the following:

- this proposal would weaken current labelling provisions by downgrading the prescribed statements into advisory statements;
- a warning statement in 6 mm type to the effect that artificial formula feeding can be dangerous to the health of the infant should be mandatory on all infant formula;
- the labelling requirements do not warn consumers of the health risks to the child or mother of using artificial formula;
- consumers will not generally seek information from health professionals and advice from health professionals may be incorrect;
- the required statement that “breast is best” is ambiguous. It may maintain the misconception that feeding infants artificial formula is ‘standard’ or normal. It does not convey that there are adverse health risks associated with use of the formula; and
- the labelling requirements do not require information to be on the product that would enable consumers to avoid being deceived about the relative merits of formula and human milk.

**Mr Dunstone** had made an application (A376) to require the statement 'this formula may harm your baby' on the label of the formula in addition to specific label statements targeted to health professionals. ANZFA considers that there are two main issues arising from Mr Dunstone's application. These issues are:

- should messages targeted to health professionals be on the labels of infant formula? ; and
- will the warning statements and explanatory messages in the application from Mr Dunstone increase the incidence of breastfeeding in Australia and New Zealand?

### Assessment

Breastfeeding is the preferred method of feeding for infants. Government supported public health initiatives strive to promote breast-feeding to all new mothers. Limitations in scientific knowledge mean that formula prepared for infants does not support the nutrition of infants as well as human milk. However, infant formula is intended to be a substitute for breast milk when breastfeeding is not possible. The food standard sets provisions for the safest and healthiest formula for babies. Infant formula available in Australia and New Zealand are safe products and are the best alternative to breast milk when breastfeeding is not medically possible.

Mothers and carers of infants, who cannot breastfeed, should not be made to feel guilty about the fact that they use infant formula. Warning statements in the label of infant formula stating that infant formula is dangerous, are not only false and misleading, but might also cause carers to use other less suitable alternatives.

The proposed labelling provisions encourage the use of breast milk rather than infant formula and the required statements are intended to fulfill this task. Comments received from submitters suggested that these required statements are not strong enough because manufacturers will be permitted to use their own words as long as the intent of the statement is correct. Currently the required statement in Australia reads:

‘ATTENTION – BREAST MILK IS BEST FOR BABIES. BEFORE YOU DECIDE TO USE AN INFANT FORMULA, CONSULT YOUR DOCTOR OR CLINIC FOR ADVICE’

In the light of public concern, ANZFA considers that the words of the statement should be mandated. The current statement has been amended slightly to;

- Cover the inclusion of follow-on formula in addition to infant formula
- The term health worker was considered more appropriate than clinic.

The mandated statement will be;

*‘Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.’*

**Mr Dunstone** suggested that requiring the statement “this formula may harm your baby” on the labelling of the formula in addition to specific label statements targeted to health professionals will increase the rates of breastfeeding in Australia and New Zealand. **Mr Dunstone** did not present ANZFA with specific evidence to indicate that implementation of the specific statements on all infant formula would increase breastfeeding rates in Australia and New Zealand. There are a number of complex, social, physiological and cultural factors, which could affect the rate of breast-feeding.

It is therefore unlikely that breast-feeding targets can be achieved through implementing the warning statements and explanatory messages proposed in the application by **Mr Dunstone** alone.

#### *Advice to health professionals*

There is no evidence that health professionals view these particular food labels at retail level. Therefore there is no justification for label messages targeted to these particular non-purchasers. Health professionals who advise carers of infants are more effectively reached with direct information dissemination strategies. It is considered that the most appropriate way to communicate to health professionals is using specific education campaigns directed through professional associations.

However, ANZFA considers that education in conjunction with labelling can be an effective means of communicating public health messages to consumers. There are a number of education initiatives planned or being undertaken in Australia and New Zealand to improve breastfeeding rates in both countries. These initiatives differ in both countries but may include family education, education of health professionals, development of national accreditation standards for health care services, training for indigenous health workers, workplace support and monitoring.

#### *Use of unprescribed text and print size*

Advisory statements and other mandatory information, except warning statements, are not required to have a specified print size. Mandatory information, with the exception of warning statements, is simply required to be legible. Warning statements are required to be in 3 mm type and on small packages in 1.5 mm type. Submitters did not think that this was appropriate.

The mandatory labelling statements required in the label of infant formula are necessary to ensure that products are used as they are intended to be used. Therefore ensuring that the statements are noticed by users of the product and are prominent is essential. In addition ensuring the words presented on all infant formula products are the same will ensure that the messages being sent to consumers are consistent.

It is proposed that the drafting be changed to require all mandatory warning and advisory statements on the label of infant formula to appear in 3 mm type, or in the case of small packages, in 1.5 mm type. The wording of advisory statements should be mandated as is the case for warning statements.

#### Recommendations

The following amendments to the draft standard are recommended.

Clause 19 (3) – Infant formula product must contain the following statement under the heading of ‘Important Notice’:

*“Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice”* in a minimum print size of 3 mm.

### 4.3.2 Statement about additional foods

#### Proposed at Inquiry

*‘except in the case of packages of pre-term formula, infants over the age of 6 months should receive foods in addition to the infant formula product’.*

#### Industry issue at Inquiry

Industry submit that the requirement for a statement indicating that infants over 6 months should receive foods as well as formula should be removed.

#### Assessment

Standard R7 currently requires a similar statement and it is also required by Codex for infant formula and follow-on formula. Stakeholders and members of the External Advisory Group considered this statement and it was agreed that the intent of this statement be retained but the drafting be amended to *‘... it is recommended that infants over 6 months be offered foods as well as the infant formula product’.*

#### Recommendation at Supplementary Final Assessment

The drafting is amended to *‘... it is recommended that infants over 6 months be offered foods as well as the infant formula product’.*

### 4.3.3 Clause 19 (1) Use of the term ‘very ill’

#### Proposed at Preliminary Inquiry

The following warning statement should appear in the label of infant formula in type of 3 mm.

*“Warning – Follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder or concentrate (–use whichever is applicable) except on medical advice. Inappropriate use or preparation can make your baby very ill.”*

#### Issues

**Nestlé Australia Ltd, Wyeth Australia Pty Ltd, InforMed Systems Ltd and Bristol-Myers Squibb Australia Pty Ltd** state that the reference to ‘very ill’ in the warning statements of Clause 19(1) needs to be changed to ‘ill’ as the use of the term ‘very’ is too extreme and could cause unnecessary anxiety to carers, which is not justified.

**Maureen Minchin (IBCLC)** submitted that the following statement should be required:



## **‘WARNING**

Follow the instructions below. Infant formula can harm your baby if you do not. Always read the instructions on every can of formula you use, as they may be different. Never use more or less powder or water or a different measuring scoop and use only shrink proof bottles with reliable markings. DO not overheat infant formula, as you can destroy important ingredients. Do not heat infant formula in a microwave.’

### Assessment

The intent of the proposed statement is to warn users of infant formula that if the product is not prepared correctly it could cause serious harm to the infant. Deleting the term ‘very’ but retaining the word ‘ill’ does not convey the potential seriousness of the health risk to infants if formula is made incorrectly. The use of the term ‘very ill’ was used as a softer alternative than the terms ‘seriously ill’ or ‘fatally ill’. Industry has not given significant justification for the deletion of the word ‘very’ and there was no opposition to the use of this word from consumers or most public health organisations. Therefore the word ‘very’ should remain in the drafting of the proposed warning statement.

### Industry issue at Inquiry

The term ‘inappropriate use’ should be changed to ‘incorrect use’ and the term ‘very ill’ is too alarmist.

### Assessment

Representatives at a Stakeholder forum agreed this should be revised to: delete the words ‘use or’ in the last sentence; and replace the word ‘inappropriate’ with ‘incorrect’, thus to read ‘incorrect preparation’.

Again it was not agreed to alter the term ‘very ill’ as non–industry participants believed this to be an accurate representation of the consequences of incorrect preparation and they did not agree this would stop carers purchasing these products.

### Recommendation at Supplementary Final Assessment

The clause be amended to:

*‘Warning –.... Incorrect preparation can make your baby very ill’.*

## **4.3.4 Clause 19 – Ready to drink formula**

### Proposed at Preliminary Inquiry

The following statement is required in the label of ready to drink formula:

*‘Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or concentrate this ready to drink formula except on medical advice. Inappropriate use or preparation can make your baby ill’.*

## Issue

**Wyeth Australia Pty Ltd** state that it is difficult to concentrate ready to drink formula so in Clause 19 it may be more appropriate to say ‘do not dilute this ready to drink formula except on medical advice.’

## Assessment

Ready to drink formula may be concentrated by the addition of powdered formula or milk powder. Such practices should be discouraged except under medical or dietetic advice. Therefore, the intent of the provision should be retained but the wording should be amended to clarify that nothing should be added to the ready to drink formula.

## Recommendation

The clause be amended to “Warning..... do not dilute or add anything to this ‘ready to drink’ formula.....”.

### **4.3.5 Clause 19 – Instructions on the preparation of bottles**

#### Proposed at Preliminary Inquiry

The label on an infant formula product must contain directions for the preparation and use of the infant formula product, which include words and pictures that instruct:

- (a) that each bottle should be prepared individually;
- (b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours;
- (c) that potable, previously boiled water should be used;
- (d) where a package contains a measuring scoop, that only the enclosed scoop should be used; and
- (e) that formula left in the bottle after a feed must be discarded.

## Issue

**InforMed Systems Ltd** state that Clause 19(2) should be deleted or amended to state ‘that each bottle should preferably be prepared individually.’ This is commonly ignored and they have seen no problems arising if it is made up and stored correctly.

## Assessment

This issue was discussed at length at Full Assessment and Preliminary Inquiry. The requirement has been misinterpreted by InforMed Systems. Infant formula may be made in advance and stored as long as each bottle is made up individually rather than in bulk.

## Recommendation

No changes to the drafting are required.

### **4.4 Clause 20 Print and package size**

#### Proposed at Preliminary Inquiry

Mandatory information must be clear, legible and noticeable; warning statements required on infant formula products should be in 3 mm standard type (legibility being the key criteria) or in the case of packages of less than 1 kg, 1.5 mm standard type.

#### Issues

**Wyeth Australia Pty Ltd, Nestlé Australia Ltd and InforMed Systems Ltd** suggest that Clause 20(2) be redrafted to state that a package having a net weight of 1 kg or less should have standard type of not less 1.5 mm. Codex requires that the print size must be 'easily readable'. They question whether specifying an actual size could be more restrictive.

**Maureen Minchin (IBCLC)** suggests a net weight of 450g of formula rather than the 1 kg tin for a small package of infant formula.

#### Assessment

At Preliminary Inquiry a 1 kg tin was considered to be a small package in terms of infant formula products. However, on further investigation the majority of packages sold at retail are less than 1 kg in weight. This means that any warning statements would be in small type of 1.5 mm on almost all retail tins of formula. This is not considered to be appropriate. There is ample space on a 1 kg tin of formula for the required mandatory labelling statements in type of 3 mm.

The size of a small package of infant formula is therefore recommended to be considerably smaller than the 1 kg tin. On investigation of tin weights available it seems that the 450g tin, as suggested by Maureen Minchin, should be classed as a small package. Manufacturers would have difficulty fitting all the required information on this size tin if type had to be 3 mm. Inclusion of all the prescribed information is still required despite the size of the package. However, for a small package the mandatory warning statements may be in 1.5 mm type rather than 3 mm. All other type simply needs to be legible. The print size for warning statements should be consistent with the requirements for warning statements on the label of other food products.

#### Recommendation at Inquiry

A small package for infant formula products should be 450 g or less. The print size for mandatory warning statements in the label of small packages of infant formula products should be 1.5 mm or more.

### Industry issue at Inquiry

Many imported products come in one pound [454g] cans, which have the same sized cans as smaller amounts, for example a can height of 121 mm compared to a height of 163 mm for a 900 g can; yet both require the same type size on the label. Using a break point of 500g for this requirement could obviate this problem. Since there is an overall requirement that label information be legible, it is debatable whether specifying type size actually benefits anyone. This should conform only to general labelling requirements for legibility.

### Assessment

It was necessary to define a small package of infant formula product for the purpose of specifying the print size of mandatory label information. The 450g was chosen as it represented the small pack sizes in the market. However, it appears some imported products are packaged in 454g packs. Therefore there is a case to increase the 'cut-off' from 450 g to 500 g for 1.5 mm versus 3.0 mm print size for warning statements as requested by industry.

### Recommendation at Supplementary Final Assessment

Drafting is amended to replace the package size '450g' with '500g'.

