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PROPOSAL P93 – REVIEW OF INFANT FORMULA

SUPPLEMENTARY FINAL ASSESSMENT (Inquiry – s.24) REPORT

EXECUTIVE SUMMARY

This Proposal makes recommendations on draft standard (Standard 2.9.1 - Infant Formula Products) for adoption into Volume 2 of the *Food Standards Code* (Volume 2) and a variation to Standard A11 of Volume 1 of the *Food Standards Code* (Volume 1).

The specific **objectives** of the review of infant formula regulation are to:

- protect the health and safety of formula fed infants;
- provide carers with sufficient information about infant formula products to enable them to make appropriate choices in feeding their infant and in the safe use of products;
- develop unambiguous food regulations that reflect contemporary scientific knowledge; and
- harmonise the food regulations applying to infant formula products in Australia and New Zealand.

The review of the standard for infant formula (Proposal P93) has been in progress since 1993. Public submissions were received in the preparation of the Proposal in 1993, at Full Assessment in 1995 and at Preliminary Inquiry in May 1999. The Australia New Zealand Food Authority (ANZFA) completed an Inquiry into the proposed draft standard in November 1999. However, Industry requested further consultation on the draft standard as proposed at Inquiry (Nov 1999).

Therefore, this Supplementary Final Assessment (Inquiry - s.24) Report (Feb 2002) consolidates ANZFA's assessment of all issues raised following Preliminary Inquiry (May 1999), including those issues raised by Industry following Inquiry (Nov 1999) and recommends the draft standard to the Ministerial Council (ANZFSC) for adoption into Volume 2, and an amendment to Standard A11 of Volume 1. An assessment of the issues raised since Preliminary Inquiry is given at Attachment 1, and a summary of changes to the draft standard since Full Assessment (1995) and the rationale for these changes is provided in the Statement of Reasons at Attachment 5.

This report also includes at Attachment 2, a safety assessment of certain microbial oils (DHASCO and ARASCO) that are currently added to infant formula as sources of long chain polyunsaturated fatty acids (LCPUFA). The regulation impact statement as assessed at Preliminary Inquiry (May 1999) has been revised in recognition of the significant time delay and changes that have been made to the draft standard as proposed at Preliminary Inquiry and is at Attachment 3.

In conclusion, ANZFA proposes that draft Standard 2.9.1 – Infant Formula Products, as proposed at Supplementary Final Assessment (Inquiry – s.24) (Attachment 4), be adopted into Volume 2 and that Standard 1.3.4 of Volume 2 and Standard A11 of Volume 1 be amended to include specifications for DHASCO and ARASCO oils.

1. INTRODUCTION

This Proposal makes recommendations on a draft standard (Standard 2.9.1 - Infant Formula Products) for adoption into Volume 2 of the *Food Standards Code* (Volume 2). It is part of the Review of Food Standards, which aims to reduce prescriptiveness and simplify food regulations, and as such reviews the Australian infant formula standard (Standard R7) of the *Food Standards Code* (Volume 1) and Regulation 242 - Infant Formula of the New Zealand *Food Regulations 1984.*

This Proposal has been progressed with regard to the Australia New Zealand Food Authority (ANZFA) objectives as outlined in section 10 of the ANZFA Act 1991. However, the specific **objectives** of the review of infant formula regulation are to:

- protect the health and safety of formula fed infants;
- provide carers with sufficient information about infant formula products to enable them to make appropriate choices in feeding their infant and in the safe use of products;
- develop unambiguous food regulations that reflect contemporary scientific knowledge; and
- harmonise the food regulations applying to infant formula in Australia and New Zealand.

Infant formula products provide for the sole or principal source of nutrition for a very vulnerable population group and in accordance with the level of risk, necessitates a more prescriptive regulation than for other foods. This review has not only considered the needs of healthy infants but also the needs of infants requiring specialised infant formula products. These types of infant formula products have been included in Proposal P93, although in acknowledgement of the specialised nature of these products ANZFA proposes to develop more specific provisions for infant formula products for special dietary uses under a new proposal in the next five years.

This Supplementary Final Assessment (Inquiry – s.24) (Feb 2002) consolidates ANZFA's assessment of all issues raised by stakeholders following both Preliminary Inquiry (May 1999) and Inquiry (Nov 1999), and makes recommendations on the draft standard as proposed at Preliminary Inquiry (May 1999).

