November 1999

INQUIRY REPORT

SUBJECT: P93 – INFANT FORMULA PRODUCTS

EXECUTIVE SUMMARY

This proposal was prepared and progressed to full assessment as a revision of Australian Standard R7 prior to the Review of the Australian Food Standards Code (the Review) and is now part of the Review which aims to reduce prescriptiveness and simplify food regulations. The report prepared at full assessment forms the basis for a joint Australia New Zealand (ANZ) food standard for infant formula. A Preliminary Inquiry was prepared to incorporate the principles of the Review of food standards and to provide the opportunity for 'formal' consultation in New Zealand.

The **objectives** of this proposal are to ensure that:

- the health and safety of infants is protected;
- carers have adequate information about infant formula to enable them to make appropriate choices in feeding their infant; and
- consistent with advances in scientific knowledge about human milk and infant nutritional requirements, innovation in the infant formula industry is not unnecessarily hindered.

The approach taken to achieve the objectives is to:

- stipulate the nutritional composition of infant formulas to provide fully for the nutritional needs of infants, including infants with special dietary needs, at all stages of growth and development;
- ensure that a risk-based assessment is used to determine the prescribed composition of infant formula;
- harmonise provisions with international standards where possible; and
- inform carers appropriately so infants are fed safely and healthily.

In response to the draft Preliminary Inquiry standard released in 1999, ANZFA received 58 submissions from infant formula manufacturers, pharmaceutical companies, health professionals, governments and individuals.

Following consideration of the public comments and an assessment against the objectives of the Review, a draft joint ANZ standard for infant formulas has now been prepared.

The joint ANZ standard for infant formula products includes provisions for different categories of infant formulas to cater for different ages and special purpose formulas intended for infants with specific diseases or disorders which contraindicate breastfeeding or the use of formulas for healthy infants

Formulas which cater for different ages are: infant formula (birth -12 months), follow-on formula (6-12 months), pre-term formula (infants of less than 37 weeks gestation).

Special purpose formulas cover the same age ranges but are intended for infants who require modifications to suit specific diseases or disorders or are for preterm infants. Categories are pre-term formulas, lactose free or low lactose formulas, formulated infant formula for metabolic, immunological, renal, hepatic or malabsorptive conditions, including formulas based on protein substitutes. Special purpose formulas are not suitable for general use.

The provisions proposed are aligned internationally or are less prescriptive than proposed at full assessment except where necessary to protect the health of infants in Australia and New Zealand. The following elements are proposed for this standard:

- The quality and quantity of the protein content of infant formulas is regulated but it is not considered necessary to regulate the protein source. However, information about the source of protein should be declared on the label to assist carers make suitable product selection.
- The total energy, total fat and essential fatty acids content is regulated to ensure infants who are formula fed receive sufficient but not excessive energy and fatty acid intakes. Fatty acids which are considered harmful to infants are restricted where necessary to protect infants from adverse health consequences. Limits are recommended for *trans*- fatty acid and erucic acid contents of infant formula.
- The carbohydrate content of infant formula is indirectly controlled by the regulations on protein, fat and energy content.
- Unlimited vitamin and mineral contents for infant formulas represented as human milk substitutes are not recommended as in the best interests of infant consumers, and maximum levels of these nutrients should be contained. To eliminate unnecessary cost for industry, mandatory maximum levels are only prescribed for those vitamins and minerals which are considered to pose a significant risk to infants if consumed in excess, whilst advisory maximum levels are recommended for other nutrients, whose risk characterisation is provisionally assessed as 'not of significance on the basis of current scientific knowledge'. A guideline will accompany the joint ANZ standard for infant formula to provide manufacturers with guidance as to these recommended

maximum levels.
These guidelines are expected to be implemented by Good Manufacturing Practice. ANZFA intends to monitor the performance of industry against the guidelines.

- The potential renal solute load of follow-on formula and formulated infant formula for metabolic, immunological renal, hepatic or malabsorptive conditions is regulated to minimise the risk of dehydration illness from formulas with high protein and electrolyte contents.
- Specific long chain polyunsaturated fatty acids, specific nucleotides, carnitine, taurine, choline and inositol are permitted to be voluntarily added to infant formulas. The maximum permitted content of these substances in infant formula is regulated, as is the minimum claimable level.
- Novel nutrient or nutritive substances or novel sources of these for formulas should be assessed as safe and suitable for infants before use in formulas in Australia or New Zealand.
- Limits for lead and aluminium contents are imposed to protect infants. The limit for lead is controlled within the standards for metals and contaminants in foods and hence does not appear in this standard. Other potential contaminants are regulated by other mechanisms, such as water quality guidelines or do not pose a safety concern for infants. An advisory labelling statement to alert carers to seek specific health advice is proposed for formulas with unnecessarily high fluoride contents.
- It is considered the risk to infants in Australia and New Zealand from potential gluten content of infant formulas is such that a prohibition on gluten inclusion in formulas is required, although not specifically prohibited in the Codex standard.
- Microbiological criteria and the use of specific food additives are recommended to ensure safety of infant formulas. The microbiological criteria are contained within the Standard for microbiological limits in foods.
- Specific labelling is recommended to inform carers to seek health advice to determine whether formula is the most appropriate method of feeding and if so whether the specific formula is the most appropriate formula for the individual infant. Labelling is also required to ensure carers have advice as to the nutritional content of the formula and the safe preparation, storage, and use of the formula. The relevant labelling provisions of the WHO International Code of Marketing Breast-milk Substitutes are also reflected within the Standard. These include a reference to breast milk as the optimum source of nourishment for infants so that potential purchasers of formula products can be informed of the full range of feeding options.

It is recommended that soy-based formula for infants be consumed only by infants for whom human milk or a modified cow's milk formula is contraindicated. ANZFA is considering strategies in a separate project to reduce the incidence of

inappropriate soy-based formula consumption in Australia and New Zealand to the level necessary on medical grounds.
Soy-based infant formula products will be regulated as special purpose infant formula products if a nutrient claim or a claim for special medical purpose is made for the product; other wise they will be regulated as general purpose infant formula products.

Conclusion:
A food standard for infant formula products which protects the health and safety of infants who are routinely fed substitutes for human milk is necessary and should be included in the joint ANZ Food Standards Code. Infants are the most vulnerable group in the Australian and New Zealand population and may consume infant formula as the sole or principal source of nourishment. Therefore the proposed joint standard which provides for a food which is intended to be the principal source of nourishment for a vulnerable group is necessarily more prescriptive than standards for other foods which form part of a varied diet. The standard should provide for suitable formulas for healthy infants and for infants with diseases or disorders who require specialised formulations. The Standard also provides general provisions for formulas for preterm infants. ANZFA proposes to develop more specific provisions for preterm formulas in a new proposal.

Previous Authority consideration

ANZFA undertook a Preliminary Inquiry of P93 – Infant formula products in April 1999 and the matter was subsequently advertised on 5 May 1999.

Summary of new submissions received

Fifty-eight submissions were received to the Inquiry of draft Standard 2.9.1. The following issues were raised in relation to the draft standard:

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. Preterm formula
    1.8. Protein substitute
    1.9. Soy protein formula
    1.10. Fat modified.

2. Calculations

    2.1. Potential Renal Solute Load (PRSL)

2.2. Calculation of PRSL
2.3. Calculation of amino acid score

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)
    3.5. Aluminium

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.Clause 19 (1) – Use of the term 'very' ill'
        4.3.3.Clause 19 Ready to drink formula
        4.3.4.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 formulas
    4.10 Prohibited representations

5 Division 4 General Microbiological Requirements

6 PART 2 INFANT FORMULA AND FOLLOW ON FORMULA

    6.1 Composition
    6.2 Protein content
    6.3 PRSL of Follow on formula (and Special Purpose formulas)
    6.4 Fat
        6.4.1 ALA
        6.4.2 Trans fatty acids
        6.4.3 LCPUFAS
            6.4.3.1 The regulation of LCPUFAS
            6.4.3.2 Levels of addition of series-6 fatty acids

6.4.3.3 LCPUFAs in follow on formula
6.4.4 Vitamins and minerals
6.4.4.1 Policy for safety of vitamins and minerals
6.4.4.2 Specific Levels in the Table to Clause 31
6.4.4.2.1 Selenium
6.4.4.2.2 Copper
6.4.4.2.3 Zinc to Copper ratio
6.4.4.2.4 Chromium and molybdenum
6.4.4.2.5 Pyridoxine
6.4.4.2.6 Riboflavin
6.4.5 Schedule 1 – Permitted forms of nutrients
6.4.5.1 General
6.4.5.2 Cupric carbonate
6.4.5.3 Nicotinic acid
6.4.5.4 Selenium
6.4.5.5 Choline and carnitine forms

7 PART 3 SPECIAL PURPOSE FORMULAS

7.1 Division 1 – Preterm formulas
7.1.1 Fat content
7.1.2 MCT content of preterm formulas
7.1.3 Vitamin and mineral content of preterm formulas
7.1.4 Use of preterm formulas
7.1.5 Labelling statement on preterm formulas
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 formulas

8 Issues not in draft standard

8.1 Soy formulas
8.2 Novel foods
8.3 Cadmium

ASSESMENT OF ISSUES

The assessment of issues is at Attachment 1 to this report.

CHANGES TO PRELIMINARY INQUIRY RESULTING FROM INQUIRY

The following changes are recommended to the draft standard prepared at Preliminary Inquiry. The reasons are outlined in detail in the Attachment 1.

Clause number at PI	Proposed at PI	Recommended at Inquiry
Purpose Clause	This Standard provides for the compositional, microbiological and labelling requirements of foods intended or represented for use as a substitute for human milk, herein referred to as 'infant formula products'.	Delete the word microbiological
Clause 1 - Definitions	**'follow-on formula'** means infant formula product represented as being suitable as the principal source of food for infants aged over six months.	'**follow-on formula'** means 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.
	infant formula' means an infant formula product that is represented as being suitable as the principal source of food for infants.	**'infant formula'** means 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.
	an **'infant formula product'** is 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.	an **'infant formula product'** means 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.
	'pre-term formula' means an infant formula product represented as being suitable as the principal source of food for infants born prematurely or of low birthweight	**'pre-term formula'** means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight

	Lactose free and **low lactose formula** mean infant formula products represented as being the principal source of food for lactose intolerant infants.	**'lactose free** and **low lactose formula'** mean infant formula products which satisfy the needs of lactose intolerant infants.
Clause 5 - Calculation of potential renal solute load	The potential renal solute load must be calculated as follows: 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].	The potential renal solute load must be calculated as follows: Potential renal solute load in mOsm/100 kJ = [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [P_{avail}(mg/100 kJ)/31] + [N (mg/100 kJ)/28] Where P_{avail} is P of milk- based formula + 2/3 of P of soy- based formulas
Clause 8 - Permitted nutritional substances	Title	Name change to: Permitted nutritive substances
Max permitted amount per 100kJ in Table to Clause 8 - Permitted nutritional substances	Choline – 5.4mg Inositol – 5.4 mg L- Carnitine – 0.42mg	Choline – 7.1mg Inositol – 9.5 mg L- Carnitine – 0.8mg
Clause 9- Limit on nucleotide 5'-monophosphates	Infant formula product must not contain more than a total amount of 1.2 mg of nucleotide 5'-monophosphates per 100 kJ.	Infant formula product must not contain more than a total amount of 3.8 mg of nucleotide 5'-monophosphates per 100 kJ.

Clause 18 – Requirement for a measuring scoop	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.	(1) A package of infant formula product in a powdered form must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package. (2) Subclause 1 does not apply to single serve sachets, or packages containing single serve sachets containing infant formula product in a powdered form. New clause number:16
Clause 19 – required statements- subclauses 3 and 4	(3) Subject to subclause (4) the label on an infant formula product must contain statements indicating that: (a) breast feeding is superior to the use of infant formula product in the feeding of infants; (b) the infant formula product should only be used on the advice of a medical practitioner or health worker as to the need for its use and the proper method of its use; (c) the infant formula product may be used from birth, in the case of infant formula; (d) the infant formula product should not be used for infants aged under 6 months in the case of follow-on formula; (e) 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	(3) Subject to subclause (5) the label on an infant formula product must contain the following statement: Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice. (4) The label on an infant formula product must contain statements indicating that: (a) the infant formula product may be used from birth, in the case of infant formula; (b) the infant formula product should not be used for infants aged under 6 months in the case of follow-on formula; (c) 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. (5) The statements required by subclause (3) must occur under a heading that reads: 'Important notice' or any word or words having the same or similar

	product. (4) The statements required by subclause (3) must occur under a heading that reads 'Important Notice' or any word or words having the same or similar effect.	effect. New clause number: 17
Clause 20- Print and package size	(1) Where infant formula product is in a package having a net weight of more than 1 kg, the statements required by clauses 19(1) and 36(1) must be in size of type of not less than 3 mm. (2) Where infant formula product is in a package having a net weight of 450g or less than 1 kg, the statements required by clauses 19(1) and 36(1) must be in size of type of not less than 1.5 mm.	(1) Where infant formula product is in a package having a net weight of more than 450g the statements required by clauses 17(1), (3) and (5) and 30(1) must be in size of type of not less than 3 mm. (2) Where infant formula product is in a package having a net weight of 450g or less the statements required by clauses 17(1), (3) and (5) and 30(1) must be in size of type of not less than 1.5 mm. New clause number: 18
Clause 22	(1) Notwithstanding the provisions in subclause 2 (1) of Standard 1.2.5, the label on an infant formula product must include a statement of the best before date. (2) A label on … must contain storage instructions covering the period after it is opened.	<u>Recommendations</u> Clause 22(1) deleted (since the generic provisions proposed for the date marking of foods provide the appropriate cover). Clause title is now ' Storage and handling instructions'. A label on an infant formula product must contain storage and handling instructions covering the period after it is opened.
Clause 27 – Microbiological standards	General Microbiological requirements	Transferred to the standard for the Microbiological limits for foods (Standard 1.6.1).
Clause 30 – Fat subclause (d)	have a ratio of total long chain omega 6 series fatty acids (C>= 20) to total long chain omega 3 series fatty acids (C>= 20) of 2 in an infant formula or follow-on formula which contains those fatty acids;	have a ratio of total long chain omega 6 series fatty acids (C>= 20) to total long chain omega 3 series fatty acids (C>= 20) of approximately 2 in an infant formula or follow-on formula which contains those fatty acids;

		New clause number: 26
Clause 31 – Vitamins and minerals	Selenium content 0.36-0.9 mcg/L	Selenium content 0.25-1.19 mcg/L New clause number: 27
Schedule 1 to Clause 31 – Vitamins and minerals		The following forms were added to the list of permitted forms at Preliminary Inquiry • 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 • Phytylmenoquinone 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 • Sodium selenate
Clauses 32-35 - Preterm formula	Detailed compositional requirements for preterm formula	Clauses 32-35 are deleted. Replacement Clause 28 Preterm infant formula must comply with all the other requirements of this Standard that are not inconsistent with this Division. New clause number: 28
Division 2 Title	Infant formula products formulated for metabolic and immunological conditions	Infant formula products formulated for metabolic, immunological, renal, hepatic and malabsorptive conditions
Clause 37 - composition	Infant formula product may be specifically formulated to satisfy particular metabolic or immunological conditions and must comply with: (a) this Division; and (b) with all the other requirements of this Standard that are not inconsistent with	Infant formula product may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions and must comply with: (a) this Division; and (b) with all the other requirements of this Standard

	this Division.	that are not inconsistent with this Division. New clause number: 30
Clause 38 Additional labelling	(1) The label on a package containing an infant formula product formulated for metabolic or immunological conditions must include a statement indicating that the product is not suitable for general use and should be used under medical supervision. (2) The appropriate designation of a food standardised in this division must include a statement indicating (a) the condition, disease or disorder for which the food has been specially formulated; and (b) the nutritional modifications which have been made to the infant formula product.	**Claims** Where a claim is made that an infant formula product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, then the label on a package containing the infant formula product must include a statement indicating: (a) that the product is not suitable for general use and should be used under medical supervision; (b) the condition, disease or disorder for which the food has been specially formulated; and (c) the nutritional modifications, if any, which have been made to the infant formula product. New clause number: 31
Clause 15 Composition of lactose free and low lactose formula		This clause has been relocated to within the Division 2 as this division is now more broadly specified (refer above). New clause number: 32

Clause 25 Labelling of lactose free and low lactose formula	(1) the words 'lactose free' must appear as part of the name of lactose free formula; (2) the words 'low lactose' must appear as part of the name of low lactose formula; (3) The label … 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	This clause has been relocated to within the Division 2 as this division is now more broadly specified (refer above). New title: Claims relating to lactose free and low lactose formulas. Where a claim is made that the infant formula product is lactose free, low lactose or words of similar import, then the label on a package containing the lactose free or a low lactose formula product must include: (a) the words 'lactose free' as part of the name of lactose free formula; (b) the words 'low lactose' as part of the name of low lactose formula; © the following statements: (i) the amount of lactose expressed in g per 100 mL; and (ii)the amount of galactose expressed in g per 100 mL. New clause number: 33
Clause 42 – Other permitted additions	DATEM – maximum amount 0.4g/ 100mL No permission for Citric acid esters of mono- and di-glycerides of fatty acids (E472c) Mono-and di-glycerides	DATEM (E472e) – maximum amount 0.04g/100mL Citric acid esters of mono- and di-glycerides of fatty acids (E472c) maximum amount 0.9g/100mL Mono-and di-glycerides of fatty acids (E471) New clause number: 37

ATTACHMENTS:

1. Assessment of Issues raised.

2. Statement of Reasons.

3. Summary of Submissions.

4. Proposed Draft Standard.

Attachment 1

ASSESSMENT OF ISSUES RAISED IN PUBLIC SUBMISSIONS

The following issues were raised in submission to the Inquiry of draft Standard 2.9.1 – Infant formula products.

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 Preterm formula
1.8 Protein substitute
1.9 Soy protein formula
1.10 Fat modified.

2 Calculations
2.1 Potential Renal Solute Load (PRSL)
2.2 Calculation of PRSL
2.3 Calculation of amino acid score

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)
3.5 Aluminium

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 Clause 19 (1) – Use of the term 'very' ill'
4.3.3 Clause 19 Ready to drink 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 formulas

8 Issues not in draft standard
8.1 Soy formulas
8.2 Novel foods
8.3 Cadmium

ASSESSMENT OF ISSUES

NOTE: The clause number refers to in this assessment are those proposed at Preliminary Inquiry and may not coincide with the clause numbers in the final draft standard.

DIVISION 1 INTERPRETATION

1. CLAUSE 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* formulae 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 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. Regarding the draft Standard, it is proposed to maintain the inclusion of follow-on formula, but to amend the definition of follow-on-formula (refer to discussion on follow-on formula 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
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".*

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*".

Issues
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.

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 be amended to *'lactose free and low lactose formulas mean infant formula products which satisfy the needs of lactose intolerant infants*'.

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 categorization:

- 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 preterm 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 5th 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*".

Issues
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 should 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 should 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 PI to control the PRSL of formulas 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. Submission was 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.

2.2 Calculation of Potential Renal Solute Load

Proposed at Preliminary Inquiry
5. The potential renal solute load must be calculated as follows:

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].

Issues
The calculation for estimating the PRSL provides for total phosphorous content. This calculation was recently revised by the original authors Fomon and Ziegler (1999) to exclude 'unavailable phosphorus'[1].

[1] Fomon AJ and Ziegler EE (1999) Renal solute load and potential renal solute load in infancy. J Pediatr 134: 11-4.

Assessment
For formulas, unavailable phosphorus is that part of the phosphorus content of a formula likely to be bound to phytate in the formula. 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 formulas. Should they become significant ingredients in the formula they may also impact on available phosphorus content. Currently these foods are not significant ingredients of formulas 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 formulas 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.