## **4.5 Clause 21 Declaration of nutrition information**

### **Use of 100g in the Nutrition Information Panel (NIP) / Reconstitution**

#### Proposed at Preliminary Inquiry

Clause 21 (2)

- (a) *The average amount of each of protein, fat and carbohydrate expressed in g per 100 mL in the case of ready to drink formula;*
- (b) *In the case of powdered or concentrated infant formula products*
  - (i) *the average amount of each of protein, fat and carbohydrate expressed in g per 100 mL of infant formula products that has been reconstituted according to directions; and*
  - (ii) *the amount of each of protein, fat and carbohydrate expressed in g per 100g of infant formula product prior to reconstitution in the case of powdered infant formula product or g per 100 mL prior to reconstitution in the case of liquid concentrated infant formula products.*

### Issues

**Nestlé Australia Ltd, Wyeth Australia Pty Ltd and Bristol–Myers Squibb Australia Pty Ltd** state that it is not necessary to include the average amount of product on a per 100g basis. The relevant information is as per the made up product. They state that a product that is to be reconstituted with water should only be labeled as the reconstituted amount not as the dehydrated or concentrated amount. All products have different densities and require different amounts of powder to be reconstituted so it does not allow consumers to compare products

**Nestlé Australia Ltd** also state that Clause 21(2)(b)(ii) needs to state ‘the average amount of’ rather than ‘the amount of’ for consistency.

#### Assessment

It was recommended at Preliminary Inquiry that the NIP include nutrients and nutritive substances as purchased as well as per 100 mL ready to consume formula.

Codex required declaration of the nutrients in infant formula products per serve when reconstituted and per 100 g as sold. Therefore the requirement proposed at Preliminary Inquiry is consistent with Codex.

It is noted that the 'per 100g' declaration may not be useful for consumers to compare products as every product has a different density. However, specialist health professionals often use the 'per 100g' readings to calculate any necessary concentrations or dilutions of infant formula that they may require for particular medical or dietetic reasons.

#### Recommendation at Inquiry

The 'per 100g' declaration is consistent with Codex and may be useful to health professionals, therefore, the requirement proposed above should be retained.

#### Industry issue at Inquiry

That the requirement for an NIP for nutrients expressed as per 100g as sold is deleted as industry argued that it crowds the label, leads to confusion in the general public and is only necessary for health professional use.

#### Assessment

As stated, this provision was included to provide consistency with the Codex standard (and proposed Codex standard) which requires the declaration of both types of information. Health professionals had also advised that information about nutrients per product as sold was necessary for some purposes. However, the External Advisory Group members considered that provided information about the weight of the product per scoop and the percentage solution on a weight/volume basis for the product was provided on the label, health professionals would be able to calculate nutrients per 100 g product as sold from the information provided on an ‘as consumed’ basis. Therefore it is agreed that the requirement for a NIP to express nutrients per 100g of product (as sold) be deleted.

#### Recommendation at Supplementary Final Assessment

Drafting be amended to only require nutrient declaration per 100 mL as consumed and to require the declaration of the weight of product per scoop (if included) and the percentage solution on a weight/volume basis for the product.

## 4.6 Clause 22 Date marking and storage instructions

### Proposed at Preliminary Inquiry

The label on an infant formula product must include a statement of the best before date and must contain storage instructions covering the period after it is opened.

### Issues

**Nestlé Australia Ltd, Wyeth Australia Pty Ltd, InforMed Systems Ltd and Bristol-Myers Squibb Australia Pty Ltd** state that a use by date must be permitted as well as a best before date otherwise they will not be permitted to sell a product with a use by date. A use by date would prohibit the sale of goods after that date.

### Assessment

At Preliminary Inquiry it was decided that a ‘best before’ date is suitable for infant formula as it is safe for an infant to consume the formula after this date. There may be some degradation of nutrients, but the formula will not harm the infant. Codex recommends a best before date.

In general, a ‘use by’ date will only be used in the future where a food is unsafe to consume after the use by date has expired. Such food will not be permitted for sale.

However, manufacturers believe a ‘use by’ date which prohibits sale after the date may be necessary in some circumstances to provide for losses in nutrient stability particularly, vitamin stability. Therefore to accommodate the concerns of industry the label of an infant formula product should include a statement of the ‘best before’ date or a ‘use by’ date. This requirement is consistent with the generic provisions for the date marking of foods (Standard 1.2.5) and hence special provision is not in the standard for infant formula products.

It is proposed that the label of an infant formula product must provide advice about storage of the product after it is opened. It was intended that this provision would also cover advice about correct handling of the remaining product to ensure it is safe for the infant when used. The drafting may not reflect this intent; therefore it is recommended that the drafting be amended to expressly require advice about correct handling of the remaining unused food in the container.

### Recommendations

1. The label of an infant formula product should include a statement of the ‘best before’ date or a ‘use by’ date. The date marking requirements proposed at Preliminary Inquiry should be deleted from the standard for infant formula products as the generic provisions for the date marking of foods provide the appropriate cover.
2. The label should also expressly provide information about safe handling of the remaining infant formula product to ensure it is safe and healthy for infants when used.

## 4.7 Clause 23 Statement on source of protein

### Proposed at Preliminary Inquiry

The label on an infant formula product must contain a statement of the source of protein in an infant formula product immediately adjacent to the name of the infant formula product.

### Issues

**Bristol–Myers Squibb Australia Pty Ltd** and **Nestlé Australia Ltd** state that the requirement to declare the source of protein appears to be overly prescriptive, particularly when manufacturers include the ingredients in the ingredient list. Where cow's milk is used as the protein source the ingredient statement will claim this as a milk ingredient. Where a different protein source other than cow's milk is used manufacturers would declare this in the name of the food anyway. The proposal for the naming of foods requires manufacturers to name their products so consumers are not misled. The information provided by manufacturers on labels must not be false, misleading or deceptive.

**Wyeth Australia Pty Ltd** state that this requirement should only apply to products that do not have cow's milk as a source, as other cow's milk products do not need to state that the source is from a cow.

**Maureen Minchin (IBCLC)** agrees there should be a statement of protein source.

### Assessment

The declaration of the protein source of infant formula is necessary for consumer information. It is true that a product must not be represented in a manner that is false, misleading or deceptive and that the protein source would be declared in the ingredient list. It is also apparent that if manufacturers used a product other than cow's milk they would advertise the fact.

However, specific declaration of the protein source adjacent to the name of the product is considered to be necessary to ensure that consumers are aware of the protein source of the food at the time of purchase. The protein source will be noticeable and not hidden in the label. Codex requires the protein source of the formula to be in the label in close proximity to the name of the food. Such a requirement is difficult to regulate because 'close proximity to the name' is subjective. The proposed requirement is consistent with Codex recommendations and provides an easily enforceable requirement.

### Recommendation

Retain the requirement to declare the protein source of the formula in the label immediately adjacent to the name of the food.

### Further Issue at Inquiry

Infant formula products are required to include a statement of protein source on the label. It is intended that this information should be specific rather than general.

This specificity is not clear from the current drafting and there is a need to clarify the intent. Manufactures are uncertain how to comply with this provision where more than one source of protein is used.

#### Assessment

It is important carers are aware of the specific protein used in an infant formula product. Therefore the drafting should be amended to clarify that the declaration of source or sources of protein be specific rather than as class names.

#### Recommendation at Supplementary Final Assessment

That the drafting be amended to clarify that the declaration of source or sources of protein be specific rather than as class names.

### **4.8 Clause 24 Statement on dental fluorosis**

#### Proposed at Preliminary Inquiry

*(1) An infant formula product that:*

- (a) contains more than 17 mcg of fluoride per 100 kJ prior to reconstitution, in the case of powdered or concentrated infant formula product; or*
- (b) contains more than 0.15 mg of fluoride per 100 mL, in the case of ready to drink formula;*

*must contain the statements:*

- (a) indicating that consumption of formula has the potential to cause dental fluorosis; and*
- (b) recommending that the risks of dental fluorosis should be discussed with a medical practitioner or other health professional.*

#### Issues

**Nestlé Australia Ltd, InforMed Systems Ltd and Wyeth Australia Pty Ltd** do not agree with the need to include advisory statement on products regarding fluoride and dental fluorosis. They state that:

- there is no international equivalent legislation, it would constitute a technical barrier to trade; and
- there is no firm scientific evidence to suggest fluorosis occurs strictly from high fluoride levels in reconstituted infant formula products.

**The National Council of Women of New Zealand (NCWNZ)** state that a required maximum fluoride level should be determined if a warning statement is required on the label.



## Assessment

At Preliminary Inquiry ANZFA stated that the toxicology assessment concludes that the issue of fluoride in infant formula products is adequately covered by the current water quality guidelines. Therefore, it is proposed not to specify a maximum level for fluoride in infant formula products.

Whilst ANZFA does not dispute that at high fluoride levels dental fluorosis may occur, from the available information manufacturers of infant formula products are already taking steps to reduce fluoride content in formula. This combined with the existing water quality guidelines and proposed advisory statements (below) is sufficient to maintain protection of public health and safety.

However, due to the possibility of dental fluorosis from the use of some formula, ANZFA proposed that products with high fluoride contents should have an advisory statement on the label to advise carers of this potential risk. This statement was proposed for infant formula product powders containing fluoride levels  $>0.5$  mg/L when reconstituted with fluorine free water (formulas with approx. 17 microgram fluoride /100 kJ) and ready-to-drink formulas containing fluoride  $> 1.5$  mg/litre. These levels were also proposed to accommodate the higher levels in soy-based products (cited in published literature and surveys) arising from current manufacturing processes yet still retain protection of public health and safety.

Some water in Australia and New Zealand contains fluoride and some does not, therefore, regulation of a maximum level of fluoride in infant formula is difficult. At the levels given above the formula may not cause fluorosis if prepared with water that has been distilled. However, if used with fluoridated water it may cause fluorosis. It is impossible to regulate the water used by carers of infants when they prepare the infant formula products.

A warning statement on the label of infant formula products that contain the above levels of fluoride should warn consumers that the formula might cause fluorosis. Such a warning statement may reduce sales of infant formula products that contain fluoride and may encourage manufacturers to decrease the level of fluoride in such formula.

Doctors and health professionals may not be aware of the potential for dental fluorosis from formula consumption. Therefore it may be prudent to provide education on this issue.

## Recommendation.

That the labelling provision for fluoride be retained.

### **4.9 Clause 25 Labelling of lactose free and low lactose formula**

#### Proposed at Preliminary Inquiry

The words 'lactose free' must appear as part of the appropriate designation of lactose free formula. The words 'low lactose' must appear as a part of the appropriate designation of low lactose formula and the label on a package containing a lactose free formula or a low lactose formula must include the following statements:

- (a) the amount of lactose expressed in g per 100 mL; and
- (b) the amount of galactose expressed in g per 100 mL.

### Issues

**Wyeth Australia Pty Ltd** state that if a product is lactose free there is no benefit gained by including the amount of lactose expressed in g/100 mL. **Wyeth Australia Pty Ltd and Bristol–Myers Squibb Australia Pty Ltd** state that they do not routinely test for galactose and question the relevance of a statement of the amount of galactose present when the small proportion of infants who have galactosaemia are under strict medical supervision.

**The Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition** state that the provisions for labelling of low lactose and lactose free formula appear adequate for galactosaemia.

### Assessment

The declaration of lactose in g/100 mL in the label of lactose free formula is consistent with Standard 1.2.8 – Nutrition Information Requirements for declaration of lactose in lactose free foods. Gluten free foods are also required to have a declaration in the label of the gluten content of the food, even though the reading would be zero.

The intent is to educate consumers that a product with a ‘free’ declaration will not contain any of the nutrients that are declared to be free. In the past gluten free foods were permitted to contain some gluten; this was not considered acceptable, just as it is not acceptable for lactose free products to contain lactose.

At Preliminary Inquiry it was determined that lactose is the major dietary source of galactose. Information suggesting a reduction in lactose content may be misconstrued to imply a reduction in galactose content when this may not be true. Low lactose, reduced lactose and lactose free foods based upon milk, including infant formula products are therefore currently required to provide information about the galactose content of the food. This information enables carers of children or infants with galactosaemia to determine how much of the food, if any, is suitable for galactosaemics. It was recommended that this provision be included in the standard for infant formula.

The current provision requires all ‘lactose free’ or ‘low lactose’ formulas to carry this labelling regardless of whether or not a claim is made about lactose content. Therefore the provision has been amended to be triggered only if a claim is made about the lactose content of the formula. This amendment allows formula not specifically formulated for lactose mal-digesters but which are inherently lactose free e.g. soy-based formulas, not to be required to make a claim about lactose content.

### Recommendation

To be consistent with the requirements for lactose free and low lactose foods, the requirement for declaration of the lactose and galactose content of lactose free and low lactose infant formula, in g/100 mL, be retained and apply if a claim is made about the lactose content of the formula.

#### 4.10 Clause 26 – Prohibited representations

##### Proposed at Preliminary Inquiry

Clause 26 contains the following list of prohibited representations on the label of an infant formula product:

- (a) *a picture of an infant;*
- (b) *a picture that idealises the use of infant formula product;*
- (c) *the word ‘humanised’ or ‘maternalised’ or any words or words having the same or similar effect;*
- (d) *words claiming that the formula is suitable for all infants;*
- (e) *information relating to the nutritional content of human milk;*
- (f) *a reference to the presence of any nutrient or nutritive substance except for a reference to a nutrient or nutritive substance in:*
  - (i) *the name of a lactose free formula or low lactose formula*
  - (ii) *a statement of ingredients; or*
  - (iii) *a nutritional information statement;*
- (g) *Representation that the food is suitable for a particular condition, disease or disorder.*

##### Issues

**Wyeth Australia Pty Ltd** suggest that the prohibited representation in Clause 26 (a)(b) and (c) should be removed from the proposal because they are under the jurisdiction of the MAIF agreement as they are not health and safety issues.