2. BACKGROUND

2.1 Draft Standard 2.9.1 – Infant Formula Products

ANZFA prepared a Proposal (P93) to review the Australian infant formula standard (Standard R7) in 1993. Public submissions were requested after the preparation of the Proposal in 1993, and at Full Assessment in 1995.

In 1998, the Proposal was included as a part of the Review of Food Standards and the development of Volume 2 of the *Food Standards Code*. A further round of public consultation at Preliminary Inquiry (May 1999) was included, additional to the usual process, to provide an opportunity for consultation in New Zealand. ANZFA completed an Inquiry into the draft standard in November 1999.

However, prior to the draft standard being recommended to the Ministerial Council for adoption, the infant formula industry requested further consultation on the draft standard, claiming some provisions in the standard would affect the affordability and availability of products on the local market. A large number of issues were raised at the time. These issues were considered at a Stakeholders Forum in May 2000, and by the members of the External Advisory Group at a meeting in June 2000. Subsequent meetings between ANZFA staff and industry representatives were also held in August 2000 and in October 2001 to discuss outstanding issues.

2.2 DHASCO and ARASCO oils as sources of long chain polyunsaturated fatty acids (LCPUFA) in infant formula.

DHASCO and ARASCO are microbial oils rich in the long-chain polyunsaturated fatty acids (LCPUFA) docosahexaenoic acid (DHA) and arachidonic acid (ARA), respectively. DHASCO is extracted from the algae *Crypthecodinium cohnii* and ARASCO is extracted from the fungus *Mortierella alpina*. Infant formula products containing these oils have been available for sale in Australia and New Zealand for approximately the last three years, and elsewhere for up to seven years.

ANZFA had previously indicated at Preliminary Inquiry (May 1999), as well as at Inquiry (Nov 1999), that these substances were likely to be considered "novel" ingredients, and as such would require assessment and approval under the Novel Food Standard (Standard 1.5.1), which was not due to come into effect until 16 June 2001.

ANZFA subsequently received an application, in March 2001, from the Infant Formula Manufacturers' Association of Australia (IFMAA), the New Zealand Infant Formula Marketers' Association (NZIFMA) and Martek Biosciences Corporation to amend Standard 1.5.1 to permit the addition of DHASCO and ARASCO to infant formula. During early consideration of this application by ANZFA it became apparent that, while DHASCO and ARASCO oils would be regarded as non-traditional foods (i.e. food that does not have a history of significant human consumption by the broad community) and thus satisfy the first criterion for consideration as a novel food, they did not satisfy the second criterion. That is, ANZFA considered that because infant formula containing such substances had been

available for at least the last three years, that the majority of infants receiving such formula did so under medical supervision (i.e., in the case of pre-term infants) and that considerable evidence existed (from clinical studies) for the safe use of such formula, it could be argued that sufficient knowledge already existed in the community to enable their safe use when added to infant formula. Thus, the oils could not be regarded as novel food ingredients when added to infant formula.

The applicants subsequently withdrew their application but were invited to re-submit the data package as a submission to the review of infant formula, under which a safety assessment was undertaken for the purpose of confirming that the substances are safe sources of DHA and ARA for infant feeding.

3. ISSUES RAISED SINCE PRELIMINARY INQUIRY (MAY 1999)

3.1 Summary of Issues raised during public consultation

Fifty-eight submissions were received to the Inquiry of draft Standard 2.9.1 during the public consultation period May to June 1999 from infant formula manufacturers, pharmaceutical companies, health professionals, governments, community organisations and individuals. A summary of these submissions is at Attachment 7. Below is the list of issues raised in submissions.

In addition Industry stakeholders, namely the Infant Formula Manufacturers' Association of Australia (IFMAA) and the New Zealand Infant Formula Marketers' Association (NZIFMA), prior to the formal adoption of the draft standard requested further consultation on the standard as proposed at Inquiry (Nov 1999). Industry provided a submission detailing a large number of issues in April 2000. The issues raised by Industry's submission are indicated by **bolded** text in the following list of issues. The specific details of these issues are summarised at Attachment 6.