Therefore the PRSL should be calculated as follows:

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

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

Recommendation
That the draft standard be amended to exclude the unavailable phosphorus content of formulas. The calculation recommended is

Potential renal solute load in mOsm/100 kJ
= [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [P_{avail} (mg/100 kJ)/31] + [N (mg/100 kJ)/28].
Where P_{avail} is P of milk-based formulas + 2/3 P of soy- based formulas.

2.3 Calculation of amino acid score

Amino acid score
The amino acid content of infant formula products is regulated by the calculation of the amino acid score (at clause 6) and the requirement for infant formula products to

have a score of 0.8 at clauses 29 and 33. A table at clause 6 also provides reference values for amino acids based on human milk.

Issue

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. No other submissions were received about this value.

Assessment

This issue was addressed at Preliminary Inquiry. The levels are set against a benchmark of human milk. Codex is also planning to link the amino acid score of infant formula to that of human milk. The LSRO has also recommended the assessment of protein quality be on the basis of an amino acid score with human milk as the reference.

If the concentration of the amino acid in the formula is the same as in human milk, a ratio of 1.0 is achieved. If we took an amino acid score of 1.0 most infant formula manufacturers would need to fortify their products with selected amino acids to achieve this amino acid score. However, if we set a slightly lower score but one that is achievable from the industry context and recommend slightly higher protein content, it will be better than the current Australian standard (Standard R7) and the objective will be achievable by industry.

The minimum protein content proposed for infant formula has been set sufficiently high to enable the protein quality to be regulated at 0.8. This level is consistent with the requirement in the EC Directive for infant formula and follow up formula. Therefore it is recommended that the protein quality of infant formulae have an amino acid score of at least 0.8.

Recommendation:

The current provision be retained.

Valine value

Proposed at Preliminary Inquiry

Valine is permitted at levels of 5.5 g/ 100g protein.

Issues

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).

Assessment

The levels proposed in the Codex standard and the EU standard are expressed per 100 kJ rather than per 100 g protein. This Codex methodology creates inconsistencies since the variations in fat and carbohydrate content of the formula would affect the energy value and consequently the calculation for protein quality.

The figure of 5.5g valine per 100 g protein is recommended by the FAO/WHO[1] as the valine content of human milk. The FAO/WHO conclude in its report on protein quality evaluation that 'the amino acid composition of human milk should be the basis of the scoring pattern to evaluate protein quality in foods for infants under 1 year of age'. Therefore these figures are consistent with major recommendations.

Recommendation
It is proposed to retain permitted levels at Preliminary Inquiry.

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 formulas 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 formulas sold for Australian and New Zealand babies. (refer to item on novel foods).

Recommendation
Clause 7 should be retained as prepared at Preliminary Inquiry.

[1] Protein quality evaluation (1991), Report of the joint FAO/WHO Expert consultation 1989, FAO 1991

3.2 PERMITTED OPTIONAL NUTRITIVE SUBSTANCES - Clause 8

The term nutritive substance has been defined in the preliminary provisions of the Code, therefore the term 'nutritional substance' used in this standard at Preliminary Inquiry has been changed at Inquiry to 'nutritive substance'.

Proposed at Preliminary Inquiry

The draft standard provides for certain nutritional substances in one or more of the forms specified to be added to infant formula 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 rather than those revised levels agreed at PI were included in the draft standard. Therefore, the following correct recommended maximum levels as reflected in the PI report are recommended for the standard.

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

3.2.2 Carnitine

Proposed at Preliminary Inquiry

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

Issues raised

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 formulas 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 formulas based upon either cow or goat milk.

It is may be useful to include an editorial note to the effect that it is not the intent of the standard to regulate the maximum nutritive substance (e.g. carnitine) level of formula in the case when the nutritive substance is not added as an ingredient to the formula.

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 allowed to be added to an infant formula product is 1.7-5.4mg per 100kJ.

Issues raised
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 PI 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 and included in clause 8.

Recommendation
It is recommended choline continue to be regulated under clause 8 as an optional ingredient.

3.3 - NUCLEOTIDES - Clauses 8, 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 to the infant formula. This includes any necessary purity standards. **Wyeth Australia Pty Ltd** commented that the moisture specification and bacteriological profile may 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.

It was also commented that the safety of all optional ingredients needs to be established before nucleotides are permitted in infant formula.

Assessment

The levels of nucleotides permitted in the draft standard have been based on the 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 16mg/100kcal (3.8mg/100kJ), 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 /100kJ.

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 to be added to 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 nucleotides content could be raised to the level the LSRO of 3.8mg/100kJ.

It was commented that nucleotide specifications should not be contained in an infant formula 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 inserted into Standard 1.3.4. In addition, the microbiological specifications will be deleted from this standard, as these are incorporated under general microbiological requirements which infant formula must comply to.

Recommendation

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

3.4 CLAUSE 11 – FOOD ADDITIVES

Proposed at Preliminary Inquiry

At Preliminary Inquiry, ANZFA proposed to include the Codex provisions for food additive use in infant formulas, with adjustment for the recommendations by the European Commission's Scientific Committee for Foods.

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 products, 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 carrageenen

Issue

Nestle Australia Ltd have 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 formulas based on extensively hydrolysed protein, as this was included in the European Union 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 of formulas based on extensively hydrolysed protein at a level of 0.9g/100ml.

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 0.9g/100ml in formulas 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 for 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 which 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 these formula based upon protein substitutes. The SCF recommended 0.4g/l which should have been entered in the Table as 0.04g/100mL.

Recommendation:
The correct figure of 0.04g/100ml for DATEM be included in the Table to clause 42. The food additive number E472e should also be included in theTable to clause 42.

Summary recommendation 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 100mL".

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 0.9g/100ml in formulas 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).

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 will 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 formulas, then this level should apply to all formulas.

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 formulae, 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 formulas, therefore the level proposed at preliminary inquiry should be retained.

Recommendation
Retain levels proposed at Preliminary Inquiry.

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 should 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 products 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 in the label of the formula**.** Comments made included the following:

- This proposal would weaken current labelling provisions by downgrading the prescribed statements into advisory statements;
- A warning statement in 6mm type to the effect that artificial formula feeding can be dangerous to the health of the infant should be mandatory on all infant formulae;
- 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 has 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 formulas?;
- Will the warning statements and explanatory messages in the application from Mr Dunstone increase the incidence of breastfeeding in Australia and New Zealand?

<u>Assessment</u>
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 formulas for babies. Infant formulas 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 can 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, are 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 in 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 -Clause 19 (1) - required statements continued

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' for the following reason:

- The use of the term 'very' is too extreme and could cause unnecessary anxiety to the carer, 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.

Recommendation
The drafting should remain as proposed at Preliminary Inquiry.

4.3.2 - Clause 19 - Ready to drink formula

Proposed at Preliminary Inquiry
The following statement be 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 drafting proposed at Preliminary Inquiry should be amended to clarify that nothing should be added to the ready to drink formula except on medical advice.

4.3.4 - 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.

Issues
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 in the 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 or in the case of packages of less than 1 kg, 1.5 mm standard type. When the joint Food Standards Code comes into force, 'standard type' will no longer be specified and legibility will be the key criteria.

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 says 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 it appears that 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 is necessary to be consistent with the requirements for warning statements in the label of other food products.

Recommendation

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.

4.5 Clause 21 – Declaration of nutrition information

Use of 100g in the NIT / 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 stated 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 NIT 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

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

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.

A label on an infant formula product 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 feel 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 would then be consistent with the generic provisions proposed for the date marking of foods 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 handing 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 be deleted from the standard for infant formula products as the generic provisions proposed 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 the infant formula products 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 then 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 proposal to declare the protein source of the formula in the label immediately adjacent to the name of the food.

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 is adequately covered by the current water quality guidelines. Therefore, it is proposed not to specify a maximum level for fluoride in infant formula.

Whilst ANZFA does not dispute that at high fluoride levels dental fluorosis may occur, from the available information manufacturers of infant formulae are already taking steps to reduce fluoride content in formulae. 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 formulas, 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 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.

A warning statement in 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 that contains fluoride and may encourage manufacturers to decrease the level of fluoride in the 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 for the reference groups on this issue.

Recommendation.
That the provision at clause 27 be retained.

4.9- Clause 25 - Labelling of lactose free and low lactose formulas

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 no 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 appears adequate for galactosaemia.

Assessment
The declaration of lactose in g/100 mL in the label of lactose free formula is consistent with the current and proposed 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 formulas are therefore currently required to provide information about the galactose content of the food. This information enables carers of children or infants with galactosemia to determine how much of the food, if any, is suitable for galactosemics. It was recommended that this provision be included in the joint ANZ 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 formulas not specifically formulated for lactose maldigesters 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, should 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
There is a list of prohibited representations on the label of infant formula products in clause 26 of the Standard. These include:

(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 information has been presented by submitters that was not 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.

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.

All infant formula products have added iron. Therefore such a claim is true for all infant products for the nutrient 'iron' and as well as for all other essential nutrients. 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 has already introduced specific provisions to address the concerning early introduction of milk or milk substitutes to the diet of infants. It has recommended that an advisory statement be included in the label of all milk products including modified, dried and evaporated milks and milk substitutes. The statement will advise that health authorities recommend the product not be used to replace breast milk or infant formula products for infants under 12 months of age. Such 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. Therefore it is recommended that the proposed provision be retained.

Recommendation

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

Division 5 General Microbiological Requirements

The microbiological standards for infant formula products will be 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.

6. PART 2 - INFANT FORMULA AND FOLLOW ON FORMULA

6.1 COMPOSITION

6.2 Clause 28 - 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/100kJ for follow on formula.

Issues
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 formulas expressed in metric values to 0.45g/100kJ as does the EC Directive. It is therefore recommended that this figure be retained in the joint ANZ standard.

Recommendation
The drafting should remain as proposed at Preliminary Inquiry.

6.3 PRSL of Follow on Formula (and Special Purpose Formulas - Clauses (28) (2);(39) (1) (b)

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) (1) (b)
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
Submission was received to the effect that this parameter is more prescriptive than some international regulations and some imported formulas may not comply.

Assessment
It is now well accepted that health outcomes for infants have improved since the PRSL of alternatives to human milk has been reduced. Formulas which unnecessarily increase risks to infants are 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 for formulas where formulas 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 specific dietary use based upon protein substitutes must have a potential renal solute load value of not more than 8 mOsm/100 kJ.

6.4 Fat content - Clause 30

6.4.1 Alpha Linoleic Acid (ALA)

Current provisions and proposed provisions

	Infant formula	**Follow-on formula**
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

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 EU Directive and proposed draft Codex standard specify the minimum ALA at 12mg/100kJ 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 formulas which provide 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

Retain the ALA permissions proposed at Preliminary Inquiry.

6.4.2 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 standards allow 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% which was proposed at Preliminary Inquiry be retained in the standard.

6.4.3 Long chain polyunsaturated fatty acids (LCPUFA)

6.4.3.1 The regulation of LCPUFAs

Proposed at Preliminary Inquiry

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

Option 1: Do not provide express permission

Rationale:

The efficacy of the addition of these LCPUFAs is not proven and there are safety concerns about the effects of imbalance of the different LCPUFAs but insufficient data to determine suitable levels for a regulation. Removal of express permission would leave the LCPUFAs 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

Rationale:

There is emerging evidence that some LCPUFAs 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 given 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 LCPUFAs should be regulated at the level it is 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 LCPUFAs ratio to that in human milk.

Therefore the draft standard included the following provisions:

Long chain polyunsaturated fatty acids	**% Maximum Total fatty acids**
Long chain omega 6 series fatty acids (C>= 20)	2
Arachidonic acid (20:4)	1
Long chain omega 3 series fatty acids (C>= 20)	1

If LCPUFAs are added to the formula then:

- total long chain omega 6 series fatty acids (C>= 20) : total long chain omega 3 series fatty acids (C>= 20) must be 2; and

- the eicosapentanoic 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.

Preferred options
Options 1 and 2 were supported by 2 submitters each; and
Option 3 by 6 submitters

Safety concerns
One submitter did not indicate which option they supported but questioned the safety of addition of LCPUFAs since there would be addition of unpurified constituents.

Additional Ratio
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 LCPUFAs can interfere with each others' metabolism to varying extents, therefore regulating this ratio to the level found in human milk affords an extra measure of safety. LCPUFA substrates are expensive. ANZFA has anecdotal information that at least one overseas manufacturer is to release a formula which has only one of the series of LCPUFAs 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 formulas then they be required to be added at levels as close to those known to be in human milk. Forsyth (1998)[1] 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 formulas 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.

[1] Forsyth JS (1998) Lipids in infant formulas Nutr Res Revs 11, 255-278.

Safety of substrates

The safety of substrates used to add LCPUFAs to infant formula will be required to be assessed if these are 'novel' ingredients for infants. ANZFA would consider algael or fungal sources of these fatty acids to be 'novel' for infants and would require these to be assessed for safety before sale to infants in Australia or New Zealand. Additionally ANZFA is aware of herbal oils being used overseas as substrates for the addition of LCPUFAs to formulas for infants. Some of these oils would be considered 'novel' for the purposes of consumption by infants in Australia or New Zealand. For example, the Food Standards Code includes a prohibition on the use of 'borage' in foods and yet 'borage oil' which is also included in this prohibition has been referred to as a potential substrate for the addition of LCPUFAs to infant formulas. ANZFA would require a safety assessment of the use of such a substance before sale in Australia or New Zealand.

Recommendation
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 long chain polyunsaturated fatty acids 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.

6.4.3.2 Levels of addition of the series-6 fatty acids

Proposed at Preliminary Inquiry
That series –6 LCPUFAs and arachidonic acid be not more than 2% and 1% respectively of total fatty acids.

Issue
It was pointed out by **InforMed Systems Ltd** and **Wyeth Australia Pty Ltd** that under options 2 and 3, adding only up to 1% arachidonic acid value would be allowed 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 ECs approach.

Recommendation
The levels proposed at Preliminary Inquiry be retained.

6.4.3.3 LCPUFAs in 'follow-on-formula'

Issue
Nestle Australia Ltd. has submitted that LCPUFAs 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 LCPUFAs 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 LCPUFAs 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 LCPUFAs to 'follow-on formula'.

6.4.4 - Clause 31- VITAMINS AND MINERALS

6.4.4.1. Policy for the safety of vitamin and mineral contents of formulas

Proposed at Preliminary Inquiry
It was proposed at PI 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 provided that these levels don't become 'pseudo-regulation' and in the case of the consumer representatives support was provided that there is effective monitoring of GMP and levels of nutrients.

Assessment
Consumer representatives note that GMP guidelines were insufficient in the 1970s to protect infants from unsafe formulas in the USA and the resultant harm to infants lead to the introduction of regulation for infant formulas 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 infer that compliance be expected to be monitored.

ANZFA recommends maximum levels of nutrients be contained in formulas 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 of consumers to be aware of the levels of nutrients in formulas. 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 formulas 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 formulas.

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. ANZFA also intends to monitor industry's performance against the guidelines.

6.4.4.2 Specific Levels In the Table to Clause 31
Only those levels where are a specific request for amendment has been received are discussed below. There were submissions of support for many nutrient levels.

6.4.4.2.1 Selenium

Current and proposed provisions

	Infant formula mcg/100 kJ	**Follow-on formula mcg/100 kJ**
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/100kJ 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 PI was assessed against the 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/100kJ 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 /100kJ is consistent with a safe formulation for infants.
Hence it is recommended that the minimum level be reduced to 0.25mcg/100kJ which is consistent with the recent EC special purpose standard level.

Maximum level
The LSRO has recommended a maximum of 1.19 mcg selenium/100kJ 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 x RDI of the infant from formula as a sole source of nourishment. Additional selenium would also be contributed from other foods consumed by the infant but the contribution from formula intakes would be expected to 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 into the joint ANZ standard.

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

6.4.4.2.2 Copper

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	**Follow-on formula mcg/100 kJ**
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
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

Issues
Nestlé Australia Ltd argues that as the EC permits a minimum copper content of 4.8 mcg per 100kJ, some formulas manufactured to EC formulations will not comply with the ANZ 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/100kJ. A formula made to the minimum level of copper would not provide the necessary copper to meet the estimated safe and adequate daily intakes (ESADI) set for infants. The minimum level recommended at PI is consistent with the LSRO recommendation and also the recommendation from the American Academy of Paediatrics in 1985. The recommended level in the ANZ standard may constitute a TBT 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 preterm formulas are not under discussion in this section, preterm babies have a greater need for copper than term babies. It should be noted that the Canadian minimum recommended level for preterm formula is 23.8 mcg/100kJ, i.e. well above the EC prescribed minimum level.

Recommendation

No change to proposed minimum copper level.

6.4.4.2.3 Zinc to copper ratio

Current and proposed levels

	Infant formula & Follow-on Formula mcg/100 kJ
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

- 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.

Proposed draft Codex Infant Formula Standard	**Minimum amount per 100kJ**	**Maximum amount per 100kJ**
Zinc	0.12 mg	NS*
Zinc content in soy-based or soy &milk based formulas	0.18 mg	0.6mg
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)[1]. The Zn:Cu ratio of human milk is 10:1.

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)[2]. LSRO suggests on the basis of adult studies 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 which 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

[1] Langley A and Mangas S (1997) Zinc. *National Environmental Health Forum Monographs.* Metal Series No. 2.

[2] WHO (1996) *Environmental Health Criteria for Zinc*. International Program on Chemical Safety. In preparation.

those of human milk as possible whilst accounting for the bioavailability of the specific nutrient forms.

Recommendation

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

6.4.4.2.4 Chromium and Molybdenum

Current provisions and proposed provisions

	CHROMUIM		MOLYBDENUM	
	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-commend Min or max levels	as per infant formula	did not re-commend 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
RECOMMENDATION AT INQUIRY	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry	As proposed at Preliminary 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 formulas would be devoid of chromium or molybdenum and unsuitable for infants.

Recommendation

Retain the proposed standard.

6.4.4.2.5 Pyridoxine (Vitamin B6)

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	**Follow-on formula mcg/100 kJ**
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

Issues

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 PI 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 joint ANZ standard is 36 mcg/100kJ and the LSRO maximum level was based on 31 mcg pyridoxine /100kJ which was the 90th centile of analyses of infant formulas.

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 formulas to 75mcg/100kJ.

The proposed maximum level is 4x RDI for infants (to 6mos). A review of the formulas available in Australia whose pyridoxine content ANZFA was aware of, indicted 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.

6.4.4.2.6 Riboflavin (Vitamin B_2)

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	**Follow-on formula mcg/100 kJ**
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	14mcg/100 kJ - not specified [Advisory guideline maximum of 86 mcg/100 kJ]	as per infant formula
RECOMMENDATION AT INQUIRY	As proposed at Preliminary Inquiry	As proposed at Preliminary Inquiry

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

Assessment
The EC has prescribed a maximum level of 100 mcg/100kJ for the special purpose products.

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 5xRDI for infants. In accordance with Authority policy, it is recommended the guideline level be maintained. Manufacturers are encouraged to moderate nutrient levels where possible.

Recommendation
Retain current guideline level.

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

6.4.5.1 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 formulas sold for infants 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 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 standards. 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 formulas by the Codex standards which were not included at PI. The trade obligations of Australia and New Zealand impose a requirement to include all forms permitted by Codex if here 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.

6.4.5.2 Cupric carbonate

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

Assessment
Whilst Codex provides a permission for cupric carbonate for use in baked products and protein hydrolysate and meat based formulae no permission is provide for infant formulas based upon cows milk.

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

6.4.5.3 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 has been permitted for use in formulas as a form of niacin by some international food regulations. The LSRO has reported adverse effects with large doses of this form of niacin. Therefore despite currently being permitted by other countries, nicotinic acid is not permitted for use in infant formula as a source of niacin. The potential risks to the health and safety of infants from this form should be assessed before use in infant formulas. Therefore as alternative forms are available, 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 formulas as noted at PI.

Therefore, the following substances should 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;
- Phytylmenoquinone as a source of vitamin K;
- Sodium chloride iodized as a source of sodium;
- Cupric citrate as a source of copper; and
- Manganese carbonate and manganese citrate as sources of manganese.