They state that without a firm definition of what ‘a picture that idealises the use of infant formula product’ is this clause has little relevance to infant health and safety.

**Wyeth Australia Pty Ltd** and **Bristol–Myers Squibb Australia Pty Ltd** state that Clause 26(f), the prohibition on declaration of nutrients should be removed because it effectively removes information to the consumer about infant formula. They are unable to educate the consumer about the presence of new ingredients. They request that some sort of information be allowed with respect to new or novel ingredients such as nucleotides.

The **New Zealand Infant Formula Marketers’ Association (NZIFMA)** submitted that follow-on formula should be permitted to make a claim for added iron to discourage carers from using cows milk instead of an infant formula product for their infant.

##### Assessment

No new information has been presented by submitters that has not already considered at the Preliminary Inquiry stage. The only reason for manufacturers to want to include any of these representations or declarations of nutrients in the label of an infant formula product is as a marketing tool. ANZFA does not consider it appropriate to use such information to market infant formula products.

The prohibition of representations of infant formula products is consistent with the requirements of the WHO International Code of Marketing of Breast Milk Substitutes and with the requirements of the MAIF agreement. Inclusion of these provision in the Food Standards Code makes them mandatory requirements and enforceable by law.

#### “With added iron” claim

All infant formula products (infant formula and follow–on formula) have added iron and all are required to provide for the iron needs of infants to 12 months. Therefore such a claim is true for all infant products for the nutrient ‘iron’ and as well as for all other essential nutrients. The flexibility provided by the proposed standard would permit an infant formula product represented as suitable for infants from birth to have an iron level higher than a follow on formula product represented as suitable for infant from 6 months of age, if so formulated by a manufacturer. It is not consistent with the objectives of ANZFA or fair trade law in Australia or New Zealand to create provisions for a specified range of products when the same provisions apply to other products in the range.

ANZFA is currently reviewing the issue of labelling statements on reduced fat milk products (Proposal P240) to address public health and safety concerns on the use of such milks or milk alternatives in the diet of children under two years of age. The unsuitability of cow’s milk as the sole dietary liquid source for infants is also under consideration. It is considered that a direct message on the specific product of concern is more useful for carers than is a declaration of a nutritional modification on an infant formula product. Carers may not link the statement about ‘added iron’ on an infant formula to the importance of not introducing other beverages as the principal liquid source of nourishment.

#### Recommendation at Inquiry

The proposed requirements for prohibitions on representations of infant formula and the declaration of nutrients be retained.

#### Industry Issue at Inquiry

Following Inquiry (Nov 1999), Industry again raised the issue of a claim of ‘added iron’ for follow–on formula.

ANZFA has several times requested evidence to show that the label statement ‘added iron’ on specific infant formula products such as follow–on formula will improve the iron intake of infants aged 6–12 months. Data to show this labelling will impact positively to reduce infant iron deficiency has not been provided.

Consumer representatives and health professionals at the Stakeholder forum also did not support this proposal by Industry. Therefore, an application supported by data to show such a label statement will reduce the incidence of iron deficiency anaemia is necessary to assess the claimed public health benefit.

#### Recommendation at Supplementary Final Assessment

No change to the provisions on ‘added iron’ claims.

## 5. DIVISION 5 – GENERAL MICROBIOLOGICAL REQUIREMENTS

The microbiological standards for infant formula products are regulated in Standard 1.6.1 – Microbiological Limits for Food. Issues raised in the submissions to P93 have been referred to the review of the micro standards. Therefore Division 5 – General Microbiological Requirements will be deleted from Standard 2.9.1.

### Industry issue at Inquiry

The Standard plate count (SPC) (Standard 1.6.1) has been made more restrictive to the current Standard R7.

### Assessment

It was necessary to correct an error in interpreting the current Code when transforming to ICMSF format for SPC and Coliform levels where the intention was to retain the existing limits. For *Bacillus cereus*, the current NZMRC levels were considered to provide an adequate level of protection. The following proposed amendments have been incorporated into Standard 1.6.1.

#### *Standard plate count/g*

n=5, c=2, m=1000, M=10,000

#### *Coliforms/g*

n=5, c=2, m=<3, M=10

#### *Bacillus cereus/g*

n=5, c=2, m=10, M=100.

## 6. PART 2 – INFANT FORMULA AND FOLLOW-ON FORMULA

### COMPOSITION

#### 6.1 Protein content

#### Proposed at Preliminary Inquiry

That the protein content of infant formula have a minimum level of 0.45 g /100 kJ and a maximum levels of 0.7 g/100g for infant formula and 1.3 g/100 kJ for follow-on formula.

#### Issue

**Nestlé Australia Ltd** submit that the minimum protein level proposed by Codex of 0.43 g /100 kJ be adopted rather than 0.45 g/100 kJ. There were no other submissions about this value.

#### Assessment

The proposed Codex standard ‘rounds’ the minimum protein content of formula expressed in metric values to 0.45 g/100 kJ as does the EC Directive. It is therefore recommended that this figure be retained.

## Recommendation

The drafting should remain as proposed at Preliminary Inquiry.

### **6.2 PRSL of Follow on Formula (and Special Purpose Formula Clause )**

#### Proposed at Preliminary Inquiry

*Clause (28) (2) – Follow-on formula must have a potential renal solute load value of not more than 8 mOsm/100 kJ.*

*Clause (39) (1b) —An infant formula product for specific dietary use based upon protein substitutes must have a potential renal solute load of not more than 8 mOsm per 100 kJ*

#### Issue

Submissions was received to the effect that this parameter is more prescriptive than some international regulations and some imported formula may not comply.

#### Assessment

It is now well accepted that health outcomes for infants have improved since the PRSL of alternatives to human milk have been reduced. Infant formula that unnecessarily increases risks to infants is not desirable, even if sold overseas. Infant formula products are formulated to supply the total diet of the infant.

The wider range proposed for nutrient contents would permit the sale of a formula with an unnecessarily high PRSL but which complies with the standard, if the PRSL was not prescribed. To protect the health and safety of formula fed infants in Australia and New Zealand, it is recommended that the PRSL be prescribed where formula with high levels of permitted nutrient levels could be given to infants. No new data was provided to justify alteration to the current proposed levels for follow on formula or infant formula product for specific dietary use based upon protein substitutes.

#### Recommendation

Retain the provision that follow-on formula or an infant formula product for special dietary use based upon protein substitutes must have a potential renal solute load value of not more than 8 mOsm/100 kJ.

### **6.3 Fat content**

#### **6.3.1 Units of expression for linoleic (LA) and alpha-linolenic (ALA) acids**

##### Proposed at Inquiry

	<b>Minimum % total fatty acids</b>	<b>Maximum % total fatty acids</b>
Linoleic Acid	9	26
Alpha- linolenic acid	1.75	4

### Industry issue at Inquiry

That the levels of linoleic and alpha–linolenic acid be expressed as absolute values per 100 kJ of energy and not in terms of proportion of total fatty acids.

### Assessment

It was noted that most relevant scientific reports about the requirements of infants refer to the fatty acid levels as a percentage of total fats rather than absolute values or per 100 kJ. For example, the International Society for the Study of Fatty Acids and Lipids (ISSFAL)<sup>14</sup> in 1999 made a recommendation for the adequate intake of fatty acids for infants from formula (this has not yet passed the ISSFAL procedure to be a considered a 'policy statement from ISSFAL'). ISSFAL also recommended a level for each fatty acid, expressed as a percentage of total fatty acids.

The complexity of essential fatty acid metabolism and its potential intermediary metabolites plus the link to eicosanoid systems suggest that a system of expression where fats are interrelated seems prudent.

Additionally, the setting of a specific value per unit of energy is problematic where a range (1.05–1.5 g /100 kJ) is permitted for the fat content of formula and the problem is confounded by the influence of protein and carbohydrate levels.

### Recommendation at Supplementary Final Assessment

That the provision on the method of expression in the standard is retained as proposed.

## **6.3.2 Alpha Linoleic Acid (ALA)**

### Current provisions and proposed provisions

	<b>Infant formula</b>	<b>Follow–on formula</b>
current R7	not specified	as per infant formula
proposed at Full Assessment	2 – 4% total fatty acids	as per infant formula
Codex	not specified	not specified
proposed Codex standard	>or = 12 mg/100 kJ	Not applicable
LSRO Recommendations	1.75 – 4.0 % total fatty acids	as per infant formula
Proposed at Preliminary Inquiry	1.75 – 4.0 % total fatty acids	as per infant formula
Recommendation at Inquiry	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry
RECOMMENDATION AT SUPPLEMENTARY FINAL ASSESSMENT	1.1 – 4.0 % total fatty acids	As per infant formula

<sup>14</sup>Report from a workshop on Essentiality of and recommended Dietary intakes for Omega – 6 and Omega–3 Fatty Acids, (1999) ISSFAL <<http://www.issfal.org.uk.adequateintakes.htm>>

## Issues

The **International Formula Council** endorses the decision to reduce the proposed minimum ALA content to 1.75% of total fatty acids. However **Nestlé Australia Ltd** submits that the EC Directive and proposed draft Codex standard specify the minimum ALA at 12 mg/100 kJ which is approximately 1% of the total fatty acids. Therefore **Nestlé Australia Ltd** states consideration needs to be given to harmonising with these standards to ensure that the obligations under WTO are met.

## Assessment

The LSRO have noted that several studies have suggested that formula that provides ALA at less than the 1.75% of total fatty acids may be associated with delayed visual development and other adverse effect in infants. Therefore, should the Codex standard ALA content be reduced to 1% of total fatty acids, the safety of such formulations would need rigorous assessment before a similar permission could be agreed for Australia or New Zealand. There is no justification to reduce the ALA permissions proposed at Preliminary Inquiry.

## Recommendation at Inquiry

Retain the ALA permissions proposed at Preliminary Inquiry.

## Industry issue at Inquiry

The minimum alpha linolenic acid be 1.1% of total fatty acids or 12 mg/100 kJ.

## Assessment

Industry representatives claimed that the literature research by Makrides et al. undertaken on behalf of industry showed a minimum alpha linolenic level of 1.1% total fat is safe citing a trial by Lucas et al <sup>15</sup>. This recent, large (n = 447) randomised control trial by Lucas and others, compared development, growth, and safety outcomes at baseline, 6, 9 and 18 months of age between randomised formula-fed groups with and without LCPUFAs (ALA 1.1% total fatty acids without LCPUFA; and ALA 1.4% with LCPUFA), and found no statistical differences in overall cognitive and motor developmental scores, growth or safety outcomes of infection rates, atopy and gastrointestinal tolerance between the formula-fed groups. When compared with breast fed infants, the same outcomes were observed except that the breast fed group at 18 months had larger head circumferences than both formula-fed groups.

The EC Directive for infant formula has set a minimum of 50 mg ALA/100 kcal (=1.1% ALA at minimum fat 1.05 g/100 kJ), which corresponds to the amount in the control formula in the Lucas study. Breast milk content of ALA is influenced by dietary intake and is reported to range between 0.5– 1.0% although breast milk also contains LCPUFA.

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<sup>15</sup> Lucas A et al (1999) Efficacy and safety of long chain polyunsaturated fatty acids supplementation of infant formula milk: a randomised trial. The Lancet 345: 1948.



A workshop convened by the ISSFAL recommended intakes for omega–3 and omega–6 fatty acids in 1999 recommended an alpha–linolenic acid content of 1.5% of fatty acids as an adequate intake for infant formula /diet<sup>16</sup>.

Due to the lack of clear guidelines internationally on the most appropriate level of ALA, ANZFA believes that there is sufficient evidence from the Lucas study and Makrides review to warrant a reconsideration of the issue.

#### Recommendation at Supplementary Final Assessment

That the minimum level of alpha–linolenic acid be reduced from 1.75% to 1.1% of total fatty acids.

### **6.3.3 Trans fatty acid content**

#### Proposed at Preliminary Inquiry

It was proposed at Preliminary Inquiry that the fats in infant formula and follow–on formula must not contain more than 4% total trans fatty acids as a percentage of total fatty acids.

#### Issues

Two submissions were received from industry groups pertaining to this issue. One submitter suggested that the maximum level of trans fatty acids be increased to 8% of total fatty acids. The other submitter suggested that the level of a maximum of 4% trans fatty acids would require modification of some oil blends currently in use, therefore a maximum level of 8% total fatty acids be allowed for an intervening period of 2 years. This would allow any required modifications to oil blend compositions to be introduced with sufficient time to enable clinical trials and evaluations of stability to be completed.

#### Assessment

The current EC Directive allows a maximum level of 4% trans fatty acids as a percentage of total fatty acids. Therefore this level is achievable by industry and harmonises with a major international standard. There was no new evidence provided in the submissions to justify higher levels of trans fatty acids in infant formula.

#### Recommendation

The level of 4% proposed at Preliminary Inquiry be retained in the standard.