ISSUES

<u>General</u>

- Title of and inclusion of Follow on formula within the draft Standard

<u>PART 1 – GENERAL PROVISIONS</u>

<u>Division 1 – Interpretation</u>
<u>Definitions</u>

- Infant formula product
- Infant formula
- **Follow on formula**
- Infant
- Lactose free and low lactose
- Pre-term formula
- Protein substitute
- Soy protein formula
- Fat modified.

Division 2 – Calculations

- Potential Renal Solute Load (PRSL)
- Calculation of PRSL
- Calculation of amino acid score
- **Protein Quality – Amino acid reference profile**

Division 3 – General Composition Requirements

- Restrictions and prohibitions
- Permitted optional nutritive substances
  - Error in drafting for carnitine, choline and inositol
  - Carnitine
  - Choline

- Nucleotides
- Food Additives
  - Carrageenan
  - Citric esters of mono- and di- glycerides of fatty acids
  - Mono- and di-glycerides of fatty acids
  - Diacetyl tartaric acid esters of mono- and di-glycerides (DATEM)
  - **Locust bean gum**

- Aluminium

Division 4 – General labelling and packaging requirements

- General comments
- Requirement for a measuring scoop
- **Required statements**
  - **Use of the term 'very' ill'**
  - Instructions on the preparation of bottle
  - **Statement about additional foods**

- **Print and package size.**
- **Declaration of nutrition information**
- Date marking and storage instructions
- Statement on the source of protein
- Statement on dental fluorosis
- Labelling of lactose free and low lactose formula
- **Prohibited representations – 'added iron' claims**

Division 5 – General Microbiological Requirements

PART 2 – INFANT FORMULA AND FOLLOW ON FORMULA

- Composition
- Protein content
- Potential renal solute load (PRSL) of follow on formula (and special purpose formula)
- Fat

- **Units of expression for linoleic acid (LA) and alpha-linolenic (ALA) acid**
- **Alpha linolenic acid (ALA)**
- Trans fatty acids
- Long Chain Polyunsaturated Fatty Acids (LCPUFA)

The regulation of LCPUFA
Levels of addition of series-6 fatty acids
LCPUFA in follow on formula

- Vitamins and minerals
  - Policy for safety of vitamins and minerals
  - Specific levels in the Table to Clause 31

Selenium
Copper
Zinc to copper ratio
Chromium and molybdenum
Pyridoxine
Riboflavin
Iron
Phosphorus

- Schedule 1 – Permitted forms of nutrients
  - General
  - Cupric carbonate
  - Nicotinic acid
  - Selenium
  - Choline and carnitine forms

PART 3 – INFANT FORMULA PRODUCTS FOR SPECIAL DIETARY USE
Division 1 – Pre-term formula

- Fat content
- MCT content of pre-term formula
- Vitamin and mineral content of pre-term formula
- Use of pre-term formula
- Labelling statement on pre-term formula

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

- Scope
- Availability
- **Claims on thickened formula**
- **Composition and labelling of special purpose formula**

Issues not in draft standard

- Soy formula
- Novel foods
- Cadmium
- **Innovation**

3.2 Other

Other issues relevant to the proposed infant formula standard and the (then draft) joint *Australia New Zealand Food Standards Code* were also identified following Inquiry (Nov 1999). These are:

- Percentage labelling (Standard 1.2.10)
- Declaration of source of protein
- Composition of lactose free and low lactose formula

In addition, the safety of microbial oils (DHASCO and ARASCO) as sources of LCPUFA was included for consideration as part of Proposal P93 - Review of Infant Formula.

4. ASSESSMENT OF ISSUES RAISED

4.1 Issues raised since Preliminary Inquiry (May 1999)

A full discussion of ANZFA's assessment and recommendations on all issues raised by submissions following both Preliminary Inquiry (May 1999) and Inquiry (Nov 1999) is at Attachment 1.

4.2 Safety of DHASCO and ARASCO oils as sources of LCPUFAs

ANZFA has undertaken a safety assessment of DHASCO and ARASCO oils, which are microbial-derived oils currently added to infant formula as sources of DHA and ARA. The full safety assessment report is at **Attachment 2** to this report. The safety assessment considered the safety of the source organisms, the composition of the oils, bioavailability studies in animals and human infants, animal toxicity studies as well as clinical studies with human infants fed DHASCO and ARASCO-containing formula.