6.4.5.4 Selenium

Proposed at Preliminary Inquiry
Codex does not give permission for the use of specific forms of selenium. At PI 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
Data relating to selenium supplementation of infant formula were supplied to ANZFA by **Dr L Daniels, Flinders Medical Centre**. **Dr Daniels** notes 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 should be added to Schedule 1 in Standard 2.9.1 – Permitted forms of vitamins and minerals in infant formula products

6.4.5.5 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 joint 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 6.4.5
The following substances should 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;
- Phytylmenoquinone 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.

7. PART 3 – Special Purpose formulas

7.1 Division 1 - Preterm formulas

Refer definition of preterm formula at item 1.

Proposed at Preliminary Inquiry
Regulation of preterm prescribes energy and nutrient content of formula.

Issue
Some submitters claimed the regulation of preterm formula would result in unnecessary delay of new products (3).

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 formulas for preterm infants.

Assessment
It has been claimed that the field of nutrition in preterm 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 preterm formulas currently available and is concerned that the efficacy of these formulas has not been reviewed independently from industry evaluations. Independent assessment of these formulas is necessary for the health and safety of preterm infants.

Recommendation
ANZFA prepare a proposal to review the provisions for safe formulas for preterm and low birth weight infants.

7.1.1 Fat content of Preterm formulas

Issue

Dr Robert Gibson, Director, Child Nutrition Research Centre and Maria Makrides, Research Dietitian and NH&MRC fellow submitted that the requirement for fats in formula for preterm 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 preterm 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 preterm formulas by manufacturers are not ideal for preterm 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 formulas for preterm and low birth weight infants.

7.1.2 MCT content of preterm formulas

Issue

At full assessment it was proposed to prohibit MCTs in formulas for healthy infants and preterm infants. However, strong opposition was raised by industry in relation to banning MCTs in preterm formula. Pre-term formulas with high levels of MCTs are already in use in Australia and New Zealand and this provision would disadvantage preterm infants in these countries. Preterm formula is such a small market in Australia and New Zealand that banning MCTs in formulas 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 formulas. It was proposed that data at inquiry would be used to determine a potential MCT content of formulas prepares for preterm infants.

Assessment

Data was provided at Preliminary Inquiry by industry submitters as to the current levels of MCTs in preterm formula and levels of usage. Levels of MCTs in preterm formulas 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 formulas 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 preterm babies. However, no new information was presented to ANZFA that high levels of MCTs are safe and efficacious in preterm formula. ANZFA needs to evaluate the toxicological safety of MCT content of preterm 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 formulas for preterm and low birth weight infants.

7.1.3 Vitamin and mineral content of preterm formulas.

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 preterm formulas reveals highly variable nutrient contents from brand to brand. Preterm 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 preterm formulas needs safety and efficacy evaluation.

Supplies are generally determined by tendering process in hospitals.
Variable compositions in these formulas 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 the Canadian expert panel[1]. 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 preterm and low birth weight infants.

[1] 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 preterm formulas

There is a clear need for a degree of regulation in the compositions of preterm formulas as unsafe or less than ideal formulations are able to be marketed for use by preterm infants without independent review. The trend overseas is for preterm infants who are stabilised on a preterm 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 preterm formulas at home in the MIMS. Therefore the use of these formulas 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 'medical foods'. Therefore a provision is required within the Code to assist in the assessment of imported foods categorised as 'preterm formulas'. Therefore it is recommended that proposed standard be replaced by a generic permission for preterm 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 of the food standard for preterm formulas 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 formulas prepared for preterm 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'.

Issues

Nestlé Australia Ltd believe the statement on pre-term formula, that the product is suitable only for preterm 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 proposal be retained as it was 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 preterm 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 formulas for preterm and low birth weight infants.

7.2 Clause 37 - 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 other wise need to comply with the standard.

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

a) 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 formulas such as malabsorptive disorders including pancreatic deficiency, cholestasis, short bowel etc. She states that soy formula should be included in special purpose formulas. 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 malabsorptive disorders, other than disaccharide maldisgestion, e.g. lactose maldigestion, are frequently merely a symptom of an underlying immunological or metabolic condition. However, it seems necessary to provide more specifically for renal, hepatic or malabsorptive disorders.

Therefore it is recommended that this category be expanded to include renal, hepatic and malabsorptive conditions. This will have the effect of capturing the formulas specially prepared for lactose maldigesters within this category.

Soy-based formulas 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 formulas. 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 for about lactose content then the same labelling provisions required for dairy-based lactose free or low lactose formulas 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 formulas 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 malabsorptive conditions but other wise 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 formulas for which a special medical purpose claim or nutrient claim is made.

b) 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 medical foods 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 formulas 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 medical food standard category.

c) Availability

One submission recommended that nutritionally complete hydrolysed protein be available for general use.

Assessment
A designed formula based on non-food ingredients can not 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 factors will not be in action in these formulas e.g. folate- binding proteins. Elemental formulas are still experimental and should not be available for general use.

These formulas have been tested in babies for a shorter time than soy based formulas. 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.

d) Claims on thickened formulas

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 are "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 the APMIAF Panel represents a limited view. The APMAIF Panel comprises a diverse range of views and includes an independent chair, a community representative appointed by the Minister for Consumer Affairs and the Minister for Health and Aged Care, 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 formulas 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 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).

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.

1. 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 formulas 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 formulas on the market and were opposed to a warning statement on these products.

Recommendation
As no new evidence has been presented, it is recommended that the stance at preliminary inquiry remain. It is noted that submissions provide even stronger support for an appropriate warning statement on soy-based formulas. ANZFA is considering strategies in a separate project to reduce the incidence of inappropriate soy-base formula consumption in Australia and New Zealand to the level necessary on medical grounds. Strategies to limit the use of soy based formula could include targeted education initiatives. These initiatives would 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 formulas would be recommended as the preferred feeding choice. The education initiatives could stress that soy-based formulas should be used on the advice of a health professional and could include advice that this type of infant food be restricted to infants who have a special medical requirement that precludes breast feeding or modified cow's milk formulas. Other strategies to limit the use of soy-based formula could include labelling of the product and/or the reduction of an unrestricted access to soy-based infant formula without concurrent access to advice on its use.

2. 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 malabsorption of proteins. It was suggested we consider maximum levels of trypsin allowable or a denaturation process.

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 Formulas

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 (draft standard 1.5.1). 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 needs to 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 marine oils are triglycerides manufactured by marine algae genetically or environmentally engineered. Other examples of novel ingredients of concern were synthetic analogues of 5 of the 13 nucleotides in breastmilk and egg phospholipids.

Assessment
The proposed Novel Food Standard will require a safety assessment of novel foods and novel food ingredients before these foods can be offered for sale in Australia and New Zealand. The purpose of this Standard is to ensure that non-traditional foods that have features or characteristics that raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale for direct consumption in Australia and/or New Zealand.

The proposed Standard defines novel foods as shown 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;
(b) levels of undesirable substances in the product;
(c) known potential for adverse effects in humans;
(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 proposed 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 macrocomponents;
- 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 expect 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.

The proposed Standard for Novel Foods has been recommended to Health Ministers and a decision on its implementation is pending. While the Standard may be in place in the near future, the prohibition on the sale of novel foods will not take place until 18 months after gazettal of the Standard. This will enable any foods currently on the market deemed to be novel to be assessed through the normal application process.

Recommendation
Novel foods or novel food ingredients used in infant formula should be assessed for safety before use in Australia and New Zealand. The proposed Standard A19 – 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 the five years. Revised standards for all foods, except peanuts, were accepted by Health Ministers 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 level 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[1] 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.

[1] 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.

Attachment 2

DRAFT STATEMENT OF REASONS

PROPOSAL P93

FOR RECOMMENDING A STANDARD FOR INFANT FORMULA PRODUCTS

The Australia New Zealand Food Authority has before it a proposal to develop a draft standard for infant formula products for inclusion in the proposed Joint Australia New Zealand Food Standards Code.

The Australia New Zealand Food Authority recommends the adoption of the draft variation, as amended, for the following reasons:

- to protect the health and safety of infants, who are the most vulnerable group in the Australian and New Zealand population and may consume infant formula products as the sole or principal source of nourishment;
- to ensure carers have adequate information about infant formula to enable them to make appropriate choices in feeding their infant;
- to maintain consistency with advances in scientific knowledge about human milk and infant nutritional requirements;
- to ensure that innovation in the food industry that can benefit infant health is not hindered; and
- to align internationally, except where necessary to protect public health and safety of infants in Australia and New Zealand.

The drafting prepared after Preliminary Inquiry has been amended for the following reasons (Clause numbers refer to those at Preliminary Inquiry):

Purpose

- The word 'microbiological' has been deleted from this part of the standard to reflect the change to Clause 27 detailed below.

Clause 1 - Definitions

- The definitions for infant formula product, infant formula, follow-on formula, preterm formula, lactose free and low lactose formula have been altered as follows:

- Concerns were raised in submissions about the proposed definition of infant formula products stating that these are suitable as the principal source of nourishment for infants, since some products are intended for infants over 6 months of age who are being introduced to weaning foods.

- The definition for infant formula product has therefore been revised 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

- The definition of infant formula has been changed to be consistent with the intent of the draft Codex standard. The new definition is:

  an infant formula product represented as a breastmilk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months.

- The definition of follow-on formula has been changed to be consistent with the direction of the Codex standard for follow-up formula to acknowledge that it can either replace breastmilk or infant formula and to identify the place of follow-on formula in the diet of infants who are being introduced to new foods. The new definition is:
-

  an infant formula product represented as either a breastmilk 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.

- The definition of pre-term formula has been changed to accommodate concerns that pre-term formulae can be used for infants who are both born early or who are of low birth weight. The new definition is:

  an infant formula product specially formulated to satisfy the particular needs of infants born prematurely or of low birth weight.

- The definition of 'lactose free and low lactose formula' has been changed to be consistent with the format of the amended definitions. The new definition is:

  infant formula products which satisfy the needs of lactose intolerant infants.

Clause 5 – Calculation of Potential Renal Solute Load (PRSL)

- The calculation of PRSL has been modified to exclude the unavailable phosphorus content of formulae from the estimation of PRSL. The calculation has also been modified to calculate PRSL using nitrogen as opposed to protein. Comment was received that manufacturers measure nitrogen, not protein, and therefore the protein value for inclusion in the calculation of PRSL would need to be derived from the nitrogen value.

Clause 8 – Permitted nutritive substances

- The values in the table to clause 8 for carnitine, choline and inositol have been modified to correct an error at Preliminary Inquiry. The new values are 0.8mg/100kJ for carnitine, 7.1mg/100kJ for choline and 9.5mg/100kJ for inositol.
- An editorial note has also been added to note that it is the intent of the standard to regulate the maximum level of nutritive substances of formula only when the substance is added to the formula. In this case the maximum level refers to both the naturally occurring level and that which is added as an nutritive substance. This has arisen over some concerns about the setting of a maximum level for added carnitine, which some groups claimed was lower than the level of carnitine naturally present in milk.
- These nutritive substances have been defined in the preliminary provisions of the Code as 'nutritive substances' as recommended in the review of vitamin and mineral permissions. Therefore the standard now refers to 'nutritive substances' rather than nutritive substances.

Clause 9 – Limit on nucleotide 5'-monophosphates

- The figures proposed at Preliminary Inquiry for nucleotides were based upon an EC directive, which appears to have underestimated the levels of nucleotides in breastmilk. The drafting has been amended to allow for a maximum permitted total 5'-monophosphate nucleotide content of 3.8mg/100kJ as recommended in the Life Sciences Research Office (LSRO) report.

Clause 11 – Food additives

- The drafting for the permission to add carrageenan has been amended slightly to more expressly permit its addition. The wording proposed at Preliminary Inquiry was interpreted as implying that carrageenan was not permitted to be added.
- The appropriate food additives numbers have been added to the mono- and di- glycerides entry to clarify which food additives are permitted.

Clause 15 – Composition of lactose-free and low-lactose formulas

- This clause has been moved to Part 3, Division 2 – Infant formula products formulated for metabolic, immunological, renal, hepatic and malabsorptive conditions as it is more appropriately situated in this part of the Standard.

Clause 18 – Requirement for a measuring scoop

- The drafting of this clause has been amended to exempt both single serve sachets, or a package containing single serve sachets from being required to contain a scoop to enable the use of infant formula products in accordance with the directions contained in the label on the package.

Clause 19 – Required statements

- It was proposed at Preliminary Inquiry that manufacturers place a statement on the label that contained information about the superiority of breastmilk over infant formula and that formula should only be used on the advice of a medical practitioner or health worker. The actual wording of the statement was left to manufacturers to develop. There was considerable concern expressed about this in submissions. The drafting of this clause has therefore been amended to require the following statement on labels:

  Breastmilk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.

Clause 20 – Print and package size

- The drafting of this clause has been amended to classify a small package as 450g or less. This means that the wording of the warning statements and other required statements will be 1.5mm on these packages, and 3mm on larger packages. This change was made as a result of concerns with the proposal at Preliminary Inquiry that a small package was defined as 1kg, as the majority of packages of infant formula products are less than 1kg.

Clause 22 – Date marking and storage instructions

- The subclause relating to date marking has been deleted because the generic date marking provisions provide appropriate control. These provisions provide for either the use of a 'best before' date or in circumstances where health and safety concerns require food not to be used after a particular date, the generic provisions provide for the use of a 'use by date'.

- The drafting of subclause 2 has been amended to expressly require advice about correct handing of the remaining unused food in the container. This change was made as a result of concerns that carers may cause contamination or nutrient loss of the unused formula by inappropriate handling. The title to this clause has been amended to 'Storage and handling instructions'.

Clause 25 – Labelling of lactose-free and low-lactose formulas

- This clause has been moved to Part 3, Division 2 – Infant formula products formulated for metabolic, immunological, renal, hepatic and malabsorptive conditions as it is more appropriately situated in this part of the Standard. It has also been amended to apply only when claims are made about the lactose content of the product.

Clause 27 – Microbiological standards

- The microbiological standards for infant formula products will be regulated in Standard 1.6.1 – Microbiological Limits for Foods. This clause has therefore been deleted from the infant formula products standard.

Clause 30 - Fat

- The drafting of clause 30(d) has been amended to provide for the ratio of total long chain omega 6 series fatty acids (C>= 20) to total long chain omega 3 series fatty acids (C>= 20) of approximately 2 in an infant formula or follow-on formula which contains those fatty acids. This change was made in recognition of the difficulty in ensuring that the ratio is exactly 2.

Clause 31 – Vitamins and minerals

- The selenium values proposed at Preliminary Inquiry (0.36-0.9mcg/100kJ) have been modified to 0.25-1.19mcg/100kJ. The maximum level is consistent with the maximum level of selenium recommended by LSRO based upon the upper limits of selenium in breastmilk. The minimum level is consistent with the minimum level recommended in the standard for Foods for Special Medical Purposes (infants) recently adopted by the European Commission.

- The Table to clause 31 has been amended to permit the following forms of vitamins and minerals to be added:

- 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;
- Phytylmenoquinone 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

Clauses 32-35 – Pre-term formula

- There was considerable concern expressed by submitters about the levels of vitamins, minerals and fats proposed at Preliminary Inquiry for pre-term formula, particularly in the absence of any international precedents. Clauses 32-35 have therefore been deleted and replaced with the following clause:

  Preterm formula must comply with all the other requirements of this Standard that are not inconsistent with Division.

- ANZFA will raise a separate proposal to investigate the nutritional requirements of preterm infants in more detail.

Part 3 Division 2 – Infant formula products formulated for metabolic and immunological conditions

- The title of this Division has been amended to: Division 2 - Infant formula products formulated for metabolic, immunological, renal, hepatic and malabsorptive conditions. This amendment has been made to more specifically provide for formulas for these conditions.

Clause 38 – Additional labelling

- The wording of this clause has been amended slightly to require the additional labelling on the broader range of products now covered under this part of the Standard (ie products for metabolic, immunological, renal, hepatic and malabsorptive conditions) and to be triggered by 'claims' for special medical purpose rather than the manufacturers' 'intent' for the product as determined by 'specially formulated'.

Clause 42 – Other permitted additions

- The following changes have been made to the Table to clause 42:

- The appropriate food additives numbers have been added to the mono- and di- glycerides entry to clarify which food additives are permitted;
- Citric esters of mono- and di-glycerides of fatty acids are permitted for formulas based upon protein substitutes; and
- The value for DATEM was changed to correct a typographical error of a factor of 10 in the Table at Preliminary Inquiry.

Specifications for nucleotides

- As noted at Preliminary Inquiry, the specifications for nucleotides will be moved to Standard 1.3.4 – Identity and Purity.
- The provisions for bacteriological profile under part 9 of this section have been deleted as they are covered by Standard 1.6.1 – Microbiological Limits for Foods.

The commencement date of the draft standard will be October 2000.

REGULATION IMPACT

The Authority has undertaken a regulation impact assessment process that also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the draft standard is necessary, cost effective and of benefit to both producers and consumers.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed

standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter was notified to the WTO as a technical barrier to trade matter as some of the proposed revisions are more restrictive than other standards for infant formulae internationally.

DRAFT STANDARD FOR INCLUSION IN THE JOINT AUSTRALIA NEW ZEALAND *FOOD STANDARDS CODE*

(DRAFTING WILL BE INSERTED HERE)

Attachment 3

SUMMARY OF SUBMISSIONS

List of Submitters

Fifty-eight Submissions were received in response to the Preliminary Inquiry Report of P93, including consumer, public health and food industry representations. The names of submitters are listed below.

Abbott Australasia Pty Ltd
Abbott Laboratories (NZ) Ltd
Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)
Attwood, Elaine
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria)
Bowman, Diane
Bristol-Myers Squibb Australia Pty Ltd
Compston, Fiona
Consulchem Pty Ltd
Consumer Food Network of the Consumers Federation of Australia
Dairy Goat Co-operative (NZ) Ltd
Daniels, Dr Lynne, Flinders Medical Centre, Centre for Perinatal Medicine
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition
Dunstone, Mark and Smith, Julie
Embassy of the United States of America, Office of the Agricultural Counselor
Food Technology Association of Western Australia Inc.
Food Technology Association of Victoria Inc
Freyer, A G
Gastric Reflux Association for Support of Parents/Babies
Gibson, Robert A, Director, Child Nutrition Research Centre and Makrides, Maria, Research Dietitian and NH&MRC Fellow
Glare, Barbara
Guy, Camille
Home Economics Institute of Australia Inc
InforMed Systems Ltd
Institute of Environmental Science and Research Ltd, New Zealand
International Baby Food Action Network (IBFAN)
International Formula Council (IFC)
James, R F
James, Valerie
Kamerman, Marg

Killalea, Dr Sheila and Mc Neil, Dr John , Department of Epidemiology and Preventive Medicine, Monash University
Kingett Mitchell and Associates Ltd
La Leche League NZ for Breastfeeding Supports and Information
La Roche, Patricia
Ministry of Agriculture, Fisheries and Food (MAFF), UK
Marsh, Raeura
McIntyre, Gail
McVeagh, Patricia, Consultant Paediatrian
Minchin, Maureen, IBCLC
National Council of Women of New Zealand
Nestle Australia Ltd
New Zealand Dairy Board
New Zealand Ministry of Health
Nursing Mothers' Association of Australia
NZ Dairy Marketing and Customer Services
NZ Infant Formula Marketers' Association
Royal Australasian College of Physicians - Division of Paediatrics
Royal New Zealand Plunket Society Inc
Safetywize Consultants
Simmer, Karen , Neonatologist and Associate Professor
Soy Information Network
Toth, Peter
Toth, Susan
Tudehope, Dr David , Director Division of Neonatology, Mater Hospital
Parnell, W, University of Otago, Human Nutrition Department
Victorian Food Safety Council Food Standards Sub-Committee
Western Australian Food Advisory Committee
Wyeth Australia Pty Ltd

General Comments

Submittor	Comments
NZ Infant Formula Marketers' Association	- recognises that breast-feeding during the first four to six months of life is the best way to ensure good health and development of babies - where the mother does not breast-feed, or when breast-milk alone is insufficient to meet all the baby's nutritional needs, access to safe alternative foods is essential - health authorities and infant food manufacturers have responsibility to provide balanced, factual and objective information about benefits of breast-feeding and proper use of infant formula and appropriate weaning foods when needed - states infant formula cannot replicate all the qualities of breast-milk - states it is important to note that many substitutes for breast milk are totally unsuitable and often dangerous (eg. raw milk, gruels made from rice, cassava etc.) - committed to the development and implementation of appropriate infant nutrition policies based on the principles and aims of the WHO Code of Marketing of Breast-Milk Substitutes - proposal lacks balance: there is no commentary on the contra-indications of breast-feeding, after an infant reaches 6 months of age, and the benefits of complementary feeding ignored - findings concentrate on well-meaning desire for breast-feeding to be maintained during the first 12 months; totally silent on needs of 40% mothers who are not breastfeeding after 6 months - concerned about the negative impact the proposed standard may have on some members of the NZ health sector, which would impact on the NZ Ministry of Health's ability to effectively monitor the NZ Interpretation of the WHO Code

Marg Kamerman	- believes the dangers of feeding babies with artificial milk are not publicised enough - parents are not given enough information to make an informed choice regarding whether to breast-feed or not - suggests infant formula be available via prescription only - suggests WHO Code on the Marketing of Breast Milk Substitutes written into standard on infant formula - suggests women who choose not to breast-feed tend to have less education, and do not seek relevant information before making a choice - believes multi-national companies selling infant formula have huge influence and "can apply pressure and bend the rules"
Karen Simmer, Neonatologist and Associate Professor	- overall, thinks report is sound - issues a plea for ANZFA not to weaken standards further in response to pressure from industry
InforMed Systems Ltd	- concerned that standard is extremely prescriptive, significantly more so than current Codex draft revision - serious danger that standard will become outdated and require amendment
International Formula Council	- pleased to note several proposed changes to earlier drafts, which were overly restrictive and not supported by the scientific literature, were not adopted
Dairy Goat Co-Operative (NZ) Ltd	- goat milk follow-on formula will need to be significantly reformulated to comply -accept the rationale for the majority of the formulation modifications - seek a lead-in time of two years instead of the proposed 12 months to allow for product reformulation, trial production(s), and stability trials.