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<sup>16</sup> Workshop on the essentiality of and Recommended Dietary Intakes from omega–6 and Omega –3 fatty acids. [http://www.issfal.org.uk/adequate\\_intakes.htm](http://www.issfal.org.uk/adequate_intakes.htm)

## 6.3.4 Long chain polyunsaturated fatty acids (LCPUFA)

### 6.3.4.1 The regulation of LCPUFA

#### Proposed at Preliminary Inquiry

At Preliminary Inquiry, it was noted that there was no consensus about the public health benefit of the addition of LCPUFA to infant formula and that there are safety concerns about the potential sources of LCPUFA and inappropriate levels of these fatty acids. The following three options were proposed for the addition of LCPUFA to formula.

#### *Option 1: Do not provide express permission*

The efficacy of the addition of these LCPUFA is not proven and there are safety concerns about the effects of imbalance of the different LCPUFA but insufficient data to determine suitable levels for a regulation. Removal of express permission would leave the LCPUFA content regulated by the general permissions for the addition of other foods, the safety assessment of novel foods or ingredients from novel foods and the due care of manufacturers.

#### *Option 2: Align permissions with those of the EC and UK*

There is emerging evidence that some LCPUFA may be beneficial for visual and neurodevelopment in infants. However, there is also evidence to suggest that different LCPUFAs of the 3- and 6-series may interfere with each other's metabolisms to varying extents. Therefore it is proposed as at Full Assessment to give a broad permission for a LCPUFA content similar to that found in human milk, sourced from food ingredients (subject to the novel food standard requirements) rather than individual fatty acids and control the maximum levels as per the EC and UK since these are currently in force.

#### *Option 3: Align permissions with those of the EC and UK but require a series 6 to series 3 ratio of 2 as in human milk.*

As proposed at Option 2 but the ratio of series 6 to series 3 LCPUFA should be regulated at the level reported to be in human milk i.e. 2.

ANZFA's preferred option was Option 3 as this was consistent with known international regulations but afforded an extra safety measure of aligning the series 6 to series 3 LCPUFA ratio to that in human milk.

Therefore the draft standard includes the following provisions:

<b>Long chain polyunsaturated fatty acids</b>	<b>% Maximum Total fatty acids</b>
Long chain omega 6 series fatty acids (C $\geq$ 20)	2
Arachidonic acid (20:4)	1
Long chain omega 3 series fatty acids (C $\geq$ 20)	1

If LCPUFA are added to the formula then:

- total long chain omega 6 series fatty acids ( $C \geq 20$ ) to total long chain omega 3 series fatty acids ( $C \geq 20$ ) must be 2; and
- the eicosapentaenoic acid (20:5 n-3) content should not exceed the docosahexanoic acid (22:6 n-3) content.

### Issues

Comments were made on this issue in 11 submissions. Options 1 and 2 were supported by 2 submitters each, and Option 3 by 6 submitters. One submitter did not indicate which option they supported but questioned the safety of the addition of LCPUFA since there would be addition of un-purified constituents. A number of submissions expressed an interest in why ANZFA was proposing to include a ratio of omega 6 to omega 3 fatty acids.

### Assessment

This issue was addressed at Preliminary Inquiry. There is evidence to suggest that the series-6 and series-3 LCPUFA can interfere with each other's metabolism to varying extents, therefore regulating this ratio to the level found in human milk affords an extra measure of safety. Additionally, LCPUFA substrates are expensive. ANZFA had anecdotal information that at least one overseas manufacturer was to release a formula which has only one of the series of LCPUFA added due to cost concerns. This formulation would comply with the provisions at Option 2. The regulation to maintain the LCPUFA ratio to that of human milk series would not permit this formulation, which has the potential to be harmful to infants. Therefore it is recommended that if these fats are added to infant formula then their addition should be at levels as close to those known to be in human milk. Forsyth (1998)<sup>17</sup> reports that the series 6 to series 3 LCPUFA ratio in breast milk remains relatively constant at 2. There was significant support for this additional safety measure.

Submissions were made that the ratio in human milk is not always exactly 2 and making the ratio exactly 2 is extremely prescriptive. It was the intent at Preliminary Inquiry, that the series 6 to series 3 LCPUFA ratio in formula should be approximately 2 or as close to 2 as possible. Therefore it is recommended that the draft standard be amended to reflect this intent.

### *Safety of substrates*

The safety of substrates used to add LCPUFA to infant formula will be required to be assessed if these are 'novel' ingredients for infants. ANZFA as part of Proposal P93 has recently conducted a safety assessment of certain algal and fungal sources of these fatty acids (refer to Supplementary Final Assessment Report – Attachment 2). Additionally ANZFA is aware of herbal oils being used overseas as substrates for the addition of LCPUFA to formula for infants. ANZFA would require a safety assessment of the use of such a substance before sale in Australia or New Zealand.

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<sup>17</sup> Forsyth JS (1998) Lipids in infant formulas Nutr Res Revs 11: 255–278.

### Recommendation at Inquiry

The provisions proposed at Preliminary Inquiry should be retained with an amendment to clause 30(d) to effect the intent that the ratio of the different series of LCPUFA be changed to “the fats in infant formula and follow-on formula must have a ratio of total long chain omega 6 series to total long chain omega 3 series fatty acids of **approximately 2**.”

### Industry issue at Inquiry

That the specification for the ratio of series 3 fatty acids to series 6 fatty acids be abandoned on the basis that it does not exist elsewhere.

### Assessment

There is a high degree of interrelationship between these sets of fatty acids as well as incomplete knowledge of metabolic pathways. Although the levels of some of these fatty acids may be lower in human milk, given the proposed levels harmonise with those of the EC Directive and the uncertainties around absorption rates and bioavailability of the source materials, the levels of LCPUFA prescribed in the proposed standard should be retained.

### Recommendation at Supplementary Final Assessment

That the provisions proposed at Inquiry be retained.

## **6.3.4.2 Levels of addition of the series-6 fatty acids**

### Proposed at Preliminary Inquiry

That series -6 LCPUFA and arachidonic acid be not more than 2% and 1% respectively of total fatty acids.

### Issue

**InforMed Systems Ltd** and **Wyeth Australia Pty Ltd** pointed out that under Options 2 and 3, only up to 1% arachidonic acid is allowed to be added but a total of 2% long chain omega 6 fatty acids. They felt this was nonsensical to only allow the addition of 1% arachidonic but 2% total omega 6 fatty acids.

### Assessment

Arachidonic acid is only one of several series-6 fatty acids. Therefore, there are other minor series-6 fatty acids that could also contribute to the total series-6 content of the formula. There is not sufficient scientific data to support any more detailed regulation for these fatty acids. What has been proposed in terms of levels of arachidonic acid and total series-6 fatty acids is consistent with the approach by the EC.

### Recommendation

The levels proposed at Preliminary Inquiry be retained.

### **6.3.4.3 LCPUFA in 'follow-on-formula'**

#### Issue

**Nestle Australia Ltd.** has submitted that LCPUFA should not be permitted to be added to 'follow-on formula' as they are not permitted by the EC Directive.

#### Assessment

There is no consensus about the public health benefit of the addition of LCPUFA to infant formula although there is greater evidence that such fatty acids may be more useful for infants born prematurely than for infants born at term or older infants. The permissions given for the addition of LCPUFA in the standard approximate the levels found in human milk as best as is possible with current scientific knowledge.

#### Recommendation

There is no case to prohibit the addition of these LCPUFA to 'follow-on formula'.

## **6.4 Vitamins and minerals**

### **6.4.1. Policy for the safety of vitamin and mineral contents of formula**

#### Proposed at Preliminary Inquiry

It was proposed at Preliminary Inquiry to prescribe mandatory maximum levels for vitamins and minerals classified as of 'significant risk' to infants when consumed at excess intakes. Advisory maximum levels were recommended for other nutrients whose risk classification was provisionally assessed as 'not of significance on the basis of current scientific knowledge'.

#### Issues

Although industry preferred neither prescribed levels nor recommended guideline levels for maximum nutrient content and consumers supported prescribed levels for maximum contents, there is reasonable support for the proposed approach. However, this support was provisional. In the case of industry submissions, support was indicated provided that these levels don't become 'pseudo-regulation' and in the case of the consumer representatives, support was indicated provided that there is effective monitoring of Good Manufacturing Practice (GMP) and levels of nutrients.

#### Assessment

Consumer representatives note that GMP guidelines were insufficient in the 1970s to protect infants from unsafe formula in the USA and the resultant harm to infants lead to the introduction of regulation for infant formula by the US government. Industry consider a 'guideline' may become a pseudo-regulation' and one industry submission was not in favour of nutrient levels being recommended in the guidelines as this would imply that compliance be expected to be monitored.

ANZFA recommends maximum levels of nutrients in infant formula as whilst not all nutrients are toxic in excess, an excess of one nutrient can sometimes interact adversely with other nutrients.

Manufacturers are believed and expected by carers or consumers to be aware of the levels of nutrients in formula. Whilst maximum levels were not stipulated for some specific nutrients, ANZFA has recommended a guideline level. This guideline level was stipulated to assist industry improve formulations to those considered safer by health professionals. It is generally accepted that the current health outcome of formula fed infants is not as good as those who are fed human milk; the causation being multifactorial. ANZFA has not been provided with data about the maximum levels of nutrients in infant formula sold in Australia or New Zealand. Therefore ANZFA is not able to exclude the current levels as implicated in the less positive outcome for formula fed infants. Until such time as current levels are specifically excluded from implication in reducing health outcome to consumers, ANZFA expects infant formula manufacturers to monitor formula nutrient levels regularly and work towards achieving the recommended level for their formula.

Consumers note that the EC Directive for foods for special medical purposes, which prescribes maximum levels for all nutrients, has recently been adopted. Industry contributed to the development of this Directive, which suggests that it is well within the capacity of industry to meet prescribed maximum levels.

#### Recommendation

ANZFA will maintain the current guideline levels unless evidence is provided that it is in the interest of infants to amend these levels.

### **6.4.2 Specific levels in the Table to Clause 31**

Only those levels where a specific request for amendment has been received are discussed below. There were submissions of support for many nutrient levels.

#### **6.4.2.1 Selenium**

##### Current and proposed provisions

	<b>Infant formula mcg/100 kJ</b>	<b>Follow-on formula mcg/100 kJ</b>
current R7	not specified	as per infant formula
proposed at Full Assessment	0.42–0.89	0.79–0.89
Codex	not specified	not specified
proposed Codex standard	not specified – 0.7	Not applicable
LSRO Recommendations	0.36–1.19	as per infant formula
Proposed at Preliminary Inquiry	0.36– 0.9	as per infant formula
RECOMMENDATION AT INQUIRY	0.25–1.19	as per infant formula

## Issues

No new data was supplied about the safety of the levels of selenium.

**Abbott Australasia Pty Ltd, Abbott Laboratories (NZ) Ltd and the International Formula Council** submitted for the maximum level to be increased to 1.1–1.19 mcg/100 kJ as per the LSRO recommendation for a maximum level. **Dr Simmer, Neonatologist and Associate Professor** submitted that lower levels of selenium may meet the needs of infants.

## Assessment

### *Minimum level*

The minimum level set at Preliminary Inquiry was assessed against the recommended dietary intake (RDI) and would meet the needs of most infants. Given the variation in individual requirements and daily consumption levels, a lower level may also meet the needs of most infants. The EC has recently adopted a standard which includes a minimum selenium level of 0.25 mcg/100 kJ for foods for special medical purposes prepared for infants. Adoption of this minimum level would provide 60–70% of the RDI for infant to 6 months and the needs of older infants. The RDI is a population based recommendation rather than an indicator of the need for a particular individual. The minimum level of 0.25 mcg selenium /100 kJ is consistent with a safe formulation for infants. Hence it is recommended that the minimum level be reduced to 0.25 mcg/100 kJ which is consistent with the recent EC foods for special medical purposes standard level.

### *Maximum level*

The LSRO has recommended a maximum of 1.19 mcg selenium/100 kJ based on the upper limits of selenium in breast milk. Manufacturers have requested the maximum level be raised to that recommended by the LSRO. This upper level would provide 2–3 times the RDI for an infant from formula. Additional selenium would also be contributed from other foods consumed by older infants but the contribution from formula intakes would therefore be reduced in this case. There is no evidence that this level would pose a risk to infants and therefore it is recommended that the limit recommended by the LSRO be adopted.

## Recommendation

The selenium values in the Table to Clause 31 of the draft standard be amended to 0.25–1.19 mcg/100 kJ.

### **6.4.2.2 Copper**

#### Current provisions and proposed provisions

	<b>Infant formula mcg/100 kJ</b>	<b>Follow-on formula mcg/100 kJ</b>
current R7	14– not specified	as per infant formula
proposed at Full Assessment	14–36 (non soy based formula) 21–43 ( soy based formula)	as per infant formula
Codex	14– not specified	not specified
proposed Codex standard	4.8–19	Not applicable

	<b>Infant formula mcg/100 kJ</b>	<b>Follow-on formula mcg/100 kJ</b>
LSRO Recommendations	14.3–38.1	as per infant formula
Proposed at Preliminary Inquiry	14–43	as per infant formula
RECOMMENDATION AT INQUIRY	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry

### Issue

**Nestlé Australia Ltd** argues that as the EC permits a minimum copper content of 4.8 mcg per 100 kJ, some formulas manufactured to EC formulations will not comply with the proposed standard. The implication is that the minimum level should be reduced to meet the EC level.