Neither of the source organisms are known to be pathogenic to humans nor other mammals and specific studies with the biomass from both organisms have confirmed the absence of any toxin production.

The extracted oils are free flowing triglyceride oils with a fatty acid profile that is comparable to that of a number of other edible oils. No unusual fatty acids are present and there are no detectable (< 0.1%) cyclic or *trans* fatty acids present in either oil. Bioavailability studies indicate that the efficiency of intestinal absorption of ARA and DHA from ARASCO- and DHASCO-supplemented infant formula is similar to that from breast milk with the oils being able to support maximal tissue accretion of ARA and DHA.

There is no evidence of toxicity associated with the administration of ARASCO and DHASCO to laboratory animals at dose levels up to 2500 mg and 1250 mg/kg bw/day, respectively. These dose levels are approximately 18 – 35 fold greater than the maximum levels being added to infant formula. Clinical studies with human infants also indicate that

formula supplemented with DHASCO and ARASCO is well tolerated by human infants and is not associated with any apparent adverse effects.

Overall, the evidence does not indicate any safety concerns regarding the addition of ARASCO and DHASCO oils to infant formula as sources of LCPUFA.

Recommendation

To permit the addition of DHASCO and ARASCO oils as sources of LCPUFA in infant formula products and include their respective specifications in Standard 1.3.4 – Identity and Purity of Volume 2 and in Standard A11 of Volume 1.

5. CHANGES TO PRELIMINARY INQUIRY (MAY 1999) RESULTING FROM SUPPLEMENTARY FINAL ASSESSMENT (INQUIRY - s.24) (FEB 2002)

The following changes are recommended to the draft standard as prepared at Preliminary Inquiry (May 1999). This is following consideration of issues and consultation with stakeholders. The rationale for these changes is detailed in this Supplementary Final Assessment (Inquiry – s.24) Report (see Section 4.1 above). Details of all changes proposed for the draft standard since Full Assessment (1995) and the justification for these changes is provided in the Statement of Reasons at Attachment 5 of this report.

Clause Number at Preliminary Inquiry	**Proposed at Preliminary Inquiry (May 99)**	**Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)**
Purpose	First paragraph includes the words 'This Standard provides for the compositional, microbiological and labelling requirements…'	**Deletion** of the word 'microbiological'. **Inclusion** of reference to Standard 1.3.1 Food Additives and Standard 1.6.1 Microbiological Limits for Food. **Inclusion** of a reference to specifications in Standard 1.3.4 of **'permitted nucleotides and added nutrients'**
1. Definitions		**Inclusion of subclause 1(1)** This subclause reads "The definitions in clauses 1 and 2 of Standard 1.2.8 apply to this Standard".
	'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.**

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
	'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.**
	'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.	**'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 birth weight	**'pre-term formula'** means an infant formula product specifically **formulated to satisfy particular needs** of infants born prematurely or of low birth weight
	'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 1 includes a definition for "protein equivalent"	The **removal** of the definition for protein equivalent from Clause 1.
4. Calculation of protein		This clause has been re-formatted to be consistent with the Food Standard Code in general.
5.Calculation of potential renal solute load	The calculation for the potential renal solute load is stated as: 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 calculation now reads: Potential renal solute load in mOsm/100 kJ = [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [$\mathbf{P_{avail}}$(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.** This clause has been re-formatted to be consistent with the Food Standard Code in general.
6. Calculation of amino acid score	Contains a definition of an amino score and the Table to Clause 6 (provides amino acid reference values expressed as g/100g protein).	**Clause removed**. Table to clause 6 transferred to Clauses 22 and 32.