Consumer Food Network of the Consumers Federation of Australia	- standard needs to be considered in the light of overwhelming evidence that formula feeding of infants poses a serious risk to the health of both the infants and their mothers - infants who are formula fed are at significantly greater risk that infants who are breast fed of suffering many health conditions including infectious diseases, hypernatremic dehydration, neonatal hypocalcemic tetany and cardiopulmonary disturbances in the neonatal period, sudden infant death syndrome, allergies and chronic diseases in later life. - estimated in USA for every 1000 babies, 4 die because they are fed artificial formula (references provided) - it is likely that similar death rates from the use formula occur in Australia, which means that hundreds of babies could be dying each year as a result of formula feeding - mothers who artificially feed rather than breast-feed their infants are at increased risk of contracting pre-menopausal breast cancer, osteoporosis, cervical cancer and ovarian cancer - proposal gives approval to a number of potentially unsafe ingredients in infant formula - proposal weakens current labelling provisions - would continue to allow unethical promotion of infant formula - does not provide sufficient warning to mothers of the deleterious effects of formula feeding on the health of both infants and mothers - concerned to read in proposal that ingredients have been added to infant formula "without rigorous, objective safety assessments, which are required for other food ingredients" - urges that no untested ingredients be permitted in infant formula - where uncertainty, or varying views, on safety of an ingredient, that it not be allowed to be included in infant formula - rigorous requirements for assessing the purity of ingredients be included in the standard
Elaine Attwood	- supports Consumer Food Network submission
Victorian Food Safety Council Food Standards Sub-Committee	- supports option 2. - there are no specific provision for MRLs for pesticide residues in infant formula - only source of assurance is from Total Dietary Surveys which are limited in the range of samples analysed - the potential for endocrine disruption from pesticide residues should be assessed before a decision about pesticide MRLs in infant formula is finalised

Nestle Australia Ltd	- has always stated that breast-feeding is the best form of nutrition for babies, however it also believes (like the WHO) that there is a place for infant formula as the best alternative for those babies who cannot be breast-fed - supports AFGC submission - supports review, particularly where it accounts for updating the standard with respect to harmonising internationally and current scientific knowledge - extremely concerned that some current infant formula products could become illegal products under the proposed standard - states ANZFA has chosen not to harmonise with international regulations in some areas and have not properly justified this against the objectives in section 10 of the ANZFA Act - this will have a major cost impact on Nestlé due to the necessity for monitoring the raw materials in use, more extensive testing of products, increased inventory to allow for the appropriate testing regime, and also the cost of clinical trials - main areas of concern: * any formula that is manufactured to comply with an international regulation would be illegal within Australia or New Zealand * products that are manufactured as speciality products in an overseas manufacturing facility for global distribution would not comply with this draft standard * specific regulation of pre-term formula will create difficulties for current products. * some proposed labelling statements are not consistent with other legislation
Patricia McVeagh, Consultant Paediatrian	- as there is no medical indication for goat's milk, safe limits should not be adapted to accommodate goat milk based infant formula
Barbara Glare	- concerned that draft standard represents a weakening of the standards, and it is vital that they be strengthened
Food Technology Association of Western Australia Inc	- prefers option 2: to regulate using the proposed revised standard and codes of practice
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria)	- widely accepted infant feeding practices have, over several generations, resulted in a common perception that artificial formula is standard or normal - strongly recommend that any statement of standards for infant formula made by ANZFA be consistent with the current standards which are recognised both in Australia and globally (WHO CoP, the Maternal and Infant Care Services Standard)

Fiona Compston	- opposes draft standard, as it appears to be a weakening of the old standard, which reflects industry objections to earlier proposals - breastmilk is known to help reduce the risk of a range of cancers in both child and mother, it helps reduce gastro and ear infections in children, it helps foster a more self confident child, it is more environmentally friendly - breastmilk can ultimately save the community millions of dollars in health costs each year - there are no requirements presently to warn consumers of the adverse health consequences of feeding babies formula - provided figures from the US illustrating the costs associated with formula feeding
Food Technology Association of Victoria Inc	- agree with regulatory option 2
International Baby Food Action Network (IBFAN)	- it is premature to finalise a standard on infant formula at this time because Codex is currently revising their standard on infant formula, and Codex is also drafting Working Principles of Risk Analysis
Embassy of the United States of America, Office of the Agricultural Counselor	- requests that the proposal be held in draft form for another round of comment, which would allow for more detailed and constructive comment - have not reviewed the risk assessment or other relevant data and information underpinning this proposal - the proposed standard has various inconsistencies with standards in other counties, that would likely result in unnecessary trade difficulties
Home Economics Institute of Australia Inc.	- expressed concern at the proposed inclusion of a very broad range of unfamiliar ingredients - urge that a precautionary approach be adopted and that substances that have no confirmed benefit not be permitted until further more specific information is provided by industry
Abbott Australasia Pty Ltd	- appreciates the amendments made to the standard to bring the document in line with international standards, namely Codex and European TSMP regulations - however, still many areas in which the proposed standard remains too restrictive - proposed standard would not enable Abbott to introduce any of its current infant formulas which are available overseas - it would remove from the market those current Abbott products which are imported fully finished into Aust and sold in very small volumes

National Council of Women New Zealand	- believes in using prescriptive regulations. However, advise that care must be taken not to hinder any future development of infant formulas.
Bristol Myers Squibb Australia Pty Ltd	-strongly disagree with many points arising from the draft. -products would need to be removed from the market and reformulation would be required if the standard were adopted. -the draft is more prescriptive and lengthy- some of the requirements are not required elsewhere in the world. -implies that the present standard does not result in products that provide adequate nutrition for growth and development of the infant. - a food standard should include prescriptive conditions only where these are shown to be necessary, such as to ensure appropriate nutrient levels. - the inclusion of sections for pre-term formula, infant formula for metabolic and immunological conditions, aluminium, fluoride and infant formula based upon protein substitutes do not reflect the Codex or EC standards for infant formula. - to require reformulation of a product - evidence must be supported eg that infants are actually suffering harm at present or are in a position of real harm. - the standard for infant formula is not the appropriate place to include specifications for any particular ingredient. It purity specifications are required, they should be included in the food additives standards and be cross referenced.
Nursing Mothers' Association of Australia	- the safety, or otherwise, of formula ingredients, both proposed and current, needs to be established. - regulatory impact analysis needs to consider the effect of increased breastfeeding rates. - if regulatory standards cannot provide sufficient protection then changes to the regulatory system should be made in order that they do so. - international standards should not be used as justification for any practices in the composition, products, distribution or sale of formula that can adversely affect the health and safety of Australian infants. - submission contains conference papers from the Nursing Mothers' Association Australia's Conference (October 23-25 1997).

Mark Dunstone and Julie Smith	- the objectives set out in the issues paper for the proposed standard are not the same as those required by the legislation. The statutory objectives relating to promotion of trade and commerce do NOT provide any latitude to ANZFA to pursue the objective of "not unnecessarily hindering innovation in the infant formula industry". - promotion trade and commerce do not, even by implication, include innovation. As infants consume a fixed quantity of milk, innovation will not increase trade or commerce, and therefore innovation would not promote trade or commerce. - innovation amounts to uncontrolled experimentation on infants without informed consent. It may risk infant health. The proposed Standard is contrary to legislation because the proposed standard's requirements on "novel ingredients", "innovation" and "soy" milk place a higher priority on industry interests than on minimising adverse public health and safety risks. - the statement on page 4 - "The Preliminary Inquiry concludes that a food standard for infant formulas which protects the health and safety of infants who are routinely fed substitutes for human milk is necessary"- does not aim to discourage the routine (or even ad-hoc) feeding of infants with artificial formula. - there is evidence that infants fed artificial formula or animal milk suffer increased risks of mortality and morbidity, including in developed countries such as Australia. These adverse outcomes are from improper use of formula (ie mixing, using unclean water) but also when formula is used as directed.
Royal New Zealand Plunket Society Inc	- supports a revision to ensure health and safety of formula fed infants and to overcome barriers to trade. -are concerned with the prescriptive approach proposed. State that the proposed approach would hinder the addition, revision or deletion of individual ingredients necessary to reflect current scientific knowledge. - suggest an approach where manufacturers must conform with a NZ Standard which is consistent with Codex requirements eg in terms of permitted quantities, ingredients, safety, special needs etc. -believe self-regulation by industry is important. -compliance with the standard should be mandatory because of the importance of infant formula as a principal source of nourishment.

Parnell, W, Department of Human Nutrition, University of Otago	-it is never possible to harmonise with several international standards which are themselves inconsistent. Suggests that ANZFA follow Codex (or USA or European standards). - does not believe that the prescriptive standards will reduce costs to government. --questioned whether any infant formula manufacturers, in a highly competitive environment, are marketing an unsatisfactory product, ie a product with an inappropriate nutrient profile or a product not microbiologically safe or with undesirable contaminant levels?

Maureen Minchin. IBCLC	-expressed a number of serious concerns in relation to the consultation process undertaken by ANZFA (see submission). - this Proposal is to protect infant health. Therefore it needs to be far more stringent scientifically. -the current proposal cannot ensure the health and safety is protected and that carers have adequate information about infant formula to enable them to make informed choices in feeding their infant. - believe that infants that are not breastfed are at greater risk from a wider range of diseases and disorders, in infancy and adulthood. -states that ANZFA has produced a standard that; * creates a basic assumption of "safe until proven unsafe" as the basis for ingredients. The more conservative approach would be to require proof of safety, and so ensure that industry funds dedicated long-term studies that limit the risk of harm, from whole populations worldwide to study participants; * creates no additional costs for greater quality control or as saving to protect infant health(not even $1300 to reduce aluminium risks) for an industry which spends billions on advertising a product with an enormous profit margin; * allows every formula currently on the market to be left there until it is re-formulated at industry's convenience. * allows any formula made anywhere in the world by the major companies to be imported into Australia under threat of WHO sanctions, by "accommodating all known market levels". * allows industry to keep publishing misleading information on labels rather than including the detailed information that would assist in educating about infant formula risk, and put s responsibility for such education on to health professionals despite the evidence that almost all health workers are never adequately educated about such risks; * sets in place no provision for regular assays of product or other monitoring of industry's compliance with the new standard. - suggests a number of changes to strengthen the standard (see suggested changes under separate issues in summary of submissions).

Wyeth Australia Pty Ltd	- do not believe that ANZFA's objectives have been adhered to in the development of the standard because: * stipulating nutritional composition is overly prescriptive; * a risk based assessment is not used to determine the prescribed composition of infant formula; * many levels of nutrients are not harmonised with international standards' * information is confusing and not easily disseminated to carers. - any change to the standard needs to be risk based. - suggest urgent discussions with industry are required. - the current draft of the standard may contravene the WTO requirements to allow products that are safe.
La Leche League NZ for Breastfeeding Supports and Information	- urges including the strongest possible protection for breastfeeding when considering a standard for infant formula
MAFF UK	- EU Directive sets a maximum limit of 0.01 mg/kg for individual pesticides in infant formula and follow-on formula, and prohibits the use of more toxic pesticides in the agricultural products intended for their manufacture

Issue: Composition of Infant Formulae

General comments on composition of infant formula

Submittor	Comments
New Zealand Dairy Board	- believe that probiotics (oligosaccharides) are significant components of human milk and have a number of benefits, so their inclusion in infant formula could be beneficial
Nursing Mothers' Association of Australia	- any foods produced using gene technology should be labelled as such to allow mothers to make an informed choice for infant feeding - the safety of the ingredients needs to be established - if safety is not established product information should carry an easily visible and easily understood message warning that the ingredient is experimental and side effects have not yet been determined

Issue: Use of Novel Ingredients in infant formula

Submittor	Comments
Nestle Australia Ltd	- does not agree with proposal - suggests ANZFA also needs to accept a history of use overseas - if Aust/NZ is retained, then ANZFA needs to ensure that there is a minimal approval time for a novel ingredient, which should be a maximum of 3 months; expect ANZFA to accept data sourced from overseas as part of an application
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria) and Fiona Compston	- proposed acceptance of untested 'novel' ingredients, including LCPUFAs, is too lax - any artificial formula sold with 'novel ingredients' should carry large warning messages that the ingredient is experimental, and the appropriate consent arrangements be put in place for its use, consistent with other medical clinical trials in humans
Mark Dunstone and Julie Smith	- experimentation and innovation should not be allowed by the Standard - unlike older children and adults, babies are not normally exposed to other foods - allowing the inclusion of "novel ingredients" on the basis of a history of safe consumption of similar food by adults or older children is unsatisfactory - such experiments should be conducted under appropriate, designed, approved and supervised clinical trials with the informed consent of the parties involved
Bristol Myers Squibb Australia Pty Ltd	- if a substance is classed as a food then it is suitable for use in a food. If this food is widely used elsewhere in the world, in the same or similar applications, there needs to be a strong argument put forward why it cannot be used in Australia - as we are signatories to world trade agreements and trade in a global marketplace, Australia cannot arbitrarily impose isolationist restrictions.
Wyeth Australia Pty Ltd	- novel nutrients are often identified initially as components of breast milk and then investigated for clinical benefit through clinical appraisal for addition to infant formula. The safety of such nutrients should not be unfairly constrained by the safety standards that apply for novel food additives - novel nutrients are added for nutritional benefit, therefore, a 100 or even 10 fold no-observed effect level (NOEL) cannot be applied to nutrients in assessing novel safety - safety assessments of novel nutrients must be made at human milk levels (with average for manufacturing)

Winsome Parnell, Department of Human Nutrition, University of Otago	- would not discount retaining a variation of Option 1 ie retaining a general recommendation such as Regulation 242 in the New Zealand Food Regulations 1984, with any necessary generic prohibitions such as on novel ingredients, not safety tested.

Issue: Lactic acid cultures

Submittor	Comments
Nestle Australia Ltd	- supports permission to add L(+) producing lactic acid cultures to infant formula; in line with Codex

Issue: Addition of nucleotides to infant formula

Submittor	Comments
Maureen Minchin IBCLC	- synthetic analogues of 5 of the 13 nucleotides in breast milk are already in infant formula in Australia, despite the fact that this breaches existing law - parents are mislead into believing "marine oils" come from healthy fish, not algae. considerable consumer resistance could be expected to a product manufactured by these organisms. - proof of benefit to infants, and absence of longer term harm in childhood, must be demonstrated before widespread use of novel products in infant formula - it is a decade since Bristol Myers warned that nucleotides might hyper-stimulate the immune system and lead to greater rates of allergic disease. Not a single study has evaluated this possibility - misleading advertising campaigns eg in the UK which implied that now "immune factors" were added to formula and had "bridged the gap" with breast milk must be prevented. This must be prevented to ensure breastfeeding rates are not affected. ANZFA needs to provide for national penalties and corrective advertising
New Zealand Dairy Board	- agree that it is appropriate that specifications are included in the joint standard - nucleotides are found in human milk and there are many suggested benefits - recommends levels as per breast milk

Abbott Australasia Pty Ltd	- proposes following changes to nucleotide levels (in mg/100kJ): cytidine 5′-monophosphate 1.56 uridine 5′-monophosphate 0.89 adenosine 5′-monophosphate 0.72 guanosine 5′-monophosphate 0.84 inosine 5-monophosphate 0.24 - proposed levels are based on Abbott research (included in submission) and are in alignment with current literature (additional information included on nucleotide production and toxicological data on nucleotides, plus relevant published information on nucleotides)
Wyeth Australia Pty Ltd	- provided specifications for 5 nucleotides for the preliminary inquiry. - recognise that the moisture specification and bacteriological profile may be redundant, as they are included in the finished product specifications - Division 5 - General Microbiological Requirements.
Bristol Myers Squibb Australia Pty Ltd	- the standard for infant formula is not the appropriate place to include specifications for any particular ingredient. This applies to nucleotides as much as any other ingredient. If purity specifications are required, they should be included in the food additives standard and be cross-referenced.
Nursing Mothers' Association of Australia	- the safety of specific nucleotides and other ingredients needs to be established. If not, the product should carry an easily visible and easily understood message warning that the ingredient is experimental and the side effects have not yet been determined.
Abbot Laboratories (NZ) Ltd	- believes the nucleotide levels in Standard R7 are too low and proposes to increase the maximum permitted nucleotide levels (see submission for levels). - the proposed levels are based on Abbott research and are in alignment with current literature (attaches a report from LSRO). States that science has evolved considerably with respect to the analysis of nucleotides and that past analytical techniques have greatly underestimated nucleotide levels in human milk. - products containing the proposed higher nucleotide levels are available elsewhere in the world (excluding the EU, Singapore, Malaysia and New Zealand). - currently international trade in infant formulas is limited to New Zealand and Australia by the maximum nucleotide limits. Applaud the inclusion of the current EC limits for the compounds but recommend flexibility to allow alignment with international limits. Without such flexibility the international trade in infant formulas will remain restricted.