### Assessment

The copper content of human milk ranges from 7–25 mcg/100 kJ. A formula made to the minimum level of copper would not provide the necessary copper to meet the estimated safe and adequate daily dietary intakes (ESADDI) set for infants. The minimum level recommended at Preliminary Inquiry is consistent with the LSRO recommendation and also the recommendation from the American Academy of Paediatrics in 1985. The recommended level in the standard may constitute a technical barrier to trade but a formula made to the minimum copper level in the EC standard would not meet minimum nutritional requirements for copper and therefore would be considered a risk to infants.

Although the level in pre-term formula are not under discussion in this section, pre-term babies have a greater need for copper than term babies. It should be noted that the Canadian minimum recommended level for pre-term formula is 23.8 mcg/100 kJ, i.e. well above the EC prescribed minimum level.

### Recommendation

No change to proposed minimum copper level.

#### **6.4.2.3 Zinc to copper ratio**

##### Current and proposed levels

	<b>Infant formula &amp; Follow-on Formula Max Zn:Cu Ratio (mcg/100 kJ)</b>
Current R7	*NS
Proposed at Full Assessment	10:1
Codex	*NS
Proposed Codex standard	*NS
LSRO Recommendations	20:1
Proposed at Preliminary Inquiry	12:1
Recommendation at Inquiry	As proposed at Preliminary Inquiry
RECOMMENDATION AT SUPPLEMENTARY FINAL ASSESSMENT	15:1 (Infant formula) 20:1 (Follow-on formula)

\*NS – Not Specified



## Issues

**International Formula Council** endorses the level of 12:1 recommended at Preliminary Inquiry. However, **Nestlé Australia Ltd** submits that the majority of **Nestlé Australia Ltd** products would not meet this maximum ratio. **Wyeth Australia Pty** also submits the need to considerable reformulation to meet the 12:1 ratio and support a ratio of 22:1. **Wyeth Australia Pty Ltd** also submitted that the Codex levels are 19–25:1

## Assessment

### *Clarification of Codex levels*

The current Codex standards for infant formula and follow-on-formula do not specify maximum levels for zinc or copper and therefore there is no Zn:Cu ratio specified. The proposed draft Codex standard for infant formula was returned to Step 3 of the 8-step process in September 1998, as consensus could not be reached. That proposed standard currently includes maximum limits for both zinc and copper and also a different set of limits for the zinc content of soy-based formula as shown in the following table.

<b>Proposed draft Codex Infant Formula Standard</b>	<b>Minimum amount per 100 kJ</b>	<b>Maximum amount per 100 kJ</b>
Zinc	0.12 mg	NS*
Zinc content in soy-based or soy & milk based formulas	0.18 mg	0.6 mg
Copper	4.8 mcg	19 mcg
Zn:Cu (ANZFA calculation)		
Milk-based formulas	6.3:1	High given the max Zn is NS
Soy-based formula and soy & milk –based formulas	9.4:1	125:1

\*NS – Not Specified

The Zn:Cu ratio in the draft proposed Codex standard ranges from 6 – high:1. Therefore harmonisation with the Codex or proposed Codex standards is not in the interest of infants as this could legitimize unsafe levels.

### *Ratio*

The threshold for adverse effects ascribed to copper deficiency caused by zinc excess needs to be defined. When the zinc: copper intake exceeds 10, retention of copper is decreased leading to copper deficiency and changes in copper dependent metabolism have been observed at ratios above 20:1 (Langley and Mangas, 1997)<sup>18</sup>. The Zn:Cu ratio of human milk is 10:1.

<sup>18</sup> Langley A and Mangas S (1997) Zinc. *National Environmental Health Forum Monographs*. Metal Series No. 2.

At a recent international meeting it was concluded that preparations intended to increase the zinc intake above that provided by the diet should not exceed the dietary reference values, and should contain sufficient copper to ensure a ratio of zinc and copper of approximately 7, as found in human milk (WHO, 1996)<sup>19</sup>. LSRO suggests on the basis of adult studies that the ratio should not exceed 20:1.

The basic premise for aligning mineral and vitamin level to those of human milk is that in general, formula-fed infants do not have the same positive health outcome as those fed on human milk. Whilst current scientific knowledge is not able to attribute the specific compositional parameters that may be involved in reducing the health outcome for infants, nutrient interactions may be one such cause. Manufacturers are advised to modify formulations where possible to bring nutrient levels as close to those of human milk as possible whilst accounting for the bioavailability of the specific nutrient forms.

#### Recommendation at Inquiry

Maintain the ratio of 12:1 proposed at Inquiry until further data on infants is available.

#### Industry issue at Inquiry

That the value be raised to 20:1, as studies have indicated that a ratio up to 25:1 is safe.

#### Assessment

The zinc to copper (Zn:Cu) ratio is a new concept in infant public health and is a separate issue from the minimum and maximum limits of zinc and copper. The Zn:Cu ratio of human milk is 10:1 but there are no studies in infants to indicate the appropriate or optimal Zn:Cu ratio for formula. However, effects on copper status have been noted at ratios of above 100:1. Given that infants have immature systems (absorption, metabolism, excretion), that infant formula is the sole source of nutrition, that infants are at a stage of development characterised by intense growth (which may make infants more vulnerable to factors such as copper deficiency) and that data on adverse effects is limited, a cautious approach was considered the best option in recommending the appropriate Zn:Cu ratios for formula.

Industry provided a literature search of papers on the zinc/copper interactions arising from 5 clinical trials from 1982 to 1994. All trials assessed healthy term infants and had an infant formula Zn:Cu ratio of 20:1 or greater. Given the inherent limitations of the design of the trials cited by the reviewer (Makrides *et al*<sup>20</sup>) the studies all reported no adverse effects of an altered Zn:Cu ratio.

Professor Bo Lonnerdal, Professor of Nutrition and Internal Medicine, Department of Nutrition, University of California provided a summary and opinion on the ratio. Professor Lonnerdal stated that animal studies show that zinc can interfere with copper absorption; however, in these studies high levels of zinc were used, often with low copper levels.

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<sup>19</sup> WHO (1996) *Environmental Health Criteria for Zinc*. International Program on Chemical Safety. In preparation.

<sup>20</sup> Makrides M et al (2000) Report to the Infant Formula Manufacturers association of Australia – “Review of amino acid profiles, zinc to copper ratios and essential fatty acid composition of infant formulas.

The ensuing Zn:Cu ratio was frequently unphysiological and beyond what can be assumed to be consumed by humans. He also noted there are few studies in human infants that have focused on Zn:Cu ratio. However, Lonnerdal and Hernell (1994)<sup>21</sup> have reported a study of healthy Swedish babies fed formula with a Zn:Cu ratio of 37:1 from 6 weeks to 6 months age that indicated no adverse effects or impairment of copper status.

Therefore in an attempt to achieve a ratio that is as close as possible to that of breast milk but which can be readily achieved by industry, a ratio of 15:1 was considered suitable for infant formula products intended for infants under 6 months.

As older babies are consuming an increasingly varied diet with infant formula contributing less of the total intake the maximum level could be increased to 20:1.

#### Recommendation at Supplementary Final Assessment

That the maximum Zn:Cu ratio in the draft standard be increased to 15:1 for infant formula intended for infants less than 6 months of age, and to 20:1 for follow-on formula based on no evidence of harm to infants in the data submitted by Industry.

#### **6.4.2.4 Chromium and Molybdenum**

##### Current provisions and proposed provisions

	<b>CHROMIUM</b>		<b>MOLYBDENUM</b>	
	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ	Infant formula mcg /100 kJ	Follow-on formula mcg /100 kJ
Current R7	NS	as per infant formula	NS	as per infant formula
Proposed at Full Assessment	NS (for prox Mod Formula 3.5 mcg to 15 mcg)	as per infant formula	NS (for prox Mod Formula 0.36 mcg to 0.71 mcg*)	as per infant formula
Codex	NS	NS	NS	NS
Proposed Codex standard	NS	NA	NA	NA
LSRO Recommendations	did not re-recommend Min or max levels	as per infant formula	did not re-recommend a Min or max	as per infant formula
Proposed at Preliminary Inquiry	[Advisory guideline max:15]  prox mod formulas: 0.35– 15.0	as per infant formula	[Advisory guideline max 3.0]  Prox mod formulas: 0.36 – 3.0	as per infant formula

<sup>21</sup> Lonnerdal B, Hernell O (1994) Iron, zinc, copper and selenium status of breast-fed infants and infants fed trace element fortified milk-based infant formula. Acta Paediatr, 83, 367–73.

Recommendation at Inquiry	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry
RECOMMENDATION AT SUPPLEMENTARY FINAL ASSESSMENT	As proposed at Inquiry	As proposed at Inquiry	As proposed at Inquiry	As proposed at Inquiry

NA – Not applicable;

NS – Not Specified

### Issues

**InforMed Systems Ltd** questioned why chromium and molybdenum must be added in this case (assumed to be in relation to Clause 41) but not for similar ordinary formula as these nutrients are essential for all infants.

### Assessment

This issue was addressed at Preliminary Inquiry. It was noted that as these nutrients are ubiquitous in nature a formula based on usual food ingredients does not need any added chromium or molybdenum. Provision was made in the draft standard for the addition of these nutrients to infant formula products based upon protein substitutes as in some cases these formula may be elemental i.e. not based upon food constituents. Therefore without the addition of these nutrients these formula would be devoid of chromium or molybdenum and unsuitable for infants.

### Recommendation at Inquiry

Retain the proposed standard.

### Industry issue at Inquiry

That the addition of chromium and molybdenum be permitted for all formula such as resulting in a requirement to the levels currently specified for special purpose formula.

### Assessment

No new data was provided by industry to show how this provision affects the affordability or availability of infant formula products. As stated previously, chromium and molybdenum are ubiquitous in nature. Formula based upon food ingredients will provide sufficient chromium and molybdenum for the requirements of infants. Therefore there is no need for the addition of these nutrients to formula made from food ingredients.

Stakeholders at a forum agreed permission could be given in the standard to add chromium and molybdenum to formula for healthy infants, provided this supplementation was reviewed long term. Additionally it was anticipated industry would supply data about base levels of chromium and molybdenum in base ingredients and any supplementation undertaken for monitoring of the intakes of infants for these two nutrients. The issue was later withdrawn by industry.

### Recommendation at Supplementary Final Assessment

The provisions for chromium and molybdenum be retained.

### 6.4.2.5 Pyridoxine (Vitamin B6)

#### Current provisions and proposed provisions

	<b>Infant formula mcg/100 kJ</b>	<b>Follow-on formula mcg/100 kJ</b>
current R7	9– not specified (> 15 mcg/g protein for form with 0.6 mg/100 kJ)	as per infant formula
proposed at Full Assessment	8.9–36	as per infant formula
Codex	9–not specified	11– not specified
proposed Codex standard	15– not specified mcg/g protein but not less than 9– not specified)	Not applicable
LSRO Recommendations	7.14–30.95	as per infant formula
Proposed at Preliminary Inquiry	9–36 mcg/100 kJ	as per infant formula
RECOMMENDATION AT INQUIRY	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry

#### Issue

**Nestlé Australia Ltd** has submitted that the inclusion of a maximum for vitamin B6 has the potential to provide a technical barrier to trade.

#### Assessment

At Preliminary Inquiry ANZFA stated that the retention of maximum level for vitamin B6 was unlikely to cause any trade restriction based on the LSRO conclusion. The maximum prescribed for the proposed standard is 36 mcg/100 kJ and the LSRO maximum level was based on 31 mcg pyridoxine /100 kJ which was the 90<sup>th</sup> percentile of analyses of infant formula.

Whilst ANZFA is not aware of any reports of pyridoxine toxicity in infants, there have been reports of toxicity in adults with excess pyridoxine intake. The EC has recently limited the maximum pyridoxine content of special purpose formula to 75 mcg/100 kJ.

The proposed maximum level is 4 times the RDI for infants (to 6 months). A review of the formula available in Australia whose pyridoxine content ANZFA was aware of, indicated they are well below the maximum level set. Justification for excessive content should be provided if manufacturers have a need to exceed this level to assist healthy infants attain their nutritional requirements.

#### Recommendation

Retain the proposed maximum level.

### 6.4.2.6 Riboflavin (Vitamin B<sub>2</sub>)

#### Current provisions and proposed provisions

	<b>Infant formula mcg/100 kJ</b>	<b>Follow-on formula mcg/100 kJ</b>
current R7	14– not specified	as per infant formula
proposed at Full Assessment	14 – 86	as per infant formula
Codex	14– not specified	14– not specified
proposed Codex standard	14– not specified	Not applicable
LSRO Recommendations	19.0 – 71.4	as per infant formula
Proposed at Preliminary Inquiry	14 mcg/100 kJ – not specified  [Advisory guideline maximum of 86 mcg/100 kJ]	as per infant formula
<b>RECOMMENDATION AT INQUIRY</b>	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry

#### Issue

**The NZ Dairy Board** submits that the maximum level of riboflavin at 86 mcg is set too low. The Board states that some products can have naturally occurring levels of riboflavin as high as 86.5 mcg and recommends that level be increased to 87 mcg to accommodate the variability of the naturally occurring nutrient.