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
Due to the removal of Clause 6, the clause numbering is reduced by one and Tables to Clauses re-numbered accordingly		
8. Permitted optional nutritional substances		**Now Clause 7** **The title is now** 'Permitted nutritive substances'.
	The Table to Clause 8 contains maximum levels per 100kJ for the following nutrients: • Choline **5.4** mg • Inositol **5.4** mg • L- Carnitine **0.42** mg	The values in the Table / 100kJ have been changed as follows: • Choline **7.1** mg • Inositol **9.5** mg • L- Carnitine **0.8** mg
9. Limit on nucleotide 5'-monophosphates	This clause states that an infant formula product must not contain more than a total amount of **1.2** mg of nucleotide 5'-monophosphates per 100 kJ.	**Now Clause 8** The clause has been changed to read that an infant formula product must not contain more than a total amount of **3.8** mg of nucleotide 5'-monophosphates per 100 kJ.
10. Lactic acid cultures	This clause reads: 'L(+) producing lactic acid cultures may be added to infant formula products **subject to Standard 1.6.1**'	**Now Clause 9** **Removal** of 'subject to Standard 1.6.1'.
11. Food Additives	General food additive permissions	**Transferred** to Standard 1.3.1 Food Additives.
12. Carry-over of food additives	Carry-over permissions for food additives in ingredients.	**Transferred** to Standard 1.3.1 "Food Additives".
Due to the removal of Clauses 11 and 12, the clause numbering is reduced by a total of three clauses and the Tables to Clauses re-numbered accordingly.		
13. Limit on Aluminium		**Now Clause 10**
14. Limit on Lead	This clause states that an infant formula product must not contain more than 2 μg of lead per 100 mL	**This Clause has been replaced by an Editorial Note** stating that 'The maximum level (ML) of lead in infant formula products is specified in Standard 1.4.1'.
15. Composition of lactose free and low lactose formulas	Subclause (3) states 'Low lactose formula must not contain more than **0.24g** per 100mL of lactose'.	**Now Clause 29** Subclause (3) now states 'Low lactose formula must not contain more than **0.3g** per 100mL of lactose'.
		This clause has been moved to the section 'Infant Formula Products for Special Dietary Uses' (Division 3).
Due to the removal of Clauses 14 and transferral of Clause 15 to another part of the Standard, the clause numbering is reduced by a total of five clauses and the Tables to Clauses re-numbered accordingly.		

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
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.	**Now Clause 13** (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.
19. Required statements		**Now Clause 14** **The title is now** 'Required warnings directions and statements'.
	Subclause (1) requires the statement '**Inappropriate** use or preparation can make your baby very ill'. This statement is contained in parts (a), (b) and (c) of this subclause.	The statement is now '**Incorrect preparation** can make your baby very ill'.

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
	Subclause (3) reads; Subject to subclause (4) the label on an infant formula product must contain statements indicating that: (a) breastfeeding 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 product. 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	Subclause (3) now reads: Subject to subclause (4) 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'** under a heading that reads **'Important notice'** or any word or words having the same or similar effect. Subclause (4) now is; **Sub clause (3) does not apply to infant formula products for metabolic, immunological, renal, hepatic or malabsorptive conditions.** Subclause (5) is now; 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, **it is recommended that infants over the age of 6 months should receive foods** in addition to the infant formula product.
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.	**Now Clause 15** Product weight has been decreased to **500g or more**.
	(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.	**Now Clause 15** Product weight has been increased to **500g or less**.

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
	The minimum print sizes specified in both subclauses only applied to the warning statements under Subclauses 19(1) and 36(1).	**The scope of the minimum print size requirement has been extended** to the newly formed advisory statement in Subclause 14(3) (see above).
21. Declaration of Nutrition Information	For subclauses (1), (2) and (3), part (b)(ii) required that nutrients are expressed as **units per 100g** for a powdered infant formula product, or units per 100mL prior to reconstitution in the case of a liquid concentrated infant formula product.	**Now Clause 16** Reference to **"units per 100g" has been deleted** from part (b)(ii). The clause has been re-formatted to improve clarity – it now contains only two subclauses.
		A new subclause 16(2)(d) has been added requiring the declaration of the weight of one measuring scoop and the proportion of the product on a weight / volume basis.
22. Date marking and storage instructions	Subclause 22(1) states: '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'.	**Now Clause 17** As a means of maintaining consistency with other Standards in Volume 2, **subclause (1) has been changed to read:** 'Paragraphs 2(1)(c) and (d) of Standard 1.2.5 do not apply to this Standard'.
23. Statement of protein source	This clause states that "…a package of infant formula product must contain a statement of the source of protein…"	**Now Clause 18** **This clause now reads**: '…a package of infant formula must contain a statement of the **specific** source, **or sources,** of protein…'
25. Labelling of Lactose free and low lactose formulas		**Now Clause 30** This clause has been moved to the section 'Infant Formula Products for Special Dietary Uses'. **The title is now** 'Claims relating to lactose free and low lactose formulas'.