Issue: Cadmium and Lead

Submittor	Comments
Maureen Minchin, IBCLC	- questioned whether the 1989 studies of Canadian and Belgian infant formula revealed levels of cadmium that were of concern. Pointed out that the fact that raw materials are low in cadmium does not mean there is no risk of high cadmium levels in a heavily processed product - welcomes the restriction on lead. It is strange that cadmium, which is also widespread in the modern environment, is cumulative in bodies and has long-term irreversible effects is not also restricted

Issue: Lactose free

Submittor	Comments
Abbott Australasia Pty Ltd	- current testing methodologies do not possess a detection limit of zero for lactose, therefore the requirement for any formula deemed to be 'lactose free' to not contain any detectable lactose is queried

Issue: Protein

Submittor	Comments
Nestle Australia Ltd	- protein level set at 0.45mg/100kJ. Codex level is 0.43mg/100kJ - Codex level should be adopted to ensure a harmonised approach - declaration of source of protein appears to be overly prescriptive, particularly when manufacturers include the ingredients in the ingredient statement (discusses in detail, cow's milk vs other sources, Fair Trading laws, Proposal P156 Naming of Foods, etc.) - objects to placing maximum levels for some nutrients even where the nutrient is not added (natural components of milk-based products contain choline and carnitine) - seasonal variation would render some Nestlé products illegal at certain times each year (graphs included to support claim), including products containing whey powder - it is impossible to formulate within these levels (detail on process included)
Infant Formula Council	- concerned that caline content in the reference amino acid composition of human milk is much higher than the reference cited by the EU (4.5g/100 g of protein) - suggest that 4.5g/100 g protein is more accurate

Dairy Goat Co-operative (NZ) Ltd	- goats milk infant formula and follow-on formula will be required to be supplemented with at least two amino acids (tryptophan and cystine) - levels stated are not consistent with EU directive in that the concentrations of methionine and cystine can not be added together in the proposal. Adoption of EC directive protein quality requirements would mean there would be no requirement to add cystine to these products - strongly opposed to amino acid fortification of goat milk infant formula and follow-on products - no evidence to suggest that protein quality of these products is inadequate - concerned about additional risks that can be associated with amino acid fortification (enclosed information on L-tryptophan) - suggests that protein quality requirements be included in the final standard, but that products that use unmodified cow or goat milk protein be excluded from meeting these requirements - if amino acid fortification is required, a minimum lead-in time of two years is sought (three being preferable), as sources need to be found, suitable modes of addition developed, impact on product flavour and stability investigated (in this context, shelf-life of these products is currently three years)
Maureen Minchin IBCLC	- Questioned whether ANZFA was aware of the research that indicates that the standard but excessive protein content of infant formula and its unphysiological amino acid patterns is linked with brain deficits. -indicated that there is evidence that autism is related to casein intolerance. -expressed concern about parents giving their infants (under 6 months of age) follow on formula (which is often cheaper), particularly when the protein level is almost double that meant for this age group. Questions whether anyone will monitor RSL's of infant formula independently or whether industry will do this. - ANZFA needs an intensive education campaign addressing the changes to the infant formula standard and particularly pre-term formula. -believes that ANZFA has legal duty of care to state on the can: "This product contains a level of protein that can be dangerous to infant bowel, kidney and brain. Medical monitoring of infants using this product is essential".

Issue: Levels of total fat in infant formula

Submittor	Comments
International Formula Council	- endorse proposed expanded fat range of 1.05 - 1.5g/100kJ
Abbott Australasia Pty Ltd	- question the rationale for the very narrow fat range (1.05 – 1.5g/100kJ) allowed for infant formula - there is extensive, on-going research, as well as controversy regarding fats in infant formulas - unnecessary restrictions on fat levels and sources of fat for infant formulas could prevent significant progress in infant nutrition - would like to propose a minimum level of 0.8g/100kJ which is the level stated by Codex and the EC for follow-on formula
Dairy Goat Co-Operative (NZ) Ltd	- to meet the ALA requirements, fat blend will need to be reformulated

Issue: Addition of Long Chain Polyunsaturated fatty acids to Infant formula

Submittor	Comments
Western Australian Food Advisory Committee	- it is recommended that the proposed standard be adopted, with the amendment that the Codes of Practice be adopted by reference (ie. become mandatory)

InforMed Systems Ltd	- it is true evidence for benefit for LCPUFAs is not yet conclusive, but more recent studies are increasingly persuasive - arachidonic acid produced by fermentation technology from single-cell sources has been approved in major overseas jurisdictions and levels resemble those in human milk. Can see no justification for further restrictions on their use - while there may be evidence that ARA:DHA ratio in human milk is roughly 2:1; it would be extremely improbable on biological grounds that such a ratio would be so precisely fixed - requiring such a precise ratio is technologically infeasible. If a definition is required, it should include 'roughly' or 'approximately' - it seems unlikely that a manufacturer would deliberately use a ratio markedly divergent from this value because of the use of human milk patterns as a model - table values are puzzling; the predominant VLC omega-6 acid is arachidonic acid, so setting a value of 2% but only 1% for ARA seems illogical - recommends entry for ARA be deleted - although reports (Koletzko in Germany) reported values of ARA and DHA well under 1%, in more primitive circumstances values for ARA over 1% have been recorded - recommends option 2 be adopted with the deletion of the line on ARA
Nestle Australia Ltd	- no good scientific data showing benefits of addition of LCPUFAs to follow-on formula and the scientific data is still being evaluated with respect to starter formulas - EU directive does not permit addition of LCPUFAs to follow-on formula and this permission should be deleted for follow on formula - acknowledged that there is a provision for these to be added into infant formula within the EU Directive - option 3 (ratio requirement 2:1 for total long chain n-6 to total long chain n-3 for C≥20) is extremely prescriptive requirement; variation in the natural sources of LCPUFAs and the errors involved with analysis will make this requirement extremely difficult to attain (data supplied) - this provision would constitute a barrier to trade
Patricia McVeagh, Consultant Paediatrian	- option 3 is preferable - should recall there are a number of PUFA in human milk and that they share the same desaturase enzyme - we have learnt the hazards of adding only one PUFA
New Zealand Dairy Board	- agree that the preferred option is option 3 - agree that there needs to be some suitable purity specifications for LCPUFAs, which assure the safety of the LCPUFAs

Food Technology Association of Vic Inc	- agree with option 3 on general policy issues – LCPUFAs
Wyeth Australia Pty Ltd	- agree with option 3 to amend express permission proposed at full assessment "to align with the EC and UK but require a series 6 to series 3 ration of 2 as in human milk' - believe LCPUFAs in infant formula have demonstrated beneficial effects on early infant development
Nursing Mothers' Association of Australia	- concerned about unpurified constituents in infant formulas - particularly for the addition of LCPUFAs and nucleotides - the long term safety of all optional ingredients needs to be established by well designed trials before allowing them to be added to formula
Bristol-Myers Squibb Australia Pty Ltd	- acknowledge the addition of VLCPUFAs is contentious. BM indicate that it is the actual levels of two fatty acids, docosahexaenoic acid (DHA, 22:6 n-3) and arachidonic acid (AA 20:4 n-6) and the ratios of one to another - research indicates that dietary and geographical factors influence the levels and ratios of DHA to AA in human milk. Codex has not set a ratio level. It would be premature to set a fixed ratio on present evidence as they can be difficult to change at a later date - recommends that ANZFA include levels and ratios but that these are not prescribed in the standard.

Robert Gibson Director , Child Research Centre Maria Makrides Research Dietitian & NH&MRC Fellow	- indicated there is no scientific basis for having one aspect of option 3 as the preferred option - indicated that the ratio of n-6:n-3 LCPUFAs in the breast milk of Australian and American mothers is currently about 2:1 but this is entirely a phenomenon of the current diet in these two countries. Examples given of how the ratio varies in different countries according to the diet of the mothers. - recommend that the Authority have the maximum levels of LCPUFA in formulas as shown in Option 3 (n-6 LCPUFA - max 2%; 20: 4n-6 - max 1%; n-3 LCPUFA - max 1%) but NO ratio IMPLIED for n-6:n-3 - oils containing n-3 LCPUFA should have a ratio of DHA to eicosapentaenoic acid (EPA) of at least 2 so that high EPA oils such as Maxepa are not used in infant formula - If the committee had reservations about this it could add the expression: "If n-3 LCPUFA are added to infant formula, n-6 PUFA should be added in such a way as to prevent a decline in the arachidonic acid (AA) status of the infant (as measured by plasma total fatty acid) below that of infant fed unsupplemented formula". In that way, manufacturers have the option of adding either AA itself or a precursor of AA in order to maintain plasma AA levels in the infant. - table to clause 30 is accepted without qualification - the suggestion that fats in formula for preterm infants must comply with the fats in formula for term infants is not based on scientific evidence. There is little known about the fat requirement for term infants. EG the accretion rate of DHA of an infant in utero is such that the fats in the formula should contain at least 1% DHA and not the 0.25% in current preterm formula. Therefore, it is incongruous to be basing the fat composition of formula for preterm infants on the fats that are in breast milk of mothers who gave birth to term infants. It is clear that this model was totally inadequate for dietary protein, calcium, iron and many other nutrients for preterm infants, and there just isn't the data available to be making these recommendations for the fats for preterm infant.
Maureen Minchin IBCLC	- option 3 is the only option consistent with ANZFA's primary duty for care of infant health - ANZFA needs to work with APMAIF to restrict industry claims being made to suggest that LCPUFAs alone account for better cognitive development. There is no evidence to date of better cognitive development in term bottle-fed infants.

Issue: Use of medium chain triglycerides in infant formula

Submittor	Comments
Karen Simmer, Neonatologist and Associate Professor	- to ban the addition of MCT to preterm formula is not based on evidence
InforMed Systems	- if there is evidence that these substances are dangerous for preterm infants they should be prohibited, otherwise the presence or absence should be left to the judgement of those using these special products - Codex does not having any restrictions on MCTs
NZ Dairy Marketing and Customer Services	- endorses recommendations of ANZFAs expert panel that MCT be present to a maximum of 10% total fatty acids in infant formula. However, do not agree that MCT from vegetable oils should not be permitted. An imposition of a maximum MCT content of 10% fatty acids would provide a practicable way of controlling the level of MCT in infant formula products without targeting the vegetable oil industry. The current MCT levels in vegetable oil blends used in infant formula range from less than 1% up to 8%. MCT is present in coconut oil which is used in many of the vegetable oil blends currently used in infant formula. It is also present, to a lesser extent, in other vegetable oils. - represents a barrier to trade
International Formula Council	- endorse decision to permit addition of MCT to specific dietary use formulas - remain concerned regarding the prohibition regarding the addition of MCTs to other formulas
Victorian Food Safety Council Food Standards Sub-Committee	- agrees that there have been no adequate long term studies on MCTs and these should be prohibited - it is not clear how this provision will provide for current formulas that contain added MCTs - since provision only provides for levels of MCTs naturally present the interim measure is supported
New Zealand Ministry of Health	- supports approach, particularly that evidence must be presented to ANZFA to show MCTs at currently used levels are safe and efficacious
Nestle Australia Ltd	- disagree with prohibition on use of MCTs in formulas for healthy infants and for pre-term infants. This would make pre-term formula manufactured by Nestlé illegal - provided details of MCT content of their formulas and units sold in Australia and New Zealand - literature review on favourable effect of MCTs

Wyeth Australia Pty Ltd	- on the basis of risk assessment, there is no evidence that the health and safety of low birth weight babies has been compromised by inclusion of MCT to their formula. - provided details of MCT content of their formulas and units sold in Australia and New Zealand - provided details of specific studies that had shown beneficial effects of MCTs (see submission). - the current draft Standard provides for an MCT content that is the natural constituent of the milk based ingredient of formulas. The Vegetable fat blends used in most infant formulas contain MCT as natural components, therefore the draft standard should provide for a MCT content that is the natural constituent of the plant or milk-based ingredients. - provided some background on MCT and their metabolism (see submission).
Robert A Gibson Director, Child Nutrition Research Centre Maria Makrides Research Dietitian and NH&MRC Fellow	- recommended that MCTs be permitted to be added to all formulas - up to 20%. Could see no scientific reason for preventing their use. commented that there are about 15% MCT in breast milk fats (albiet of more complex structure than coconut oil). - acknowledged initial concerns that if MCT's were too high then infants may become EFA deficient, that evidence about the absorption of MCT was poor and that high levels of MCT meant that the fat composition deviated too much from breast milk.
Maureen Minchin IBCLC	-sees no reason to permit high levels of MCT if there is any health risk and because companies are making and selling these products. -if there were to be any danger of restricted supply of formula the requirement could have a lead in time of 3 years for industry to reformulate. - all novel food ingredients - those not natural constituents of the milk-based ingredients of formula should be proven to be safe and efficacious prior to addition. - permitting nucleotides while prohibiting MCTs would be discriminatory.

Bristol Myers Squibb Australia Pty Ltd	- do not agree that the use of MCFA should be prohibited. BM is not aware of any manufacturers lowering the content of MCT in their infant formulae and have no plans to do this themselves. The proposal to change existing products of longstanding is highly questionable. - prohibition of MCFA in infant formula is totally inappropriate as they are found in human milk (4-12%) depending on which fatty acid groups are included, animal and vegetable fats. The fatty acid profile of human milk will vary - however the aim of infant formula manufacturers is always to match a "typical" profile of human milk fat as closely as possible. The amount of MCFA added will only be added to match the typical profile. MCFA are expensive therefore their addition in formula is self limiting. - the fact that MCFA are not normally present in large quantities in human milk is essentially irrelevant as an argument. Bovine albumin and B-lactoglobulin are not present in human milk - the nitrogen is present in the form of human milk proteins and significant quantities of non-protein nitrogen. - up until now cows milk protein has been accepted as a relatively safe, inexpensive and convenient form of protein to use in an infant formula. MCT's can be viewed in a similar light when regarding the special needs of infants where there are concerns with fat malabsorption. MCT's have been used for 30 years in several Mead Johnson formulations. Several studies confirm the efficacy and safety of the use of MCT's in the standard. - provided details of MCT content of their formulas and units sold in Australia and New Zealand
Nursing Mothers' Association of Australia	- health and safety of infants needs to be the primary consideration at all times. The argument that pre-term infants may be disadvantaged by disallowing MCT's needs to be clarified to ensure that it is infant health which is the main consideration here, and not the industry market share.
Abbott Australasia Pty Ltd	- proposed prohibition of MCT is inappropriate, particularly for pre-term formulas - improvement of lipid absorption with MCTs in the pre-term infant has been documented in the scientific literature - provided details of MCT content of their formulas and units sold in Australia and New Zealand

Issue: Trans fatty acids

Submittor	Comments
NZ Dairy and Marketing services	- 4% would require modification of some oil blend currently in use. It is recommended that a max level of 8% TFA be imposed for an intervening period of 2 years to enable any required modifications to oil blend compositions to be introduced with sufficient time to enable clinical trials and evaluations of stability to be completed.
Nestle Australia Ltd	- limitation of a maximum of 4% trans fatty acids in infant formula may exclude use of significant amounts of milk fat - natural levels of trans fatty acids in milk fat can be as high as 6-7% of total fatty acids - trans fatty acids can also occur at these same levels in human milk

Issue: Fatty acids: alpha-linolenic acid

Submittor	Comments
International Formula Council	- endorse decision to reduce proposed minimum to 1.75% of total fatty acids
Nestle Australia Ltd	- EU Directive and draft Codex standard specifies the minimum alpha-linolenic acid at 12mg/100kJ which is approximately 1% of the total fatty acids - consideration needs to be given to harmonising with these standards to ensure that the obligations under WTO are met

Issue: Linoleic acid to alpha-linolenic fatty acid ratio

Submittor	Comments
International Formula Council	- endorse proposed ratio of not less than 5:1 and no greater than 15:1

Issue: Valine

Submittor	Comments
Abbott Australasia Pty Ltd	- valine content of 5.5g/100kJ of protein is much higher than the reference cited by the EU (4.5g/100kJ of protein) - believe 4.5g/100kJ of protein is a more accurate value

~~**Issue: Vitamin and mineral supplementation**~~

Issue: General comments

Submittor	Comments
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- monitoring required to ensure that good manufacturing practice occurs - see no problem in having the same level of vitamins and minerals in special formula as in formulas for healthy infants - special need cases would be monitored on an individual basis
Karen Simmer, Neonatologist and Associate Professor	- the removal of maximum levels for many nutrients is not acceptable
NZ Dairy Marketing and Customer Services	- recommended guideline for maximum level of vitamins and minerals in infant formula products is commended
International Formula Council	- commend evaluation of maxima for individual nutrients, and recommending levels for vitamins and minerals on basis of significant risk to infants, while establishing advisory guideline maximum levels for other nutrients
Dairy Goat Co-Operative (NZ) Ltd	- goat milk infant formula will require some minor modifications to levels of some vitamin and mineral additions - this could lead to an increased price to the consumer
Victorian Food Safety Council Food Standards Sub-Committee	- supports approach, however subsequent to the preliminary inquiry report, the EC has adopted a standard for infant formulas for special medical purposes that sets levels for 13 vitamins and 15 minerals - it would be of value to first examine the arguments for setting levels for all vitamins and minerals in the EC directive (1999/21 of 25.03.99)
Nestle Australia Ltd	- agrees there is a need to impose maximum limits on vitamins and minerals where there is a health and safety issue involved - guideline levels should not become pseudo legislation - where the minimum and maximum levels are different to the EU requirements, then formula that is manufactured in Europe would hardly ever comply to the requirements of the combined Aust NZ standard (uses example of copper) - findings of LSRO report based on some of the maximum levels on the 90th centile found in infant formula in the USA; there has been no health and safety reason for imposing the maximum limits on some of these vitamins and minerals
Patricia McVeagh, Consultant Paediatrian	- the LSRO report developed for the Center for Food Safety and Applied Nutrition, Food and Drug Administration (reference included) addresses many of the issues raised

Maureen Minchin IBCLC	- if ANZFA goes with average ingredients rather than ranges of expected maxima and minima, it must be clearly stated that these are NOT actual averages calculated by batch assay, but expected averages for this brand when made to the company's specified recipe. - ranges are less misleading and useless for clinical purposes. - nutrition information panels take up space which could be better used to give clear instructions and warning s in many languages. - recommend that nutrition information panels be abandoned. Community health workers on the ANZFA teleconference agreed here - opposed to only having advisory guidelines. - maximum levels should be set for every ingredient where this is currently possible and made mandatory for all infant formula. - as the EC Directive on Dietary Foods for Special Medical Purposes , heavily influenced by industry, specifics a narrower range of vitamin and mineral levels, these minima and maxima are clearly achievable - compliance should be monitored by an independent agency. If advisory maxima are allowed for any ingredient, widespread publication of the mandatory monitoring results should advise consumers about products which breach the advisory maxima
Bristol Myers Squibb Australia Pty Ltd	- agree with the present nutrition information panel requirements, however questions the use of the nutrition information panel for the parent who uses the information. If every formula has relatively narrow compositional guidelines to meet at present, is this panel used for comparison with other brands? The panel appears to be presented to reassure the parent that the nutrients are in the product. - it seems unnecessary to add a column of nutrients per 100g of powder per 100ml of concentrated liquid. The change would impose an enormous cost upon industry, affecting every single product on the market.
W Parnell, Department of Human Nutrition, University of Otago	- comments that the statement "recommended mandatory maximum levels be set for those vitamins and minerals which are considered...." for the reason of "eliminating unnecessary costs for industry" is wide off the mark of commercial reality - comments that no food industry uses resource unnecessarily
Nursing Mothers' Association of Australia	- the long term safety of vitamins and minerals needs to be established before allowing them to be added to formula.