#### Assessment

The EC has prescribed a maximum level of 100 mcg/100 kJ for foods for special medical purposes. The maximum level is recommended as a guideline level rather than as a mandatory level. ANZFA's policy is to maintain guideline levels unless evidence is provided that it is in the interest of infants to vary a guideline level. This guideline level provides 5 times the RDI for infants. In accordance with ANZFA's policy, it is recommended the guideline level be maintained. Manufacturers are encouraged to moderate nutrient levels where possible.

#### Recommendation

Retain current guideline level.

### 6.4.2.7 Iron

#### Current provisions and proposed provisions

	<b>Infant formula mg/100 kJ</b>	<b>Follow-on formula mg/100 kJ</b>
current R7	0.1 – 0.48	as per infant formula
proposed at Full Assessment	0.2 – 0.5	as per infant formula
Codex	min 0.04 or 0.25 (added iron claim) max. NS	0.25 – 0.50
proposed Codex standard	0.12 – 0.36	N/A
Proposed at Preliminary Inquiry	0.2 – 0.5	as per infant formula

	<b>Infant formula mg/100 kJ</b>	<b>Follow-on formula mg/100 kJ</b>
Recommendation at Inquiry	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry
RECOMMENDATION AT SUPPLEMENTARY FINAL ASSESSMENT	As proposed at Inquiry	As proposed at Inquiry

NS – Not specified

### Industry issue at Inquiry

That the permitted level of iron be reviewed in light of the discrepancy with Codex values. Industry proposed a reduction in the minimum iron content from 0.2 mg/100 kJ to 0.12 mg/100 kJ.

### Assessment

#### *Levels in other relevant standards*

The rationale for the lower level proposed by industry is that this level is the minimum level in the EC Directive for infant formula. Codex currently sets a level of 0.04 mg/100 kJ for a low iron infant formula product, although the current draft revised Codex standard proposes a minimum level consistent with the level in the EC Directive.

#### *Infant iron deficiency*

The Australian and New Zealand governments consider the issue of infant iron deficiency a public health issue. For the prevention of iron deficiency the National Health and Medical Research Council (NHMRC)<sup>22</sup> recommends iron-fortified cereals as one of the first solid foods to be introduced to infants between 4 to 6 months of age. Therefore, Standard 2.9.2 – Foods for Infants mandates the iron fortification of cereals for infants.

In 1995, health authorities on the Authority's Expert Panel recommended prescribed iron levels in the standard for infant formula products to provide an iron fortification to infants. Therefore, the iron level proposed in draft Standard 2.9.1, which is set for all formula regardless of base ingredients, provides a mild degree of iron fortification for infants. It is not considered necessary to set different nutrient levels for different base ingredient contents in the standard as manufacturers are expected to address issues of bio-availability of the base ingredients in their formula. The levels are set at higher than the level in human milk because the iron added to infant formula is of lower bio-availability. This proposal for iron fortification has been supported in submissions, including those from industry, to the development of this standard since 1995.

The proposal by industry to reduce the proposed minimum iron level was discussed by a range of stakeholders. Consumer representatives and health professionals favoured the degree of iron fortification required by the proposed levels because iron deficiency anaemia is a public health concern in Australia and New Zealand and noted the benefits of iron supplemented formula are well established.

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<sup>22</sup> NHMRC 1995 Dietary guidelines for children and adolescents

## Recommendation at Supplementary Final Assessment

It is recommended that the proposed draft standard for infant formula products retain the proposed minimum iron level of 0.2 mg iron/100 kJ to address concerns of iron deficiency in infants in Australia and New Zealand

### **6.4.2.8 Phosphorus**

#### Proposed at Inquiry

Phosphorus levels of 6–25 mg/100 kJ were prescribed and an advisory guideline maximum of 22 mg/100 kJ was also included in the standard to encourage industry to reduce phosphorus levels of infant formula products.

#### Industry issue

That the maximum phosphorus content of formula be increased to 40 mg/100 kJ. Industry stated that for follow-on formula, protein limits are increased to 0.45 to 1.3 g/100kJ. Typical cow's milk phosphorus levels are shown as 28 mg phosphorus/g protein in the Annex VII of the EC Directive for infants/follow on formulas. Therefore, as an example, if a follow-on formula contained the maximum 1.3 g protein/100 kJ, the average phosphorus level would be 36 mg phosphorus/100 kJ, which would exceed the maximum permission.

Support for a level of 37 mg phosphorus /100 kJ was later expressed by the industry representative from Wyeth.

#### Assessment

Significant interactions that affect bioavailability and utilisation of other nutrients have been reported for phosphorus. Phosphorus makes a significant contribution to renal solute load, as excess intake is required to be excreted by the kidneys. Therefore it is considered high intakes of phosphorus pose a significant risk for infants and the maximum level of phosphorus should be regulated in the standard. The maximum phosphorus level recommended by the LSRO Report<sup>23</sup> is 16.7 mg/100 kJ.

The levels proposed in the standard will provide for the needs of infants to 12 months of age and the maximum aligns with that in the EC, the UK regulations and those currently proposed for use in the revised Codex standard for infant formula (not follow up formula).

As previously noted in the discussion on the definition of follow-on formula, Australian and New Zealand usage of follow-on formula is different to the usage in Europe where it is not used as a 'formula' but rather a drink. Therefore the maximum level should be safe for infants who are fed this formula in the quantities that provide for the sole source of nutrition.

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<sup>23</sup> Raiten DJ et al (1998) Assessment of nutrient requirements for infant formulas. JON Supplement Vol 128 N 15 – Report prepared for the Centre for Food Safety and Applied Nutrition, Food and Drug Administration, Department of Health and Human Services, Washington DC



At Preliminary Inquiry, the maximum level proposed for phosphorus at Full Assessment was increased to 25 mg/100 kJ to provide for seasonal variation of ingredients. However to encourage industry to reduce the maximum phosphorus content of infant formula to 22 mg/100 kJ the level consistent with the Codex level, a guideline level of 22 mg/100 kJ was incorporated into the standard.

Members of the External Advisory Group noted that the phosphorus in milk is linked to the casein fraction and industry endeavours to limit the casein content, hence the high level of phosphorus, is not likely. Health professionals are also concerned about the high protein levels permitted by the standard and manufacturers are not expected to use the maximum levels in the standard other than for exceptional circumstances. The External Advisory Group agreed that the level proposed in the standard be retained.

#### Recommendation at Supplementary Final Assessment

That the levels in the proposed standard be retained.

### **6.4.3 Schedule 1–Permitted forms of vitamins & minerals**

#### Proposed at Preliminary Inquiry

Infant formula and follow-on formula must contain the vitamins and minerals specified in Clause 31 in the forms permitted in Schedule 1. The amount of vitamins and minerals in infant formula and follow-on formula must contain more than the minimum amount per 100 kJ specified in Clause 31 and no more than the maximum amount per 100 kJ specified in Clause 31.

#### **6.4.3.1 General**

##### Issue

Only manufacturers of infant formula products addressed this issue, claiming a list was unnecessary and may impede innovation. No new information was provided. Manufacturers called for permission to use any nutrient form permitted elsewhere.

##### Assessment

To protect the health and safety of infants, new forms of nutrients should be assessed before use in infant formula in Australia and New Zealand. **Nestlé Australia Ltd** has submitted that several specific forms of nutrients should be permitted because they were permitted in the EC or New Zealand Food Regulations (NZFR). Forms permitted by other agencies for many years may not necessarily still be considered safe in the light of more recent evidence. For example, nicotinic acid is permitted by a number of regulations, including the Codex standard. Recent evidence suggests this form may cause adverse effects in high amounts, whilst other forms of niacin do not.

## Recommendation

Codex has stated its intention to review its list of permitted forms of nutrients for addition to foods for infants. ANZFA will maintain a watching brief on the Codex developments. ANZFA has proposed a much broader range of permitted forms than currently permitted by Codex. However, there are some substances permitted to be used in infant formula by Codex which were not included at Preliminary Inquiry. The trade obligations of Australia and New Zealand impose a requirement to include all forms permitted by Codex if there is no health or safety concern. Therefore, with the exception of nicotinic acid (refer below for discussion), forms permitted by the Codex standard have been added to the list of permitted forms of nutrients for use in infant formula products.

### **6.4.3.2 Cupric carbonate**

#### Issue

**Nestlé Australia Ltd** has submitted that cupric carbonate should be permitted as it is permitted by Codex.

#### Assessment

Whilst Codex provides permission for cupric carbonate for use in baked products and protein hydrolysate and meat based formula no permission is provided for infant formula based upon cows milk.

#### Recommendation

That cupric carbonate not be added to the list of suitable permitted forms of nutrients for infant formula.

### **6.4.3.3 Nicotinic acid**

#### Issue

**Nestlé Australia Ltd** has submitted that nicotinic acid should be permitted as it is permitted by Codex, the NZFR and the EC.

#### Assessment

Nicotinic acid is permitted as a vitamin compound for use in infant formula by some international food regulations including Codex. However, the LSRO has reported adverse effects with large doses of nicotinic acid. The potential risks to the health and safety of infants from nicotinic acid should be assessed before use in infant formula. Therefore as alternatives are available, e.g. niacinamide, manufacturers wishing to use nicotinic acid should make an application for permission including the necessary scientific data to justify with the application.

### Recommendation

Nicotinic acid should be reassessed for safety before being permitted for use in infant formula.

#### **6.4.3.4 Selenium**

##### Proposed at Preliminary Inquiry

Codex does not give permission for the use of specific forms of selenium. At Preliminary Inquiry ANZFA requested data about the bioavailability of sodium selenate so as to consider its inclusion as a source of selenium in infant formula products.

##### Issues

**Dr L Daniels, Flinders Medical Centre** supplied data relating to selenium supplementation of infant formula to ANZFA. **Dr Daniels** provided information on reports which conclude that infant consumption of formula unsupplemented with selenium does not produce the same blood levels as in breastfed infants. **Dr Daniels** also notes whilst there is insufficient evidence to define the optimal form of selenium for supplementation, recent studies have concluded that ‘fortification of foods with either selenate or selenite would be equally efficient in providing ‘bioavailable selenium’.

##### Recommendation

Sodium selenate be added to Schedule 1 in Standard 2.9.1 – Permitted forms of vitamins and minerals in infant formula products.

#### **6.4.3.5 Choline and carnitine forms**

##### Issue

**Nestlé Australia Ltd** has also requested permission for choline (per se), choline citrate and the hydrochloride of L–carnitine claiming the EC permits the use of these forms.

##### Assessment

At Preliminary Inquiry it was stated that requests to extend the list of permitted forms would need to be accompanied by data suitable for safety assessment or an application should be made after the standard is gazetted. Data has not been provided to assess the safety of these forms of carnitine and choline.

##### Recommendation

These forms should not be added to the list of permitted forms of vitamins and minerals until such time as a full assessment has been made.

### **Summary recommendation for Section 6.4.3**

The following substances be added to Schedule 1 in Standard 2.9.1 – Permitted forms of vitamins and minerals in infant formula products:

- Retinyl propionate as a source of vitamin A;
- Cholecalciferol–cholesterol as a source of vitamin D;
- DL–alpha– tocopheryl succinate as a source of vitamin E;
- Phytylmenquinone as a source of vitamin K;
- Sodium chloride iodized as a source of sodium;
- Cupric citrate as a source of copper;
- Manganese carbonate and manganese citrate as sources of manganese; and
- Sodium Selenate as a source of selenium.

## **7. PART 3 – INFANT FORMULA PRODUCTS FOR SPECIAL DIETARY USE**

### **7.1 Division 1 – Pre–term formula**

Refer to definition of pre–term formula at Item 1.7.

#### **Proposed at Preliminary Inquiry**

Regulation of pre–term prescribes energy and nutrient content of formula.

#### **Issues**

Some submitters claimed the regulation of pre–term formula would result in unnecessary delay of new products. The proposed standard will mean that some product currently on the market will be illegal in Australia and New Zealand.

Concern was raised that there was no international regulation for pre term formula ANZFA requested data to assist with the safety assessment of the inclusion of Medium Chain Triglycerides in formula for pre–term infants.

#### **Assessment**

It has been claimed that the field of nutrition in pre–term or low birth weight (LBW) is rapidly changing and needs to respond to scientific advances. ANZFA has noted the highly variable compositions of the vitamin, mineral and medium chain triglyceride (MCT) contents of pre–term formula currently available and is concerned that the efficacy of these formula has not been reviewed independently from industry evaluations. Independent assessment of these formula is necessary for the health and safety of pre–term infants.

#### **Recommendation**

ANZFA prepare a proposal to review the provisions for safe formula for pre–term and low birth weight infants within 5 years of draft Standard 2.9.1 being adopted.