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
	Subclause (1) The words 'lactose free' must appear as part of the appropriate designation of lactose free formula. (2) The words 'low lactose' must appear as part of the appropriate designation of low lactose formula. (3) 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.	The drafting has been changed to: **'Where a label contains a claim that the infant formula product is lactose free, low lactose or words of similar import, the label on a package of lactose free or a low lactose formula product must include** (a) the words 'lactose free' as part of the name of lactose free formula; and (b) the words 'low lactose' as part of the name of low lactose formula; and (c) 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.
27. Microbiological standards		**Transferred** to Standard 1.6.1 Microbiological Limits for Food
Due to the removal of Clause 27, and the transferral of Clause 25 to Clause 30, clause numbering has reduced by a total of seven and the Tables to Clauses re-numbered accordingly.		
29. Protein	Subclause (1) requires "The protein in infant formula and follow-on formula must have an amino acid score of no less than **0.8**".	**Now Clause 22** Subclause (1) has been **removed.**
	In the Table to Clause 6, amino acids are expressed as **g/100g**.	The **Table to Clause 6 has been transferred to this clause** with minimum amino acids expressed as **mg/100kJ**.
	Separate values for methionine and cysteine, and phenylalanine and tyrosine, in the Table to Clause 6.	A single value for the respective **summation** of [methionine and cysteine] and [phenylalanine and tyrosine] is included in the Table to Clause 22

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
	Subclause (2) 'L-amino acids may be added solely for the purpose of achieving the amino acid score specified in subclause (1)'	Subclause (2) has been added to provide the requirement: **'Infant formula or follow-on formula must provide no less than 6mg cysteine per 100kJ and 17mg phenylalanine per 100kJ'** **Subclause (3) is now** 'L-amino acid may be added to infant formula or follow-on formula only in an amount necessary to improve protein quality'.
30. Fat	Subclause 30(d) contains the statement '…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**…'	**Now Clause 23** The statement now reads '…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**…'
	Column 2 of the Table to Clause 26 specifies a maximum level of **1.75%** of total fatty acids for alpha-linolenic acid.	Column 2 of the Table to Clause 24 specifies a maximum level of **1.1%** of total fatty acids for alpha-linolenic acid.
		Inclusion of an Editorial note that contains reference to specifications for docosahexanoic acid (DHA) rich oil and arachidonic acid (ARA) rich oil derived from algal or fungal sources in Standard 1.3.4.
31 Vitamins and Minerals	In the Table to Clause 31, selenium content is listed per 100kJ as • a minimum of **0.36**µg • a maximum of **0.9**µg	**Now Clause 24** In the Table to Clause 24, selenium content is now listed per 100kJ as • a minimum of **0.25**µg • a maximum of **1.19**µg
	Subclause (4) requires the ratio of zinc to copper in infant formula and follow-on formula must be no more than **12 to 1**.	Subclause (4) has been changed to require that the ratio of zinc to copper: (a) in infant formula must be no more than **15 to 1**; and (b) in follow-on formula must be no more than **20 to 1**.
	The Editorial Note below this clause contains the statement **'While there are no maximum levels specified in relation to a number of the vitamins and minerals in this table the Australia New Zealand Food Authority has recommended** guidelines…'	The Editorial Note now reads **'The standard contains** guidelines…'

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
Schedule 1 to Clause 31 – Vitamins and minerals		The following forms were added to the list of permitted forms at Preliminary Inquiry (now **Schedule 1, Clause 24)** • 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
32-35. Pre-term formula	Clauses 32 – 35 contained detailed compositional requirements for pre-term formula.	**Now Clause 25** **Clauses 32-35 have been replaced with a single clause titled "Composition and Labelling".** Clause 25 states: 'Infant formula products may be specifically formulated for premature or low birthweight infants provided that in all other respects they comply with this Standard'.
Due to the changes to clauses 32-35, the clause numbering is reduced by a total of ten clauses and the Tables to Clauses re-numbered accordingly.		