Wyeth Australia Pty Ltd	- maximum levels should be determined by risk assessment and harmonisation with international standards - inference of unlimited nutrient contents for infant formula without R7 regulation is unrealistic and misleading, as all infant formula manufacturers are committed and legally bound to producing safe products both at common law and under various State and Federal Legislation - it is not appropriate to state that human milk has a self-limiting level for all vitamins and minerals. The composition of human milk varies considerably, dependent on maternal diet, stage of and even during a feed. The setting of maximum levels should therefore, be based on risk assessment. Advisory maximum levels which are recommended for nutrients whose risk is insignificant should not be included in guidelines. Although guidelines do not have force of law, compliance is expected to be monitored. The question arises of who will monitor compliance, monetary constraints within government agencies and even industry make the process seem unlikely and it adds unnecessary complexity and prescription to the Standard. (see references)

Issue: Selenium

Submittor	**Comments**
Karen Simmer, Neonatologist and Associate Professor	- suggests available data does not support proposed maximum and minimum selenium values - RDI for selenium (Aust) is 10µg/day, equivalent to amount a breastfeed baby receives. Lower levels may meet nutritional needs of infants - cites Adelaide: breastmilk selenium 13±4µg/l (mean±SD) and formula selenium varies from 3-10µg/l.
International Formula Council	- recommends a higher max of at least 1.1mcg/100kJ, if selenium is added to infant formula - establishing a selenium maximum based on added selenium would enable continued use of manufacturers' existing premix systems, which has been shown by experience to be safe and reliable. It is critical to add selenium in an accurate, safe and reliable way because the range between adequate selenium and potentially selenium toxicity is relatively narrow. The most accurate, safe and reliable way to add selenium to infant formula is via a premix

InforMed Systems	- selenate: studies available on the bioavailability of selenate (reference given); papers suggests selenate may be better absorbed than either selenite or selenomethionine - it may be preferable to set a lower level for selenate on the basis of that study, but not to prohibit its use
NZ Dairy Marketing and Customer Services	fortification of some current formula will be required, which will incur additional monitoring costs
Dr Lynne Daniels, Flinders Medical Centre, Centre for Perinatal Medicine	- submits that infant formula should permit supplementation with either selenate or selenite to the levels proposed [note: detailed submission on selenium, including 30 references]
Nestle Australia Ltd	- sodium selenate is a permitted form within New Zealand Food Regulations and the EU Directive for infant formula. If sodium selenate is not permitted, formulas manufactured in NZ and Europe would become illegal products - sodium selenate is a more stable salt and is less sensitive to reduction to the inactive selenium by ascorbic acid (references included) - limits proposed for selenium are rather narrow based on the analytical methods available and the varying level of selenium found in raw materials
Abbott Australasia Pty Ltd	- limit to the amount of added selenium in infant formulas is still too low - due to variations of selenium in soil, and therefore raw materials, a higher maximum level is needed - selenium in human milk varies, depending on geographic region and maternal selenium intake - proposed level of 1.19mcg/100kJ, which is in line with LSRO recommended maximum of 5.0mcg/100kcal - level is consistent with the levels found in human milk from women consuming foods from selenium adequate areas, and their infants have no problems with this level - proposes inclusion of sodium selenate as a permitted form, in line with EU Directive

Abbott Laboratories (NZ) Ltd	- agree that it is appropriate to limit the amount of added selenium in infant formulas. -state the new limit still remains too low given the natural variation in selenium content in soils and therefore the raw materials used in the manufacture of infant formulas. -propose a maximum level for selenium of 1.1ug/100KJ because it is consistent with the level found in human milk from women consuming foods from selenium adequate areas. The level is also in line with the LSRO (Life Sciences Research Office) recommended maximum of 1.19ug/100KJ. -propose the addition of sodium selenate as an allowed selenium fortifier in accordance with EC Directive 91/321/EEC Annex III.

Issue: Manganese

Submittor	**Comments**
International Formula Council	- pleased an advisory guideline maximum level is recommended for proximate modified human milk substitutes - concur the required maximum is not warranted - remain concerned that proposed manganese maximum for preterm formulas is unchanged at 1.8mcg/100kJ; recommendation should be rescinded or justification for this recommendation provided
Abbott Australasia Pty Ltd	- preterm formulas have not been addressed in the proposed standard - do not support proposed maximum levels for preterm formula

Issue: Aluminium

Submittor	**Comments**
International Formula Council	- endorse decision to raise proposed aluminium max for non-soy formula to 0.5mg/L
NZ Dairy Marketing and Customer Services	- additional monitoring costs will be incurred
Maureen Minchin IBCLC	- the lower level should be universal, not the higher - $1300 per annum is not too much to pay for assays that ascertain industry compliance with aluminium and cadmium levels

Nestle Australia Ltd	- prescription of an aluminium level is consistent with international regulations - if there is no issue with the level of aluminium proposed for soy-based products, then there should be one limit only - in keeping with WTO obligations, it would be more suitable to retain the aluminium levels in a guideline
Bristol Myers Squibb Australia Pty Ltd	- suggest there is no international agreement on limits for aluminium. There has been no demonstrated danger to public health and safety with present levels of aluminium under the present standard - any level imposed, must be regarded as a public health and safety issue and supported with clinical evidence that present levels are actually harmful. If this is the case, then one level of aluminium must be applied to all formulae. To do otherwise is inconsistent. The level set also needs to be achievable. ANZFA needs to consult with industry to set this level.

Issue: Fluoride

Submittor	**Comments**
International Formula Council	- endorse decision not to set a maximum for fluoride
InforMed Systems Ltd	- function of advisory label on high fluoride seems superfluous - if unnecessarily high fluoride levels might be present, this should be addressed in an entry in the table of permitted levels of vitamins and minerals, giving a max level of 17µg/100mL - Codex makes no reference to fluoride
NZ Dairy Marketing and Customer Services	- additional monitoring costs will be incurred

Dr Sheila Killalea, Dr John McNeil, Department of Epidemiology and Preventive Medicine Monash University	- there is increased evidence to suggest that prolonged intake of infant formula may contribute to dental fluorosis, which is increasing in prevalence in Australia and many other countries (references included) - fluoride intake from infant formula reconstituted with low-fluoride or optimally-fluoridated water may exceed the recommended intake in infancy, in some cases, more than two-fold (included information on estimates of intakes in fluoridated and non-fluoridated areas for children up to one year of age) - reduction of dry formula fluoride level to negligible amounts would reduce fluoride intake from this source by up to 30% - acknowledges that many factors may contribute to the increase in dental fluorosis, and that a multifaceted approach to the reduction of inappropriate ingestion of fluoride is needed. Nevertheless, feels there is sufficient evidence to warrant a limitation of the fluoride content of infant formula at this time (references included) - suggests two ways of limiting excessive fluoride intake from infant formula: * regulate the fluoride content of water used at the manufacturing site, which some manufacturers already monitor
Dr Sheila Killalea, Dr John McNeil, Department of Epidemiology and Preventive Medicine Monash University (cont)	* infant formula be reconstituted with low-fluoride water in a natural or artificially fluoridated area; would add to cost of infant formula if distilled or mineral water has to be purchased; likely to result in variable compliance; less effective method of lating rise in prevalence of dental fluorosis in Australian children
New Zealand Ministry of Health	- received expert advice on this issue - the upper limits for fluoride are, although on the high side, acceptable - advisory statement required under clause 24 should refer to "a dentist"; although preference would be to delete reference to a medical practitioner or other health professional, as there is some confusion amongst health professionals on this issue
Nestle Australia Ltd	- do not agree that there is a need to include advisory statements on products regarding fluoride and dental fluorosis - no international equivalent legislation and would constitute a technical barrier to trade
National Council of Women of New Zealand	- suggest a regulated required maximum level should be determined

Bristol Myers Squibb Australia Pty Ltd	- fluoride is not mentioned in either the Codex or EC standards - if fluoride intake by infants is truly a public health and safety issue, the fluoridation of the water supply around Australia needs to be reviewed - concerns have been expressed previously regarding the safety of fluoridation of water supplies; in this case, a level of intake of 1mg fluoride per litre of formula from the powder or concentrate was regarded as the proper limit of safety, assuming the water itself contained 1mg fluoride per litre - this translates to approximately 36ug fluoride per 100kJ for a routine formula, compared to the 17ug/100kJ in the draft; this level is unnecessarily low

Issue: Tocopherols

Submittor	**Comments**
International Formula Council	- endorse decision relative to food additives, to allow for carryover from ingredients - concur the antioxidant, mixed tocopherols concentrate, should be allowed up to 1mg/100mL

Issue: Zinc to copper ratio

Submittor	Comments
International Formula Council	- endorse proposed ratio of 12:1
Nestle Australia Ltd	- ratio will mean that the majority of Nestlé products will be illegal under this draft standard - ANZFA is obviously not aware of the current situation in Australia - recommends that 20:1 be adopted, as per LSRO report - ratio not included in Codex or EU Directives, therefore be considered a technical barrier to trade with no scientific justification for its inclusion

Issue: Permitted form of nutrients

International Formula Council and Abbot Australasia Pty Ltd	- object to a prescriptive list of nutrients, which prohibits the use of any nutrient or source not listed - can disrupt and impair the development and provision of special infant formulas for those vulnerable infants who critically need them - standard should be based on practical and timely criteria which would allow new nutrients based upon science to be used - such a standard would enable use of ingredients when approved by major authorities (eg. Codex, US FDA, EU)
Nestle Australia Ltd	- nicotinic acid is currently allowed as a permitted form of niacin in the EU Directive, NZFR, and Codex. Should be a permitted form within draft standard - magnesium citrate and magnesium hydroxide are permitted forms of magnesium and sodium selenate is a permitted form of selenium in both NZFR and EU Directive - cupric citrate, cupric carbonate and copper-lysine complex are allowed forms of copper in NZFR and EU Directive - chromic chloride is a permitted form of chromium in NZFR, have information that form of chromium sulphate is not always readily available
Wyeth Australia Pty Ltd	- permitted forms of nutrients should be harmonised with the EU and Codex standards - includes list of permitted forms in table - see submission

Issue: Iodine

Submittor	Comments
InforMed Systems Ltd	- questioned reducing the maximum iodine level from 11 to 10? - questioned having different values of vitamin and mineral levels for special purpose food for infants. In almost all cases nutritional requirements same as for normal infants except for the constraints of the metabolic disorder

Issue: Chromium and Molybdenum

Submittor	Comments
InforMed Systems Ltd	- it is not clear why chromium and molybdenum must be added in this case but not for similar ordinary formula. Are they not essential for all infants? - assumes permitted, though not prescribed, since they are listed in the recommended guidelines maxima on page 29

Issue: Carnitine and Choline

Submittor	Comments
Dairy Goat Co-Operative (NZ) Ltd	- carnitine composition of goat milk needs to be considered in relation to protein quality requirements included and the recommended maximums set for carnitine
Nestle Australia Ltd	- the way this clause is written will require infant products where the optional nutritive substances are not added to comply with the maximum levels specified for each of the nutrients - range proposed for carnitine too narrow - this does not take into account the natural variation of these nutrients that can occur with the ingredients of the products - permission should also be included for lecithin: lecithin also naturally contains a proportion of choline - these permissions do not harmonise with any international legislation and would be considered as technical barriers to trade. EU Directive allows addition of choline and choline citrate as well as choline chloride and choline bitartrate - EU Directive allows addition of the hydrochloride of L-carnitine - - these forms need to be permitted for choline and carnitine

Abbott Australasia Pty Ltd and Bristol Myers Squibb Australia Pty Ltd	- proposed level for carnitine is still too low - carnitine is naturally present in cows milk, typically at concentrations as high as 1mg/100kJ - therefore the restriction to 0.8mg/100kJ is unrealistic - propose a level of NMT 1mg/100kJ

Issue: Choline

Submittor	Comments
InforMed Systems Ltd	- suggests that as choline is now officially recognised as an essential nutrient (Codex 3.2.1) and has an American RDI - it should be listed under 'vitamins'

Issue: Vitamin B6

Submittor	Comments
Nestle Australia Ltd	- report stated that the retention of maximum level for vitamin B6 unlikely to cause any trade restriction based on the LSRO conclusion - inclusion of a maximum for vitamin B6 has the potential to provide a technical barrier to trade

Issue: Riboflavin

Submittor	Comments
New Zealand Dairy Board	- maximum level of riboflavin at 86µg is set too low - some products can have naturally occurring levels of riboflavin as high as 86.5µg - recommends that level be increased to 87µg to accommodate the variability of the naturally occurring nutrient

Issue: Follow on-formula

Submittor	Comments
NZ Infant Formula Marketers' Association	- it is essential for infants from four to six months to be introduced to a progressively diversified diet - main area of contention in definition is 'principle source of food for infants' - follow-on formula should have a separate and stand-alone standard from infant formula - definition should include "an important liquid component of a weaning diet" - proposal in conflict with WHO Code and Codex Standard for follow-on formula - neither European Directive nor the UK refer to follow-on formula as an infant formula product - believes proposed standard represents a major potential trade barrier - follow-on formula has been excluded from the NZ Interpretation of the WHO Code (refer to Ministry of Health Publication: Infant Feeding). ANZFA will "inevitably create unnecessary code interpretation and management problems for NZ, therefore, undermining the ability of the Ministry of Health to effectively monitor the NZ Interpretation of the WHO Code - believes it is totally inappropriate for ANZFA to impose restrictions on advertising. Currently do not advertise infant formula in NZ, in line with WHO Code - believes proposed labelling would breach the Fair Trading Act - understands that only five countries (Bahrain, Botswana, Malaysia, Tanzania, Vietnam) have extended the interpretation of the WHO Code to include follow-on formula - strong scientific evidence available proving that iron-fortified formulas are nutritionally necessary for the continued growth and development of infants, especially those who are no longer breast-feed - supports current wording, which is basically identical to the recommended WHO Code wording - ANZFA must reassess the essential differences between infant formula and follow-on formula, and to correctly define follow-on formula as a weaning or complementary food in a separate stand-alone standard

InforMed Systems Ltd	- in the diet of an infant over 6 months, formula (or breastmilk) will remain an important component - it is incorrect after early weaning stage to define it as the principal source of nutrition - prefers Codex definition (a food intended for use as a liquid part of the diet for the infant from the sixth month on)

Issue: Special Purpose Formulas

Submittor	Comments
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- queries why special purpose formulas are limited to infants with metabolic or immunological diseases or disorders - other medical conditions such as gastrointestinal and renal diseases may necessitate the use of lactose-free or low lactose formulas, as they should not be for general consumption, but on medical advice only - congential lactose is very rare and secondary lactose intolerance occurs after infancy; transitory post-gastroenteritis lactose intolerance is also not common in Aust and NZ and needs to be managed medically
Nestle Australia Ltd	- draft standard proposes additional labelling stating that these products are not suitable for general use and that they should be used under medical supervision - formulas that are based on hydrolysed proteins and that are nutritionally complete would also be suitable for general use - current provision allowing infant formula to be formulated for a particular need based on a physical or physiological condition, disease or disorder needs to be retained
Patricia McVeagh, Consultant Paediatrian	- definition refers to metabolic and immunological conditions but needs to be broader to include other infants requiring special purpose formulas such as malaborptive disorders including pancreatic deficiency, cholestasis, short bowel etc., lymphatic disorders, chronic renal failure, hepatic disorders - appropriate indication for their use would be galactossaemia, proven cow protein allergy or cow milk protein intolerance with tolerance of soya protein, vegetarian parents who elect not to give their children feeds of animal origin - lactose is also a suggested use although there is no need to change the protein source of the infant formula in the condition

Issue: Preterm formula

Submittor	Comments
Nestle Australia Ltd	- does not agree with the regulation of a pre-term formula, as the area is changing rapidly, especially where micronutrients are concerned - no other country regulates this products - products exclusively used for sick infants under strict medical supervision in hospitals only. Risk of improper use is therefore at a minimum - pre-term formulas are only available in hospitals for babies under specialist medical supervision; therefore unnecessary to include a statement on the label to this effect as it is the only way that the products can be made available to infants - pre-term formulas should be based more on weight than age - scientifically, it is now being recognised that this segment needs to be split into two parts:- one for infants less than 1.5kg and one for infants greater than 1.5kg (attachment included on Nestlé publication: Nutrition of the very low birth weight infant) - number of pre-term infants is approx. 3% total births, so from a commercial point of view amount of pre-term formula used is very small and companies generally make one formulation which is used globally
Nestle Australia Ltd (cont)	- when segment is divided into two, quantities in each segment will be even smaller and companies will not make special pre-term formulas to suit different regulations in each country - therefore these regulations run the risk of these products of not being available to Australia and NZ infants and the regulations will be out-of-date very quickly - Nestlé's pre-term formula contains less vitamin D than specified within draft standard; level in product corresponds to ESPGAN, which recommends a max of 3µg/100kcal (0.7µg/100kJ) - ESPGAN also recommends a minimum folic acid content of 60µg/100kcal (14.3µg/10okJ) in pre-term formulas; product meets these requirements and contains the minimum amount - pantothenic acid content of product complies with ESPGAN recommendation of 0.45mg/100kcal (0.11mg/kJ) which is lower than the levels specified in the draft. This would mean that the pre-term formula would not comply with the standard

Dr David Tudehope, Director Division of Neonatology, Mater Hospital	- preterm formulas comprise approximately 3-5% of the total market of infant formulas - because of the relatively small market, there is not a wide range of preterm infant formulas available - most infant formulas take 7 – 8 years of formula development - it is not reasonable to expect Australia to play a significant role in development of preterm formulas - preterm formulas are prescribed by a relatively small number of paediatricians specialising in neonatology - individual hospitals make decisions regarding availability or purchase of preterm formulas based on scientific evidence - nutritional committees are established to make these difficult decisions - the regulation of preterm formulas would result in an unnecessary delay in introduction of recently developed formulas - any decision regarding regulation of preterm infant formula needs a great deal of consideration with extensive input from neonatologists, nutritionists and probably the pharmaceutical industry

Issue: Infant formula products for special dietary uses based on protein substitutes

Submittor	Comments
Nestle Australia Ltd	- clause 41 requires a chromium content of between 0.35 and 2µg/100kJ - table on page 118 of preliminary inquiry report states proposed maximum is 15µg/100kJ both as a guideline for infant formula and follow-on formula and as a requirement for products based on protein substitutes - EU Directive recently allowed a claim for reduction of risk to allergy to milk proteins for hydrolysed protein formulas where they meet the specific requirements regarding the amount of immunoreactive protein in the product - recommend that this claim also be included in draft standard for this category of product - inclusion would harmonise with EU

Issue: Anti reflux/ thickened formula

Submittor	Comments
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- not allowing a physiological claim for anti reflux formula does not go far enough because these formulas could be named 'anti reflux' - additional labelling is required for these formulas that breastfeeding is the preferred feed for infants with reflux - these formulas should not be available without a prescription
National Council of Women New Zealand	- are unsure what can be gained by eliminating the term "physiological" in this recommendation - understand that thickened formulas marketed as "anti-reflux" may influence carers to cease breastfeeding. They believe that medical advice should always be sought before changing feeding programmes. For those with babies suffering from regurgitation problems who already use infant formulas, these products may well bring relief - adequate labelling needs to be on the package outlining the most appropriate use of the formula
Gastric Reflux Association for Support of Parents/Babies	- supports breastfeeding (enclosed specific pamphlet on breastfeeding and gastric reflux). Acknowledge that some parents choose to bottle feed for a number of reasons - based on over 2000 families in the last two years, there has been no increased evidence of breast feeding parents switching to a milk formula simply because they are thickened - the use of thickeners is a common and well respected treatment for babies with gastric reflux. Thickened formula may be suited to these babies because the specific modifications to the formula suit their specific condition - thickened formula takes less to prepare, is easier than mixing in other glutinous products to unthickened formula, and reduces stress for already stressed parents - for these parents there is a need for thickened formula which: * is in an obvious consumer location eg supermarkets * should be priced to make them easily accessible to all socioeconomic groupings * should be available without prescription
Maureen Minchin, IBCLC	- formulas such as anti-reflux (currently on the market) are not "special purpose formulas" - their principal reason for existence is clearly commercial, not medical - all special purpose formula as defined by ANZFA should not be widely displayed or readily available at retail outlets, and marketing to health professionals should be approved by ANZFA's proposed TAG in conjunction with APMAIF