### **7.1.1 Fat content of Pre-term formula**

#### Issue

**Dr Robert Gibson, Director, Child Nutrition Research Centre and Maria Makrides, Research Dietitian and NHMRC fellow** submitted that the requirement for fats in formula for pre-term infants to comply with the fats in formula for term infants is not based on scientific evidence. **Dr Gibson** and **Ms Makrides** stated there is little known about the fat requirement for term infants. Therefore, it is incongruous to be basing the fat composition of formula for pre-term infants on the fats that are in breast milk of mothers who gave birth to term infants

#### Assessment

There are now concerns being raised that the type and levels of fatty acids added to pre-term formula by manufacturers are not ideal for pre-term babies, therefore there appears to be a need for some regulatory control. Whilst it is acknowledged that the usual nourishment for infants 'in utero' is not human milk but rather transfused nutrients via the placenta, there is insufficient data to base nutrient levels on transfused nutrient levels. Hence the current most appropriate model in this case would be the human milk nutrient contents with modifications for 'known' safe variations to nutrients. This is the model proposed at Full Assessment (and unchanged at Preliminary Inquiry).

#### Recommendation

ANZFA prepare a proposal to review the provisions for safe formula for pre-term and low birth weight infants within 5 years of draft Standard 2.9.1 being adopted.

### **7.1.2 Medium Chain Triglyceride (MCT) content of pre-term formula**

#### Issue

At Full Assessment it was proposed to prohibit MCTs in formula for healthy infants and pre-term infants. However, strong opposition was raised by industry in relation to banning MCTs in pre-term formula. Pre-term formulas with high levels of MCTs are already in use in Australia and New Zealand and this provision would disadvantage pre-term infants in these countries. Pre-term formula is such a small market in Australia and New Zealand that banning MCTs in formula in these countries may mean that companies withdraw their products from this market rather than reformulate them. At Preliminary Inquiry, ANZFA asked for assistance in resolving the requirements for the MCT content of pre-term formula. It was proposed that data at Inquiry would be used to determine a potential MCT content of formula prepares for pre-term infants.

#### Assessment

Data was provided at Preliminary Inquiry by industry submitters as to the current levels of MCTs in pre-term formula and levels of usage. Levels of MCTs in pre-term formula currently used in Australia and New Zealand vary from 15% to 40% of total fatty acids as MCTs.

The predominant formula used in New Zealand has levels of about 15% MCTs as a percentage of total fatty acids. The predominant formula used in Australia have 40% or less MCTs as a percentage of total fatty acids. Submitters were also asked to provide information that MCTs at currently used levels are safe and efficacious as recent reports have questioned the efficacy and safety of high MCT fat intake by premature infants.

Evidence was provided that MCTs may be more readily absorbed than other fats in pre-term babies. However, no new information was presented to ANZFA that high levels of MCTs are safe and efficacious in pre-term formula. ANZFA needs to evaluate the toxicological safety of MCT content of pre-term formulas but does not have sufficient resources to do this within the scope of this Inquiry into the draft Standard 2.9.1.

### Recommendation

ANZFA prepare a proposal to review the provisions for safe formula for pre-term and low birth weight infants within 5 years of draft Standard 2.9.1 being adopted.

### **7.1.3 Vitamin and mineral content of pre-term formula.**

#### Issue

The ranges of vitamins and minerals proposed at Full Assessment was not reviewed at Preliminary Inquiry due to insufficient resources.

#### Assessment

ANZFA's initial review of generally available data about the micronutrient levels of pre-term formula reveals highly variable nutrient contents from brand to brand. Pre-term formula manufactured by some manufacturers do not comply with the proposed standard and would have to be withdrawn from the market if the proposed standard proceeds. The highly variable micronutrient content of the available different brands of pre-term formula needs safety and efficacy evaluation.

Supplies are generally determined by tendering process in hospitals. Variable compositions in these formula may inadvertently create difficulties for medical specialists when hospital supplies change due to tendering outcomes.

There are also significant differences exist between the levels proposed at Full Assessment and those recommended by a Canadian expert panel<sup>24</sup>. ANZFA wishes to consult with technical experts in the feeding of premature infants for recommendations as to the most appropriate regulation for these micronutrients.

### Recommendation

ANZFA prepare a proposal to review the provisions for safe formulas for pre-term and low birth weight infants within 5 years of draft Standard 2.9.1 being adopted.

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<sup>24</sup> Guidelines for the composition and clinical testing of formulas for preterm infants (1995) Report of an ad hoc expert consultation to the Health Protectorate Branch, Health Canada, Canada.

#### **7.1.4 Use of pre-term formula**

There is a clear need for a degree of regulation in the compositions of pre-term formula as unsafe or less than ideal formulations are able to be marketed for use by pre-term infants without independent review. The trend overseas is for pre-term infants who are stabilised on a pre-term formula at discharge to continue the use of the same formula at home. It is noted that at least one major Australian manufacturer includes instructions to doctors on making up pre-term formula at home in the MIMS. Therefore the use of these infant formula may increase and may not necessarily be under hospital care.

An alternative to a food standard such as a 'pre-market clearance' program may be more appropriate for Australia and New Zealand. Such options need further consideration. Issues arise for the implementation of the Australian Quarantine Inspection Service duties where no food standard exists, particularly for so called 'foods for special medical purposes'. Therefore a provision is required within the Food Standards Code to assist in the assessment of imported foods categorised as 'pre-term formula'. Therefore it is recommended that proposed standard be replaced by a generic permission for pre-term formula within the standard and the detailed provisions be assessed in a separate project.

#### Conclusion

ANZFA intends to undertake an assessment of the compositional requirements for pre-term formula however, insufficient resources are available to do this assessment within this Inquiry into draft Standard 2.9.1. It is recommended that a new proposal be prepared to assess the safety and efficacy of formula prepared for pre-term babies and the current specific regulation be replaced by a temporary general provision.

#### **7.1.5 Clause 36 –Labelling statement on pre-term formula**

##### Proposed at Preliminary Inquiry

The label of pre-term formula must include the statement, '*Suitable only for pre-term infants under specialist medical supervision*'.

##### Issue

**Nestlé Australia Ltd** believe the statement on pre-term formula, that the product is suitable only for pre-term infants under specialist medical supervision, is not needed because these products are only available in hospitals for babies under specialist medical supervision.

##### Assessment

If pre-term formula is only permitted to be used in hospitals and are not available for general sale then the statement is superfluous. However, ANZFA is unaware of any restriction on their sale, therefore there is a potential that they may be sold in a retail outlet. As noted above advice is available to all doctors on how to prepare these formula at home. In such a case the statement is necessary.

## Recommendation

That the labelling requirement be retained as proposed at Preliminary Inquiry.

### **Summary recommendations for Section 7.1**

1. Clauses 32–35 be deleted from Standard 2.9.1 and replaced by a clause to the effect that infant formula product may be specifically formulated to satisfy the needs of pre-term or low birth weight infants but in all other respects must comply with the standard for infant formula products. This provision will provide temporary regulatory status for these foods and require manufacturers to be able to justify their variations from the general standard.
2. ANZFA prepare a proposal to review the provisions for safe formula for pre-term and low birth weight infants within 5 years of draft Standard 2.9.1 being adopted.

### **7.2 Division 2 – Infant formula products formulated for metabolic and immunological conditions**

#### Proposed at Preliminary Inquiry

Infant formula product may be specifically formulated to satisfy particular metabolic or immunological conditions but otherwise need to comply with the standard.

#### Issues

Issues were raised in relation to the scope of the standard, position of special purpose formula within the general standard for infant formula, suitable availability, and claims on thickened formula. These issues are addressed separately below.

#### **7.2.1 Scope**

**Patricia McVeagh, a consultant pediatrician**, states that the definition of special purpose formula refers to metabolic and immunological conditions but needs to be broader to include other infants requiring special purpose formula such as malabsorptive disorders including pancreatic deficiency, cholestasis, short bowel etc. She states that soy formula should be included in special purpose formula. Appropriate indication for their use would be galactosaemia, proven cow protein allergy or cow milk protein intolerance.

Two submissions did not believe that the draft regulation was broad enough to cater for special purpose formula for conditions such as gastrointestinal or renal diseases.

#### Assessment

ANZFA intended a wide interpretation of the descriptor 'metabolic' as it was considered that mal-absorptive disorders, other than disaccharide mal-digestion, e.g. lactose mal-digestion, are frequently merely a symptom of an underlying immunological or metabolic condition. However, it seems necessary to provide more specifically for renal, hepatic or mal-absorptive disorders.



Therefore it is recommended that this category be expanded to include renal, hepatic and mal-absorptive conditions. This will have the effect of capturing the formula specially prepared for lactose mal-digesters within this category.

Soy-based formula are used for both medical and non-medical purposes. Claims about nutrient content or about a special medical purpose for a soy-based product should trigger labelling consistent with that required of 'other' special purpose formula. This would allow a soy-based formula to be positioned as a standard infant formula product if no nutrient claims are made and if no special medical purpose is claimed; or alternatively to be positioned as a special purpose product if certain claims are made. Specifically, if a claim is made about lactose content then the same labelling provisions required for dairy-based lactose free or low lactose formula should apply. Equally a statement about 'suitability for infants with lactose intolerance' on a soy-based infant formula product should trigger the same labelling provisions as are required for dairy-based formula making the same claim.

### Recommendations

This clause be expanded to the effect that infant formula product may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or mal-absorptive conditions but otherwise need to comply with the standard.

The drafting should be amended to require the Division 2 composition and labelling provisions to apply where applicable for soy-based formula for which a special medical purpose claim or nutrient claim is made.

*Position of special purpose in the general standard.*

Submissions questioned the inclusion of special purpose formula in the general standard and recommended that they should be regulated either in a separate standard or as part of a 'foods for special medical purpose' standard.

### Assessment

At Preliminary Inquiry, it was noted that there is confusion about the regulatory status of these foods and provision in the standard even if on an interim basis would provide clearer regulatory status for these products. Presently these formula are largely confined to use under medical or dietetic care. However, with the trend for more pharmacy items to be available in supermarkets, more specific labelling is warranted such as that proposed in Clause 38.

### Recommendation

It is proposed to retain this provision within this standard with the additional labelling requirement. This does not preclude this category being reassessed within any proposal to review a 'foods for special medical purpose' standard category.

## **7.2.2 Availability**

One submission suggested that formula based on hydrolysed protein and nutritionally complete would be suitable for general use.

## Assessment

A designed formula based on non-food ingredients cannot be considered 'nutritionally complete' for infants whose organs are still undergoing maturation, as current nutritional requirements are not fully known. Intact proteins impact on the bioavailability of micronutrients and this factor will not be in action in these formula e.g. folate-binding proteins. Elemental formula is still experimental and should not be available for general use.

These formula have been tested in babies for a shorter time than soy based formula. There are no provisions for restricted sale of foods therefore reliance is placed upon the additional labelling to inform that this product is not for general use and should be used under medical supervision.

## Recommendation

This should remain as proposed at Preliminary Inquiry.

### **7.2.3 Claims on thickened formula**

#### Proposed at Preliminary Inquiry

ANZFA proposed not to provide specific permission for claims in relation to physiological conditions (e.g. gastric reflux) until evidence is presented to show that thickened formula are not detrimental to breastfeeding rates in Australia and New Zealand.

#### Issues

The **Gastric Reflux Association for Support of Parents/Babies of New Zealand** and some industry submissions supported having “anti-reflux” products on the market and did not believe that use of thickened formula is detrimental to breastfeeding. Industry commented that thickened formula is “marketed” to health professionals, not consumers e.g. the decision is based upon recommendation by a professional. **Bristol-Myers Squibb Australia Pty Ltd** stated that the fact that the Advisory Panel on the Marketing in Australia (APMAIF) finds the use of thickened formula problematic reflects a limited view. **Bristol-Myers Squibb Australia Pty Ltd** questioned whether this view has been presented in a scientific, peer-reviewed article. **Wyeth Australia Pty Ltd** commented that if claims about physiological conditions are not permitted on formula for gastric reflux then the use of thickeners should be banned.

The **Department of Nutrition and Dietetics at the James Fairfax Institute** commented that the proposal would not prevent the term “anti-reflux” from being used. **Maureen Minchin (IBCLC), the National Council of Women of New Zealand, the Department of Nutrition and Dietetics at the James Fairfax Institute** all commented that the availability of thickened formula should be restricted e.g. prescription only, only on medical advice.

## Assessment

No new scientific evidence was submitted to indicate that thickened formula are not detrimental to breastfeeding rates in Australia and New Zealand. ANZFA does not agree that APMAIF represents a limited view.

APMAIF comprises a diverse range of views and includes an independent chair, a community representative appointed by the relevant Minister, and a member nominated by the infant formula industry. The Panel undertakes rigorous debate and examination of issues before making decisions on interpretation of the WHO Code. The same concerns about the marketing of formula making claims of 'anti-reflux' have been raised in New Zealand.

ANZFA considers that not providing specific permission for claims in relation to physiological conditions has many advantages. The prohibition would help to ensure that carers do not unnecessarily switch their infants from breastfeeding to thickened formula to treat regurgitation. It is also likely that carers will only use these products when directed under medical advice, which will enable correct use.