Bristol-Myers Squibb Australia Pty. Ltd	- recent introduction of thickened infant formula met a consumer need - the product conforms to the standard and does not pose a risk to infants. - health professionals have the training to interpret data to make considered recommendations - any restriction of use would be unjustified restriction of trade - these formula are not marketed directly to the consumer, (only health professionals) and therefore the decision is based upon recommendation - expressed concern that APMAIF find the use of thickened formula problematic. The purpose of the standard is to ensure safety and efficacy of infant formula, not partake in the agenda of another organisation
Wyeth Australia Pty Ltd	- indicate that there is no evidence at present to show that anti-reflux formulas are detrimental to breast feeding rates or put formula fed infants at any health and safety risk - state that thickened formulas are "sold" and not "marketed" in supermarkets, as marketing would contravene the MAIF agreement. - dispute the statement that "thickened formula are marketed in supermarkets at a similar price to "standard" infant formula. Recent market data indicates that the price for thickened formulas is 10%-20% more than standard infant formula - ANZFA should recognise that unlike retailers, manufacturers/ importers of infant formula have little control over the price to consumers - scientific material is only presented to health professionals who advise consumers about appropriate formulas. If claims in relation to physiological conditions are not allowed, then infant formula thickeners should also be banned. The result will be that carers will use any normal thickener to thicken the infants formula (this advice has been commonly given by health professionals prior to sale of thickened formula)
W Parnell, Dept of Human Nutrition, University of Otago	- many of the formula for special dietary needs are not sold "over the counter" but made available on prescription - legislative prescription for them would seem best to be general and separate from the formula standard

Issue: Drafting

Submittor	Comments
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	page 9 - requirement for measuring scoop:- it would be preferable to have a standard size scoop for measuring infant formula, eg. 30mL or 60mL, to reduce consumer confusion when changing brands page 10 - required statements:- 3 (a) 'breast feeding **for at least six months** is superior to the use of infant formula...' - pleased that mandatory feeding table has been deleted, as it caused anxiety for parents when their infant deviated from the recommendations of the manufacturer page 12 - labelling of lactose free and low lactose formulas:- appears adequate for galactosaemia page 14 - composition:- carbohydrate - type should be controlled; lactose should be the preferred carbohydrate in formula that is not for special purpose. Lack of regulation will allow the pre-thickened formulas, of which the scientific evidence for efficacy is questionable
InforMed Systems Ltd	Table to clause 6:- Codex provides a composition of human milk protein as its definition, which includes arginine, which is not strictly an essential amino acid. Values in Codex differ from proposed standard, and values are listed in Codex as g/100kJ, whereas proposed standard uses per 100g protein; queries whether is there is good justification for the deviation

InforMed Systems Ltd (cont)	Clause 7 - gluten:- could be seen as more restrictive than draft Codex standard, even though unlikely anyone would want to add gluten; queries whether this amounts to special pleading on the part of the Coeliac organisations Clause 8 (2):- Codex does not mention label claims for minimum levels of micronutrients, not clear what purpose clause serves; suggests that if to prevent deception, that should be covered by general requirements for labels Clauses 13 - 15:- while these may be justified on safety grounds, Codex draft does not set specific limits **Part 4 Labelling** Codex has no statement on scoops Clause 19:- suggests "could lead to serious illness" Clause 19 (2):- should either be deleted or should state "that each bottle should preferably be prepared individually"; states this is commonly ignored, and has seen no problems if directions followed Clause 20:- more restrictive than Codex in specifying actual print size Clause 20 (1):- should refer to packages "having net weight of not less than 1kg"; current wording excludes packages of exactly 1kg Clause 22 (1):- the words "best before" should be in quotes, also "or" "use by" should be added Clause 27 - microbiology:- **Part 2 Composition** Clause 28 (2) - osmolality:- see above; queries why value is in 'per L' when all others are /100mL, suggests all be 'per L' Clause 30 (b):- has not seen adequate evidence to support a prohibition Clause 30 (e):- the usual ratios are around 4 or 5:1, assumes this is meant to be that the EPA level shall not be greater than the DHA level, which is not what it says. Draft Codex standard makes no reference to these constituents - do we need to be so prescriptive? Table to clause 30 has a max level of both omega-6 (which ones are contemplated apart from ARA?) and of omega 3 (EPA plus DHA) of 1:1, which conflicts with the 2:1 mentioned in 30 (d) Clause 34:- section after clause 30 is cumbersome and redundant; simply say preterm formula must comply with sections 30 (a) to 30 (e) or whatever is left Clause 35 table:- **Schedule 1**

InforMed Systems Ltd (cont)	- specifications for nucleotides: needlessly detailed. Codex has no such requirements. Should require that a constituent be "proved to be suitable for infant feeding" as in Codex draft - the section on thickened formula is needlessly complex; these products should be categorised as special purpose formulas and restricted accordingly; it is not the function of food standards to define what is or is not clinically appropriate; it is not the function of food standard to support breastfeeding - should be left to WHO Code - section 4a - specifications. Borage oil has been widely used as a source of gamma-linoleic acid, should not be confused with whole borage plant; no justification for excluding its use in infant formula - it is not the function of the standard to be active in the implementation of WHO Code provision, except for labelling provisions; adequate mechanisms in place in Aust and NZ to care for such issues; the extensive reference to the Code in the standard should be deleted

NZ Dairy Marketing and Customer Services	Clause 8 - inositol:- analytical variation may create difficulties in determining levels of this nutrient Clause 8 - choline:- small amount of choline (0.3mg/100kJ) contributed by lecithin used as a processing/ functionality aid (emulsification) should not be considered as an addition of choline in terms of the need to comply with the max noted in table to clause 8 Clause 8 - carnitine:- natural levels typically found in milk and whey-based infant formula range from 0.6 - 1.0 mg/100kJ; total carnitine levels three times the required max (0.42mg/100kJ) can be found in non-fortified whey-based infant formulas Clause 28 osmolaltiy/potential renal solute load:- Clause 29 (1) - amino acid score:- agrees with the proposed introduction of the amino acid score; additional costs will be incurred with compliance, monitoring, and testing; some products will require reformulation and therefore be subject to additional supplementation and relabelling costs Clause 29 (2) - added amino acid maximum:- wording that "L-amino acids may be added solely for the purpose of achieving the minimum amino acid score specified in subclause (1)" is quite restrictive; would prefer the permission to add L-amino acid up to a max of X (eg. 1.1) times the level noted from the specific amino acid listed in column 2 of the Table to Clause 6, which conforms with Codex requirements and also places controls on added ingredient levels Clause 31 (3) - calcium to phosphorus ratio:- the current Codex guidelines for follow-on formula is 1.0; consideration should be given to allowing this lower min for follow-on formulas
NZ Dairy Marketing and Customer Services (cont)	**Schedule 1** - potassium iodide is missing from list of potassium containing salts - calcium pantothenate is not included under calcium salts - choline chloride is not included under chloride containing salts - magnesium hydroxide is not included under magnesium containing salts **Standard 1.3.4 - Nucleotides** - specifications need to be carefully checked prior to their inclusion; chemical nomenclature on p26 appear to be incorrect; awaiting further information from suppliers to pass on to ANZFA

Dairy Goat Co-Operative (NZ) Ltd	Table to clause 8 - the innate carnitine level in infant formula and follow-on products using unmodified goat milk protein frequently exceeds the max permitted amount - the innate carnitine level in whey-based cow milk formulations also frequently exceeds this max - recommends max be deleted or set higher
Nestle Australia Ltd	- the way clause 20 is drafted actually does not allow for a nominal weight of 1kg. Recommends clause 20(2) be redrafted to state that a package having a net weight of 1kg of less then the size of type must be not less than 1.5mm - clause 21(2)(b)(ii) needs to state 'the average amount of' rather than 'the amount of' for consistency - not necessary to include the average amount of product on a per 100g basis; this information is not used and is therefore not necessary - relevant information is per the made up product - proposed nutrition labelling standard and current labelling provisions require products that are to be reconstituted with water to only be labelled as the reconstituted amount, not as the dehydrated or concentrated amount - labelling requirements should be consistent - clause 22 (1) should state that a date mark must be included rather than a best before date - ANZFA should not pre-empt use of a best before date as our requirement for these products is that they should carry a use by date rather than a best before date - differences between best before and use by date will be picked up in the revised date marking standard. Reference to requirement for a best before date here will not allow Nestlé to sell their products with a use by date, without creating confusion. Draft date marking standard will permit products to be sold past its best before date but not past its use by date

Wyeth Australia Pty Ltd	-there is not maximum applied to the level of choline in infant formula either in Codex or the EC. Unless it can be demonstrated that this is PH issue, the maximum should be omitted. -Nutrient addition is self limiting - only those levels that are necessary are added. -Choline can be present as a carryover nutrient from the cows milk ingredient. It is possible that actual levels may be higher than the proposed maximum. -"Food additives" 11 (3) - more appropriate wording would be "Liquid infant formula product may contain not more than 0.03g carrageenan per 100ml". - Point 12 should read: " Other than by direct addition, a food additive or nutrient may be present ". This takes into account nutrients like choline. -specifying a method for measuring lactose is necessary as varying methods are inconsistent. As with levels of cholesterol and fat under the present code of practice, limits of detection and clinical significance need to be considered. Division 4, clause 18 should read: "A package, other than a single serve sachet or a package containing single serve sachets, containing infant formula product". -disagree with the use of "very" in Division 4, clause 19(a), (b) and (c) as it is emotive and unnecessary. Division 4, clause 22 (i) - the standard needs to be flexible enough to allow for "use by" and "best before" date marks. Division 4, clause 25 (3)(b)- this requirement presumably relates to the needs for infants with galactosemia. For those infants with problems digesting lactose (lactose deficiency, disaccharide intolerance etc) the level of galactose is irrelevant. -believe it is unnecessary to list the presumed galactose content on the label and will contribute to confusion. Issues relating to galactosemia are best addressed by specialises in the area of genetic and metabolic disorders. They are not issues that are considered at the retail level, as a consumer buys an infant formula. Division 4, clause 26(f) - this prevents a manufacturer from making any reference to a new formulation as distinct from a previous formulation. This restricts trade and consumer information. Food companies invest time and money supporting research into diet and nutrition and believe it is legitimate to inform consumers in this manner.

Wyeth Australia Pty Ltd (cont)	Division 4, clause 30(e) - The fatty acids are properly spelt "eicosapentaenoic acid" and "docosahexaenoic acid". Division 4, clause 31 - Codex or the EC prescribe maxima for vitamins other than Vitamins A and D. There is no maximum for Manganese or Iodine and no minimum for Selenium. The proposed levels are inconsistent with international standards and should be withdrawn. - Division 2 - Infant formula for metabolic and immunological conditions. -these formula are designed for when breast feeding is contra indicated and therefore should be used under medical guidance. -many of these products are listed, with their indications, in the Pharmaceutical Benefits Scheme, as the Federal Government contributes funding for their use. They are significantly more expensive to manufacture and to formulate. There are several points to make: Codex does not have this standard. EU includes this product as "Foods for Special Medical Purposes". It is not appropriate to control these products under a general standard. metabolic disorders are different from immunological conditions. Metabolic disorders will require the omission of a particular nutrient (eg PKU). in immunological conditions the form of nitrogen is designed to prevent the immunological or allergic reaction. The notation "not suitable for general use" is not correct". The nutritionally complete products are not designed for general use, however, their suitability is not an issue. recommend that infant formula that are not nutritionally complete and are designed to meet nutritional requirements in special medical cases be included in the standard for Foods for Special Medical Purposes. For nutritionally complete infant formula where, for instance, the protein has been hydrolysed or amino acids used as the source of nitrogen, we recommend that the standard be broad enough in its descriptions and allowances to allow these products to conform without alteration.

Bristol Myers Squibb Australia Pty Ltd	Definitions - recommend a definition of "follow-on formula" to be similar to Codex. definition for "infant formula product" is too prescriptive and should follow Code. Clause 6 - Calculations of amino acid score: the proposed increases of amino acid levels are scientifically unsubstantiated and will result in reformulation of many of BM products. Unjustified because there have been no health risks with these products. -submission contains a table where shows that if the current R7 amino acid values are converted to g per 100g protein, values do not produce the proposed amino acid score of 0.8 in all cases. Also, the current R7 standard and Codex express individual amino acid requirements on a calorie basis. Clause 9 - Limit on Nucleotide 5'-monophosphate maximum total nucleotide level should be set at 1.76mg/100kJ (the sum of the maximum nucleotide permitted) and not 1.2mg/100kj. Clause 7 - restrictions and prohibitions. (1) the clause is prescriptive and limiting and restricts innovation. Recommend the relevant Codex Clause 3.2.1. -inappropriate for ANZFA to include a clause for infant formula to contain no undetectable gluten without including a method for analysis or minimum levels of detection (see submission for explanation). The phrase "must not contain any detectable gluten" should be replaced by "must be gluten free" as defined by Section 32.991.19 of the Second Supplement to the AOAC, 15th edition (1990).

Bristol Myers Squibb Australia Pty Ltd (cont)	Suggest actual method of testing for gluten should be stated. ELISA method is not easily performed. Clause 8 - Permitted optional nutritive substances - proposed levels for choline are not achievable eg seasonable variability. Support removal of level to align with international standards. -Clause 12 should use consistent terminology eg all references to food additive or nutrient should be "food additive, nutrient, vitamin and/or mineral". Clause 15 Composition of lactose free and low lactose formula. -do not agree that a clause should be included without a method for analysis or minimum levels of lactose. Do not think there is a need to detect minuscule levels of lactose which are clinically irrelevant. Lactose free formula should be allowed, based on ingredients being naturally lactose free without further analysis. If potential lactose-containing ingredients are added then 1ppm or less lactose should qualify for the claim. -Clause 18 - Measuring scoop -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 of the package" Clause 12 Required Statements 1(a)(b) and (c) - Do not agree with statement "can make baby very ill" suggest "Inappropriate use or preparation may make your baby ill". (c) it is difficult to concentrate ready to drink formula. It is more appropriate to say "Do not dilute this ready to drink formula except on medical advice". (e) it is common practice in Australia to begin feeding additional food at ages 4 to 6 months. Clause 20 Print and package size. -clause should be modified to state "in a package having a net weight of 1kg or less". Clause 21 Declaration of nutritional information -expression of nutrient levels per 100g does not add value to the NIT and doesn't mean anything to the consumer as all products have different densities. -market research indicates the carer is interested in the volume that the infant has consumed. -this information would contribute to overcrowding the can. Clause 25 - Lactose free and low lactose; if product is lactose free then there is no benefit by including the amount of lactose expressed in g/100ml.

Bristol Myers Squibb Australia Pty Ltd (cont)	-do not routinely test for galactose when infants with galactosemia are under medical supervision. Clause 26 Prohibited representations -(a)(b)(c) these clauses are under the MAIF agreement and should be removed from the proposal. -clause (b) is subjective without a "firm picture which idealises the use of infant formula". (f)opposed to this clause - does not allow company to educate the consumer about the presence of new ingredients eg nucleotides.- Market research conducted by Wyeth indicates that consumers would be comfortable with these ingredients if they knew what they were and why they were included in infant formula. Clause 27 Microbiological standards Codex Standard is no more than 100,000 micro-organisms per g. Division 4, clause 23 - The statement of protein source is already present on the can, both as a separate statement and in the ingredient list. The requirement to add this statement adjacent to the name of the infant formula product is totally unnecessary
Maureen Minchin IBCLC	L(+) producing lactic acid cultures (Clause 10) - what trials or safety and efficacy have been produced to ANZFA. Carrageenan (Clause 11) - the restriction seems sensible.

Issue: General Definitions

Submittor	Comments
New Zealand Ministry of Health	- believes that definition of infant formula needs to be described not only as being suitable as the *principal* but also the *sole* source of nutrition for infants in the first four to six months of life (except in follow-on formula, where *sole* is not appropriate) - believes definition for follow-on formula should reflect that this formula is the principal liquid element in the diet of infants; however can agree with proposed definition - suggests an editorial note to explain reasoning behind this definition - could be helpful to cross-reference to the advisory statement required in clause 19(3)
Nestle Australia Ltd	- alternative name for follow-on formula is follow-up formula; this should be included - starter formula is also used to describe the products that are suitable for infants under 6 months of age; this term needs to be considered

Abbott Australasia Pty Ltd	- endorse the term 'Infant Formula Standard' - however, would like to suggest the use of specific terms, such as hydrolysates or amino acids instead of the proposed term "protein substitutes" - believe the definition "fat-modified" is still inappropriate due to the fact that there are other means of modifying the lipid component than through the use of MCTs

Issue: Definition of pre-term formula

Submittor	Comments
Wyeth Australia Pty Ltd	**"Pre term formula"** - recommend that a more appropriate definition be based upon the weight of the infant or at least include the weight of the infant. There can be categorisation of the Extremely Low Birth Weight infant (ELBW) as less than 1,000g and preterm as 1,00g - 1,750g in weight.
Bristol Myers Squibb Australia Pty Ltd	"pre-term" should take into account infants weight and gestation age as the amount of formula is determined by the weight of the baby.
Nestle Australia Ltd	- definition for pre-term formulas needs to be modified; infants of less than 37 weeks gestation are generally used on the basis of weight rather than age
Informed Systems Ltd	- the definition of a pre term formula should be for infants less then 38 weeks gestation, since 38 – 42 completed weeks is defined as term infant.
Maureen Minchin, IBCLC	- pre-term formula means infant formula products specially modified / intended for use by infants of less than 36 weeks gestation.

Issue: Definition of an infant

Submittor	Comments
Maureen Minchin, IBCLC	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."

Issue: Definition for lactose free and low lactose

Submittor	Comments
Maureen Minchin, IBCLC	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.

Issue: Definition of Soy Protein Formula

Submittor	Comments
Maureen Minchin, IBCLC	- it may limit the definition of soy protein formula if it only mentions soy protein isolate.

Issue: Definition of Special Purpose formula

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

Issue: Definition of Protein Substitute

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

Issue: Definition of Fat Modified

Submittor	Comments
International Formula Council	- endorses ANZFA's decision to rename the standard Infant Formula Standard and to drop the proximate modified. They had earlier expressed concern about the term "fat modified" and wish to clarify that this term has been dropped.
Abbott Australasia Pty Ltd	- 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 he use of MCTs.

Issue: Warning Statements

Submittor	Comments
Consumer Food Network of the Consumers Federation of Australia	- proposals weaken current labelling provisions by downgrading prescribed statements into advisory statements - believes infant formula should be treated as potentially dangerous products, with mandatory warning statements - recommends that a mandatory warning statement, in 6mm type, to the effect that artificial formula feeding can be dangerous to the health of the infant
Nestle Australia Ltd	- provision to require infant formula to carry statements advising carers to seek medical advice where the fluoride content is unnecessarily high imposes restrictions that would be considered a technical barrier to trade
Barbara Glare	- very worried about warning that should appear on the can - there are a growing number of additives to infant formulas, such as LCP formulas, and thickened formulas to supposedly treat reflux - there needs to be clear warnings on the can that these are experimental - these additives are completely unproven, and yet are being accepted as 'normal' - parents should have the right to know that their children are being experimented upon, and to give their informed consent, as they would in any other trial - - believes slogan "breast is best" is totally inadequate

Fiona Compston	- requirement for a statement that "Breastmilk is best" and for consumers to "seek advice from health professionals" is inadequate in informing consumers of the health risks of formula - current labelling does not warn consumers that even one formula feed is likely to affect ongoing breastfeeding of the baby, and could produce a reaction in the child - "Breast is best" also suggests artificial formula is standard or normal
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria)	- requirement for "Breast is best" and for consumers to "seek advice from health professionals" is inadequate in informing consumers of the health risks of formula
Maureen Minchin, IBCLC	- the standard allows industry to keep publishing useless and misleading information on labels. It would be preferable to include detailed information that would assist in educating about infant formula risk and put responsibility for such education on to health professionals despite the evidence that almost all health workers are never adequately educated about such risks. States that appropriate mandatory hazard warnings should be included on the label. Suggests the following statements. 'WARNING Artificial feeding can make your baby ill. It also costs a lot of money and can result in more days off work for the baby's parents. If you are having breast-feeding problems, most can be solved, so seek expert help before using this product. Breast IS best.' '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.'
The Dietitians of the New Children's Hospital	- recommend the statement 'breast feeding for at least six months is superior to the use of infant formula'. Supply of breast milk is reduced by the introduction of infant formula. The duration of breast-feeding is the problem in developed countries rather than the initiation rates.

Nursing Mothers Association of Australia	- if there are no reliable studies to establish the safety of the formula it should not be allowed. Alternatively the product should carry an easily visible and easily understood message warning that the ingredient is experimental and side effects have not yet been determined. This will allow the public to make a more informed decision about the infant feeding. It is not enough to say breast-feeding is best. Mothers have the right to know the current state of knowledge or ignorance about the safety of formula.
Mark Dunstone and Julie Smith	- 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 professions and advice from health professionals may be incorrect. - the required statement that breast milk 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. - 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. - the label does not prevent a consumer being deceived by wrong advice provided by a relative or friend etc. - the labelling requirements in the draft Standard are defective in that they fail to inform consumers of the risks from using formula; they fail to prevent deception; and they do not discourage the unnecessary use of formula.

Issue: Soy and Phytoestrogens

Submittor	Comments
Patricia McVeagh, Consultant Paediatrian	- soy formula should be included in special purpose formulas
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- these formula should be classified as special purpose formula - not recommended as first choice for infants who are not breastfeed - should be used only under medical advice considering the high levels of aluminium and unknown, long term effects of a high phytoestrogen intake
Western Australian Food Advisory Committee	- expressed concern about the metabolic effects of phytoestrogens in soy milk

International Formula Council	- Extremely disappointed regarding overly restrictive position on soy-based infant formulas. Concerns about the safety of soy formulas due to their phytoestrogen content are scientifically unfounded. For over 60 years, these products have been fed to millions of infants and studied in controlled clinical research, no adverse effects related to phytoestrogens in soy protein isolate formulas have been identified. - US FDA determined that soy-based infant formula are safe - refers to Dr Karen Kline report on isoflavones, soy-based infant formulas and relevance to endocrine function. - refers to studies by Luisa Businco and Dr Ken Setchell. - provided information on a study in infants fed a soy-based formula compared to a reference group of infants fed human milk. - IFC and US National Institutes of Health are sponsoring a study "Follow-up study of subjects fed soy-based formulas during infancy", which is currently underway - strongly urges that, as a minimum, ANZFA not implement or encourage the implementation of strategies to deter use of soy-based infant formulas pending the completion of this study, which is anticipated this year - recommend that standard clarify that, in addition to soy protein isolate, other forms of soy protein (eg. soy flour, soy extract) should be permitted
Victorian Food Safety Council - Food Standards Sub-committee	- until safety of soy-based products is resolved, recommends that use of this formula be appropriately labelled to discourage use save on the advice of a health professional

New Zealand Ministry of Health	- pleased that ANZFA is considering strategies to deter the use of soy-based infant formula - thinks clause 19(3)(b) could be altered to "*Soy infant formula should not be used except on the advice of a health professional*" - queries whether water quality guidelines are sufficient to protect infants fed soy infant formula, given that nitrates are present in soy protein - given the presence of phytates in soy formula, has ANZFA considered if there is a need to increase the levels of certain minerals (eg. calcium, iron)? - questioned whether there is a need to specify a level or a denaturation process for trypsin inhibitors - questioned whether ANZFA has considered if the level of iodine is high enough in soy formula, given possible phytoestrogen effects - concerned with the 1.0mg/L limit proposed for aluminium in soy infant formula. The toxicological assessment does not provide a robust argument demonstrating the safety of 1.0mg/L limit. Some references suggest infants may be at risk of aluminium toxicity at levels above 300 micrograms per litre (reference included)
Peter Toth	- concerned about infant soy formulae (included letter to editor of one parent, stating that there are many more worried parents)
Susan Toth	- information tells her that there is no safe level of soy for infants (or adults) - infants feed on soy formulas receive the estrogenic equivalent of at least five birth control pills a day - provides information on the adverse effects of phytoestrogens - the FDA did not give a GRAS approval for the use of soy protein
Patricia La Roche	- published evidence shows that chemicals found in soy formula may cause infertility in human adults and animals, and cause reproductive tract abnormalities in monkeys at doses similar to those in infant formula - feels that strategies suggested and the recommendations made are completely inadequate to protect children from the potential and possible risks suggested by research to date - at the very least, prominent warnings should be printed on the label - a more appropriate standard would be the elimination of soy products and their potential to cause adverse effects from infant formulas

Raeura Marsh	- cannot understand how the marketers of soy infant formulas can possibly say there is no evidence of health damage from the estrogen in these products, in light of the findings of the FDA (enclosed copy of letter discussing research is this field from Daniel Sheehan) - believes soy should be banned from baby food
Gail McIntyre	- believes it is wrong to have large quantities of chemicals in baby foods which can course thyroid damage and infertility - should be removed from sale before any more damage is done
Diane Bowman	- knows that estrogen can cause ovarian and breast cancers, and probably leukaemia - it seems unacceptably risky to have large quantities of chemicals in baby foods which are known to increase these risks - believe they should be removed; where children's health is a factor, there should never be a risk factor included in the equation - soy protein in soy products is risky
International Baby Food Action Network (IBFAN)	- safety of soy formula has not been established - high levels of phytoestrogens in soy formulas is of great concern to many researchers and health professionals - researchers found a 13000 – 20000 times plasma concentration of these substances in soy fed infants compared with levels found in breast or cow-milk fed infants - these doses are 6-11 times higher than the body weight adjusted intake which has been found to cause important changes in the hormonal regulation of the menstrual cycle in women (reference included) - since research on the short and long term effects of the phytoestrogens in soy formulas is ongoing and the information which has been found to date is very disquieting, it is recommended that a precautionary principle be applied
Valerie James	- since ANZFA has acknowledged the risk that phytoestrogen in some soy based infant formula poses, ANZFA is morally and legally bound to inform the consumer by labelling or by education (attachments supplied) - research shows that infants do metabolise phytoestrogens in exactly the same as adults (reference provided) - the use of soy protein in weaning products is not a traditional use or custom; it was introduced in 1962 (reference provided) -enclosed copies of published documents because of concern with research on perinatal exposure of rats to oestrogens. -references provided.

Abbott Australasia Pty Ltd	- concerns about 'alleged hazards associated with the consumption by infants of soy-based formula' containing phytoestrogens are not well-founded and are contradicted by scientific data - additionally, there is insufficient data to support a warning statement on soy-based formulas. For over 60 years, soy based infant formulas have been fed to millions of infants and studied in controlled clinical research; no adverse effects related to phytoestrogens have been identified - soy-based infant formulas are a safe and important feeding option for many infants - scientific data have demonstrated that infants fed soy-based infant formulas grow normally; US FDA determined that soy-based infant formulas are safe - standard should clarify that other forms of soy protein (eg. Soy flour and soy extract) also could be utilised in the production of soy-based infant formulas
Maureen Minchin IBCLC	- it is not clear why ANZFA has focussed solely on soy formula, when bovine milk not only contains phyo-oestrogens but can contain higher levels of the more active compounds. - making less hypo-allergenic infant formula available should be a priority , not simply continuing the use of products whose impact on reproductive and physical health are at least questionable - research into the impact of phyto-oestrogens in infancy on later gender differentiation might make any decision to ignore these questions now seem less than responsible in future. The NZ public statement will have little impact on parental behaviour when a desperately unhappy infant improves (as many still do, even if about 40% will also become soy allergenic) when taken off bovine formula and tried on soy - Soy protein isolate - is soy protein isolate the only possible form of soy that might be used in infant formula? It may cause problems to limit the definition this way otherwise.
Mark Dunstone and Julie Smith	- given the absence of clinical trials showing soy-based artificial formula is not harmful, and the evidence that it may be, soy-based artificial formulas should not be allowed.

Nursing Mothers' Association of Australia	- where the safety of the product cannot be established the public have the right to know that this is the situation. This will allow them to make a more informed decision about infant feeding - withholding information about the potential risk from the phytoestogen content of some soy-based formula prohibits informed choice. It is not enough to say breastfeeding is best - it is important to remember that formula can be the sole form of nutrition for an infant whose digestive system that is designed for breast milk and whose immune system relies on the protective properties of breast milk. An infant fed on soy-based formula is a very different situation from an adult having an occasional meal of soy beans
Wyeth Australia Pty Ltd	- soy based formula have been used as a sole source of nutrition for infants for over forty years - there is no potential risk to normal infants fed soy formula. Soy formula does not cause thyroid dysfunction (or hypothyroidism, which may be classed as a metabolic disorder) - For vegetarian/vegan carers who cannot, or do not wish to breast feed, soy-based formula provides complete nutrition for their infants without health or safety risks. Potential strategies to reduce the level of unnecessary soy-based infant formula consumption should not be included in this Standard
Bristol Myers Squibb Australia Pty Ltd	- the use of soy protein as an alternative source of protein continues to be a safe and a valid alternative to cows milk protein - use of soy protein is a viable, safe alternative. A recent review of data (see reference in submission) on the use of soy protein based infant formula, confirms the normal growth and development of the infant - requirement for a warning statement is unwarranted and reflects activities of "anti-soy" lobby groups, more than true science
Safetywize Consultants	- expressed concern that so many manufacturers are stating that there is no evidence of adverse effects from soy protein in infant formula - enclosed document called "Soy Infant Formula: The Health Concerns - A Food Commission Briefing Paper" which provides evidence to illustrate some adverse hormonal effects of soy products which have been know for many years

Camille Guy	- animal studies show clear evidence of reduced fertility due to phytoestogen intake. - submission discusses in some detail concerns in Japan over the country's exceedingly low birth rate, low incidence of dizygotic twinning - In the report ANZFA does not recognise that there is a great deal of recent work with a bearing on phytoestrogen risk assessment. Specific evidence is provided on Professor Clifford Irvines presentation on the Role of Soy in Preventing and Treating Chronic Disease (Brussels 1996). Other data on primate post-natal estrogen exposure is presented. - refute the Authority's claim that "there is no evidence that exposure of healthy infants to soy-based infant formula over 30 years of use has been associated with any demonstrated harm" - explained concerns relating to development of soy fed children eg menstrual disorders, early puberty, excessive breast development etc which were outlined in her NZ Herald article (26.8.95) Attachments (letters to and from Pat Tuohy to Camille Guy)
Kingett Mitchell and Associates Ltd	- does not agree with ANZFA's conclusion that there is no potential for adverse effects. Believes there is clear evidence of harm - supports some of ANZFA's comments relating to food contaminants (see submission - pleased that ANZFA talks about the precautionary approach but believes that this approach needs to be accompanied with precautionary action. Urges ANZFA to require the removal of phytoestrogens from soy- - main concern is that ANZFA does not address concerns that relate to thyroid, the accuracy of evidence presented and various issues of interpretation - see submission which includes discussion of the Ishizuki study and other relevant studies related to phytoestogens
Soy Information Network	- challenges submissions stating that "that concern over the health hazards of soy formula raised in New Zealand are not well founded" Provides discussion on scientific literature, arguments presented in submissions and in public presentations. (see detail in submission)

R F James	- isoflavones should be removed from soy protein based infant formulas, pursuant to the precautionary principle of avoidance of unnecessary risk (attached several references to support their removal) - oppose the view that "no evidence of harm" appear in the Preliminary Inquiry Report - provides numerous references to scientific literature and views of other countries (see submission) - soy formulas cause mineral deficiencies due to the high and variable amounts of phytate in them which cannot be exactly balanced by mineral addition , or the widely variable trypsin levels in soy protein isolates - states that at least a precautionary approach should be advocated, particularly when there are a number of compelling retrospective dietary studies which indicate isoflavones should be removed from soy baby foods (including "follow-on" products") - calcium levels are associated with the levels of phytate which decrease the bioavailability of calcium. Has anecdotal evidence about dental deficiencies in male children who have been fed soy formulas several years previously - food standards must be consistent with international trade obligations. SGOGS Committee have not given nitrosamine and nitrate contamination of soy protein GRAS status - perhaps because the industry has concealed the nitrate content of soy protein and soy formula. The water quality issue is a red herring which diverts attention from the issue of soy protein itself. (cites references) -disagrees with certain statements made in the preliminary report and comments on other submissions to the full assessment report (see submission) -references included in submission

Issue: Microbiological Standards

Submittor	Comments
International Formula Council	- concerned that unnecessarily restrictive, particularly for coliforms - US regulations allow 10 microorganisms per gram of dry product
InforMed Systems Ltd	queries why a standard for listeria has been omitted, recommends that it be left in place

NZ Dairy Marketing and Customer Services	proposed standards for *Bacillus cereus*, Coagulase positive staphylococci, coliforms and *Salmonella* are acceptable for powdered infant formula; proposed standard for standard plate count is too restrictive and will unnecessarily increase costs to the industry; consumer safety should be protected by the specific standards (ie other than SPC), current level much more practicable, a modification to M=5000/g would be acceptable recommend n=5, c=2, m=1000, M=10000
Abbott Australasia Pty Ltd	- proposed microbiological standards still remain too restrictive, particularly with respect to coliforms - current US microbiological guidelines for powdered infant formulas allow for a maximum of 10 micro-organisms per gram
Consulchem Pty Ltd	- highlighted errors in the report - the existing New Zealand standard is more rigorous than the others. Believes that there is a strong agreement for the maintenance of the standards.
Abbot Laboratories (NZ) Ltd	- micro standards remain too restrictive particularly with respect to coliforms - notably the current US microbiological guidelines for powdered infant formulas allow for a maximum of 10 micro organisms per gram.

Issue: Renal Solute Load

Submittor	**Comments**
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- page 4 - calculation of potential renal solute load:- There is a revised formula for calculating renal solute in Fomon, Zeigler: Renal solute load and potential renal solute load in infancy *Journal of Pediatrices 134 (1): 4-11 1999*
InforMed Systems Ltd	- suggests being more restrictive than Codex would be "most unwise"; unnecessary to be included in standard
NZ Dairy Marketing and Customer Services	- accepts change to PRSL - limit proposed will necessitate reformulation of a few products currently on the Australasian market - the imposition of a max PRSL on follow-on formula due to potential high contribution from other dietary sources appear to be unfairly targeting follow-on formulas

Nestle Australia Ltd	- renal system of infants over the age of six months is more mature than that of the 0-6 month infant - inclusion of this provision may create difficulties for manufacturers - does not comply with international legislation, therefore some imported foods may become illegal
Bristol Myers Squibb Australia Pty Ltd	- method for Potential Renal Solute Load and the proposed limits for PRSL need to be reassessed - a recent article by Fomon and Ziegler (see reference) raised the issue of available phosphorous - this method also uses total nitrogen rather than protein, thereby excluding differing conversion factors for different protein - the conversion of the nitrogen to yield the nitrogenous solutes also appears to be slightly different to the one given in the draft

Issue: Food additives - General comments

Submittor	**Comments**
InforMed Systems Ltd	- Codex does not specify precise forms of additives in their draft standard - queries if the list could be considered more restrictive than Codex

Issue: Food additives - Carageenan

Submittor	**Comments**
International Formula Council	- endorses position not to prohibit use of carrageenan in liquid infant formulas
InforMed Systems Ltd	- Codex permits up to 0.1g/100mL in hydrolysed and amino acid based formula - proposed standard is more restrictive
Victorian Food Safety Council - Food Standards Sub-committee	- recommends that carrageenan not be permitted for use in infant formula until the conflicting international results concerning its effect on immunosuppression are resolved

New Zealand Ministry of Health	- some reservations to permit carrageenan to liquid infant formula, particularly as it is the more vulnerable infants (eg. pre-term) who consume this product - JECFA review stated specifically that its ADI does not apply to infants under 12 weeks old - advised that scientific reports listed on p175 do not give reliable data on the potential toxicity of carrageenan in infant formula - data limited in terms of length of study, whereas intake of infant formula may go on for longer in some situations - appreciate use of liquid formula is usually limited to hospital situations, however there is potential for commercial sale - as additive is still under review internationally, request further consideration be given to its permission for use
Nestle Australia Ltd	- drafting does not actually give permission for addition of carrageenan into liquid infant formula - 'must not contain more than' should be written as 'may contain not more than'

Issue: Food additives - Citric esters of mono- and di-glyceride of fatty acids

Submittor	**Comments**
Nestle Australia Ltd	- where infant formulas use extensively hydrolysed protein, there is a need to use citric acid esters of mono- and di-glycerides of fatty acids - recently approved in EU (98/72/EC Nov 4 1998)

Issue: WHO Code of Marketing of Breast-Milk Substitutes

Submittor	**Comments**

Consumer Food Network of the Consumers Federation of Australia	- disagrees that the CoP is effective in limiting the advertising of infant formula products to the general public - common and widespread use of artificial infant foods by hospitals and many health professionals - many hospitals and health professionals are very ready to recommend artificial infant foods when a mother has problems breastfeeding - not convinced that all free or discount supplying of infant formula to hospitals for giving to nursing mothers has ceased - cites several reasons why a CoP will never be effective including: * it is voluntary, only applying to manufacturers who sign up to it * does not apply to retailers, importers and others involved in marketing and promotion of artificial infant formulas * does not apply to all human milk substitutes and solid foods * manufacturers frequently breach provisions with no adverse consequence (see last annual APMAIF report) * no effective enforcement provisions * has not resulted in any consumer information on the risk of artificial feeding being placed on product labels - world wide experience is that regulation through voluntary codes such as APMAIF does not work (reference included) - recommends reliance on the voluntary code cease, with the standard including specific clauses prohibiting all promotion and advertising of infant formulae
Nestle Australia Ltd	- inclusion of statements from CoP in the FSC is a duplication
Barbara Glare	- the CoP should be written into the ANZFA Act
Marg Kammerman	- the CoP should be written into the standard
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- is the code of conduct for the marketing of infant formula going to be standardised between Australia and New Zealand?

NZ Infant Formula Marketers' Association	- NZ Ministry of Health regulates the CoP in New Zealand - committed to the development and implementation of appropriate infant nutrition policies based on the principles and aims of the WHO Code of Marketing of Breast-Milk Substitutes - concerned about the negative impact the proposed standard may have on some members of the NZ health sector, which would impact on the NZ Ministry of Health's ability to effectively monitor the NZ Interpretation of the WHO Code - proposal in conflict with WHO Code and Codex Standard for follow-on formula - believes proposed standard represents a major potential trade barrier, and ANZFA may be called on by the WTO to justify the proposed changes on health and safety grounds - follow-on formula has been excluded from the NZ Interpretation of the WHO Code (refer to Ministry of Health Publication: Infant Feeding) - ANZFA will "inevitably create unnecessary code interpretation and management problems for NZ, therefore, undermining the ability of the Ministry of Health to effectively monitor the NZ Interpretation of the WHO Code -NZ Ministry of Health recently acknowledged that many health professionals are far to literal in their interpretations of the WHO Code, communicating only negative information on bottle feeding to infant carers who are unable, or wish not, to breast-feed - currently do not advertise infant formula in NZ, in line with WHO Code - quotes Chen and Palmer, who argued that banning the advertising of infant formula and follow-on formula represents a serious violation of several sections of the NZ Bill of Rights Act 1990 - understands that only five countries (Bahrain, Botswana, Malaysia, Tanzania, Vietnam) have extended the interpretation of the WHO Code to include follow-on formula - believe APMAIF have consistently over-interpreted the intent of the WHO Code

La Leche League NZ for Breastfeeding Supports and Information	- does not consider that the NZ Infant Marketers' Association's CoP for the Marketing of Infant Formula provides the same degree of protection as the WHO Code, either in its intent or in its wording - NZIFMA CoP applies only to a few companies, and only to infant formula - unlike WHO CoP, it excludes bottles, teats, follow-on formula and any other breast milk substitutes - WHO Code states no advertising, whilst NZIFMA CoP states that "general advertising of infant formula by NZIFMA companies through mass media ... or at point of purchase should be avoided" - NZIFMA CoP contravenes Australian and NZ MoH's definition of an infant as a child under twelve months of age

Draft Standard 2.9.1 – Infant formula products to be included as Attachment 4

WARNING NOTE:
The standard contains symbols which may be lost if the standard is incorporated into the Inquiry report electronically.

The loss of the symbols will create major errors in the standard!