ANZFA does not consider that manufacturers will be disadvantaged under the proposed standard as carbohydrate thickeners such as rice and cornstarch can continue to be used in thickened formula. Furthermore, these products can be described as “thickened” to ensure adequate identification by carers. Terms such as “anti-reflux” will not be permitted under the proposed standard. ANZFA does not consider that the availability of thickened formula should be restricted as the proposed prohibition aims to prevent its unwarranted use by carers.

#### Recommendation

As proposed at Preliminary Inquiry, ANZFA proposes not to provide permissions for claims relating to physiological conditions in infant formula (e.g. gastric reflux).

### **7.2.4 Composition and labelling of special purpose formula**

#### Proposed at Inquiry

That infant formula products may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions provided they comply with the requirements of the standard that are not inconsistent with the division. Specific labelling is required for these products to advise that the product is not suitable for general use and should be used under medical supervision; the condition, disease or disorder for which the food has been formulated and the nutritional modifications made to the product.

#### Industry issue at Inquiry

That formula for specific clinical purposes, including those for pre-term and low birth weight infants and infants with specific metabolic disorders be required to adhere with accepted international norms for those purposes.

#### Issues

Some special purpose infant formula for infants with highly specialised needs may not comply with the existing standard. These are made in very small quantities for nil or minimal profit by manufacturers. As these products are made offshore manufacturers have signalled that they will not be reformulating these for to meet Australian or New Zealand standards.

Many of these products are manufactured overseas and hence are imported into Australia and New Zealand. In Australia, AQIS monitor imported products against the prevailing standard and AQIS might need to place holding orders on these products to assess compliance and although unlikely, States and Territory health officials may need to request these products to be withdrawn from the market to the detriment of infants.

### Assessment

The proposed standard requires these formulations to comply with the base formulation for healthy infants whilst permitting modification of the specific nutrient or nutrients necessary for the specific condition or disorder. Health professionals have stated that it may be even more important for the base formula of the product to comply with the new standard, as these consumers are the more vulnerable infants.

Currently marketed products do not comply with the proposed base formulation and manufacturers have stated that given the small volume of this market they will not be modifying these formulations to comply with the standard, and are likely to withdraw supply of these formulations to sick babies. The supply of approved products for these infants needs to be guaranteed for obvious health and safety reasons.

Therefore, although it is proposed that special purpose products are expected to conform to the base standard for healthy infants except where necessary to meet the particular needs of the infant with the special condition, ANZFA is proposing to include a temporary exemption for the compositional requirements of the standard to permit the supply of these products. The exemption is recommended for a period of five years from the adoption of the standard. This period will allow ANZFA to develop a special standard for 'foods for special medical purposes' that could include these highly specialised infant formula products. This will ensure that the particular needs of these infants are protected.

### Labelling requirements.

It is also proposed to exempt these products from requiring the following statement;

*'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice;'*

as it is considered for most of these infants breast milk is not appropriate and the advice of a doctor is already being provided.

### Recommendation at Supplementary Final Assessment

The standard is amended to include an exemption for a period of five years on the compositional requirements for special purpose formula and that these products are exempted from requiring the statement as detailed above.

## 8. ISSUES NOT COVERED BY PROVISIONS IN THE DRAFT STANDARD

### 8.1 Soy Formula

#### Proposed at Preliminary Inquiry

There was no drafting in the Preliminary Inquiry regarding soy formula specifically. Submitters raised concern about the safety of soy formula.

#### *Phytoestrogen content*

The Preliminary Inquiry carried out an investigation into the safety of soy formula and concluded that “*while phytoestrogens at the levels found in soy-based infant formula have the potential to cause adverse effects, there is no evidence that exposure of healthy infants to soy-based infant formula over some 30 years of use has been associated with any demonstrated harm*”.

#### Issues

Consumer submitters provided strong opposition to soy-based formula being allowed on the market. Some consumers and public health groups provided support for an appropriate warning statement on it. Industry submitters supported keeping soy-based formula on the market and were opposed to a warning statement on these products.

#### Assessment

No new evidence has been presented since Preliminary Inquiry. It is noted however, that submissions provide even stronger support for an appropriate warning statement on soy-based formula. Nevertheless, ANZFA considers it more appropriate to support education initiatives that reduce the indiscriminate and inappropriate use of soy formula and which promulgate the public health policy that infants should be breast-fed where possible, and that where breast-feeding is not an option, modified cow's milk formula be recommended as the preferred feeding choice.

#### Recommendation

As no new evidence has been presented, it is recommended that the approach specified at Preliminary Inquiry remain.

#### *Levels of trypsin in soy formula.*

#### Issue

**Mr James** raised concerns about the levels of trypsin in soy formula. **The New Zealand Ministry of Health** pointed out that there are trypsin inhibitors in soy formula and these compounds cause mal-absorption of proteins. It was suggested that maximum levels of trypsin allowable or a denaturation process be considered.

## Assessment

An infant formula product is required to be suitable for infants, therefore a product which contains trypsin inhibitors at levels, which impacted adversely on the digestive process would not be considered suitable for infants

## Recommendation

No special provision is required.

## **8.2 Novel Food and novel ingredient use in infant formula**

### Proposed at Preliminary Inquiry

ANZFA proposed that novel foods should be assessed for safety before use in infant formula in Australia and New Zealand by virtue of the proposed Standard A19 – Novel Foods (now Standard 1.5.1 Novel Foods). ANZFA called for information to identify the use of potential novel foods or ingredients from novel sources.

### Issues

Some industry submissions did not agree that novel foods accepted elsewhere in the world should be required to undergo a safety assessment in Australia or New Zealand, particularly when trade is involved.

Safety concerns, relating to the use of novel foods in infant formula were raised by **Fiona Compston, the Australian College of Midwives Incorporated, Mark Dunstone, Julie Smith and Maureen Minchin (IBCLC)**. Submitters indicated that proof of benefit and absence of long-term harm in childhood must be demonstrated (e.g. in independent clinical trials) before widespread use of novel products are permitted in infant formula. **Wyeth Australia Pty Ltd** stated that safety assessments of such novel nutrients in infant formula should not be unfairly constrained by the safety standards that apply for novel food additives as novel nutrients are added for nutritional benefit. **Mark Dunstone and Julie Smith** commented that they do not support use of novel foods based on safe consumption of similar foods by adults and that the proposed standard is contrary to the objectives in the Food Act.

**Fiona Compston** and the **Australian College of Midwives Incorporated** stated that infant formula containing “novel ingredients” should contain large warning messages. **Maureen Minchin (IBCLC)** commented that misleading advertising about the benefits of infant formula containing novel foods should be prevented. **Nestle Australia Ltd** indicated that there be a maximum time of three months for the approval of novel foods.

Only **Maureen Minchin (IBCLC)** responded to ANZFA’s request for submitters to identify the use of potential novel, foods or ingredients. **Maureen Minchin (IBCLC)** stated that **Wyeth Australia Pty Ltd’s** S26 brand contains marine oils that are triglycerides manufactured by genetically or environmentally engineered marine algae. Other examples of novel ingredients of concern were synthetic analogues of 5 of the 13 nucleotides in breast milk and egg phospholipids.

## Assessment

Standard 1.5.1 – Novel Food, which came into effect on the 16 June 2001, requires a safety assessment of novel foods and novel food ingredients before these foods can be offered for sale in Australia and New Zealand.

Standard 1.5.1 defines novel foods as below:

*novel food means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account:*

- (a) the composition or structure of the product; or*
- (b) levels of undesirable substances in the product; or*
- (c) known potential for adverse effects in humans; or*
- (d) traditional preparation and cooking methods; or*
- (f) patterns and levels of consumption of the product.*

*non-traditional food means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.*

The intent of the novel food standard is to have ANZFA conduct a formal safety assessment only on those foods that have features or characteristics that raise safety concerns. The definition of a novel food in the proposed standard indicates the issues that need to be taken into account in identifying such foods. Foods regarded as novel are likely, but do not necessarily, fall into one of the following classes:

- dietary macro-components;
- extracts of plants, animals or microorganisms;
- single ingredient foods; and
- viable microorganisms.

The extent of the safety assessment necessary on a novel food will depend on the nature of the food and its proposed use. In many cases, there will be data available in relation to the use of the food in other countries. For those foods for which there has been no human exposure, or exposure at much lower dose levels, more extensive data will be required.

In relation to the use of novel foods or novel food ingredients in infant formula, there is no reason to make any exemption from the requirement for a safety assessment for these foods. Indeed, there is a strong argument that infants represent a vulnerable sector of the community and that a safety assessment of all new ingredients in infant formula is more appropriate for this group. For novel ingredients in infant formula, it is not expected that any additional studies would be required in the first instance but the applicant should provide ANZFA with all of the data that has been generated to ensure the safety of the product. ANZFA will also conduct its own research to ensure all appropriate data has been used in the safety assessment. This should not impose a significant additional regulatory burden on industry since such data should be readily available.

ANZFA does not support a three-month time frame for approval of novel foods in infant formula. This is not consistent with the statutory processes of ANZFA in relation to applications. Section 35(1) of the ANZFA Act 1991 requires that applications are processed within 12 months of receipt of the application. There is a significant lead-in time for the development of new ingredients for infant formula and this is unlikely to be disrupted by the need to make an application to ANZFA.

### Recommendation

Novel foods or novel food ingredients used in infant formula should be assessed for safety before use in Australia and New Zealand. Standard 1.5.1 –Novel Foods provides an appropriate mechanism for the safety assessment of all novel foods and novel food ingredients, including those to be used in infant formula. Therefore no change is required to the draft Standard 2.9.1 to provide for the safe use of novel foods.

## **8.3 Cadmium**

### Recommendation at Preliminary Inquiry

ANZFA's toxicological assessment of specific contaminants indicated that there was no reason to specifically restrict the level of cadmium in infant formula.

### Issue

**Maureen Minchin (IBCLC)** was concerned that a level is not proposed for cadmium. The submission suggested that there is a potential risk for contamination with cadmium in heavily processed products e.g. high levels of cadmium have been found in Belgian and Canadian infant formula.

### Assessment

A review of the Australian standards for cadmium in foods has been conducted over five years. Health Ministers accepted revised standards for all foods, except peanuts, in July 1997. A revised standard for cadmium in peanuts was accepted by Health Ministers, in August 1999. Data on exposure to cadmium from all sources was considered in this review and standards have been established for all of the major sources of cadmium in the diet. The major dietary sources of cadmium are potatoes, wheat, meat and cocoa.

Cadmium is a cumulative contaminant that can cause renal toxicity in humans following a lifetime of high dietary exposure. The levels normally found in food, even highly contaminated food, would be unlikely to cause any immediate adverse effects. Long-term exposure is required for manifestation of any adverse effects. The relatively short period of use of infant formula means this is unlikely to be regarded as a significant source of dietary cadmium over a lifetime.



Recent research on cadmium content in a range of infant formula for sale in Australia and New Zealand<sup>25</sup> indicates that the levels are generally similar to or lower than those found in comparable overseas products.

#### Recommendation

As proposed at Preliminary Inquiry, ANZFA does not propose to establish a maximum level for cadmium in infant formula.

### **8.4 Percentage Labelling**

#### Issue

The joint *Australia New Zealand Food Standards Code* (Volume 2) includes provisions for foods to be labelled with the percentage of the characterising ingredient or component of that food. These are set out in Standard 1.2.10.

#### Assessment

It is difficult to identify the characterising ingredient or component in infant formula. The mandatory labelling requirements are far more stringent than for other foods. For example, infant formula products are already required to include a statement of protein source on the label.

The objective of percentage labelling is to provide consumers with an additional information tool for comparing like products to assist them in making an informed choice. In the case of infant formula, consumers are already well informed from the label and it is unlikely that a small variation in the quantity of a particular ingredient or component will influence choice of purchase. Therefore infant formula products could be exempted from the provisions of Standard 1.2.10.

#### Recommendation

That infant formula products are exempt from the percentage labelling requirements in Standard 1.2.10 of Volume 2.

### **8.5 Innovation**

#### Industry issue

Industry made a request for a new clause to be added to the standard to the effect that nutritive substances may be added to infant formula to the levels found in human milk. Industry claim the usual ANZFA application process to vary a standard is unacceptable because this would then be assessed in the public domain and this removes any exclusivity rights to the company that has made significant resource investment.

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<sup>25</sup> Assessment of Selected Pesticides and the Elements Cadmium, Lead, Tin, Iodine and Fluoride in Infant Formulae and Weaning Foods, ESR report for Ministry of Health, 1997.

## Assessment

The current international and local regulatory systems for infant formula has led to the addition of some ingredients to formula without rigorous, objective safety assessments which are required for other food ingredients eg, food additives. Some constituents are added at unregulated levels or as unpurified forms with associated uncharacterised constituents and the safety of such ingredients may be of concern.

The food standards setting process is an open and transparent process that involves public consultation into proposed amendments to the food standards. The industry proposal is inconsistent with the ANZFA Act requirements for the setting of food standards. Members of the External Advisory Group were consulted on this matter and there was no agreement from non–industry representatives for such a provision in the proposed standard.

## Recommendation at Supplementary Final Assessment

That no new ‘innovation’ clause be included in the draft standard.