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
37. Composition (Division 2)	Subclause (1) states that infant formula products may be specifically formulated to satisfy particular **metabolic or immunological** conditions and must comply with; (a) this division (b) with all the other requirements of this standard that are not inconsistent with this division	**Now Clause 27 (Division 3, Subdivision 2) Title changed to Infant Formula Products for metabolic, immunological, renal, hepatic and malabsorptive conditions** Subclause (1) states that infant formula products may be specifically formulated to satisfy particular **metabolic, immunological, renal or malabsorptive** conditions. (2) The permission in subclause (1) only applies where the infant formula products comply with – (a) this Division; and (b) all the other requirements of this Standard that are not inconsistent with this Division. **Subclause (3) has been added** stating that 'Subclause (2) takes effect 5 years after the announcement of this Standard'.

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
38. Additional Labelling (Division 2)	(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.	**Now Clause 28** **The title is now 'Claims'** and has been re-formatted to improve clarity; '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.'
Two clauses relating to lactose free and low lactose formula (Clauses 15 and 25 at Preliminary Inquiry) have **now changed to Clauses 29 and 30**. Therefore clause numbers have reduced by a total of eight for the following clauses and the Tables to clauses re-numbered accordingly.		
40. Protein	Subclause (2) requires that 'The protein in infant formula product based upon protein substitutes must have an amino acid score of no less than **0.8**'.	**Now Clause 32** Subclause (2) has been **removed.**
	In the Table to Clause 6, amino acids are expressed as **g/100g**.	The **Table to Clause 6 has been transferred into this clause** with minimum amino acids expressed as **mg/100kJ**.
	Separate values for methionine and cysteine, and phenylalanine and tyrosine, in the Table to Clause 6.	A single value for the respective **summation** of [methionine and cysteine] and [phenylalanine and tyrosine] is included in the Table to Clause 32.
		Subclause (3) now provides the requirement: 'Infant formula for specific dietary use based upon protein substitutes must provide no less than 6mg cysteine per 100kJ and 17mg phenylalanine per 100kJ'.
		Subclause (4) has been added, 'L-amino acid may be added to infant formula or follow-on formula only in an amount necessary to improve protein quality.'

Clause Number at Preliminary Inquiry	Proposed at Preliminary Inquiry (May 99)	Recommended at Supplementary Final Assessment (Inquiry – s.24) (Feb 02)
42. Additional permitted additions		**Now Clause 34** **The title is now** 'Additional permitted triglycerides'
	Subclause (2) specified levels for permitted food additives that could be added to infant formula products for specific dietary use based on protein substitutes.	**Subclause (2) has been removed and the provisions contained therein transferred** to Standard 1.3.1 Food Additives.
	The Table to Clause 42 specified the following: • DATEM – maximum amount **0.4** g/ 100 mL • **No permission** for Citric acid esters of mono- and di-glycerides of fatty acids (E472c) • Mono-and di-glycerides	These changes have been transferred to Standard 1.3.1: • DATEM (E472e) – maximum amount **0.04** g/100 mL • **Permission** for citric acid esters of mono- and di-glycerides of fatty acids (E472c) **up to a maximum amount 0.9g /100 mL** • Mono-and di-glycerides **of fatty acids (E471)**
Nutrition information table	All features of the Nutrition Information Table are mandatory	Includes Editorial Note **"The information in column 2 is not mandatory".**
Table of Contents to Volume 2 of the Food Standards Code	Previous drafting did not include an amendment to the Table of Contents for Volume 2 as this had not been adopted and gazetted at the time of Preliminary Inquiry (May 99).	The Table of Contents as gazetted 20th December 2000 included a reference to "Standard 2.9.1 Reserved (Infant Formula Products)". The Table of Contents is amended under Part 2.9 Special Purpose Foods to read **"Standard 2.9.1 Infant Formula Products"**.

6. OTHER CONSIDERATIONS

6.1 Regulation Impact Statement

In meeting the objectives of this Proposal, ANZFA is required to assess the relative costs and benefits of regulatory options and their respective impacts on identified affected parties. As part of Preliminary Inquiry (May 1999), ANZFA undertook a regulation impact analysis. In recognition of the significant time delay and changes that have been made to the draft standard as proposed at Inquiry (Nov 1999), the previous draft regulation impact statement as assessed at Preliminary Inquiry has been revised and updated as part of this Supplementary Final Assessment (Inquiry – s.24) (Attachment 3). The Office of Regulation Review has assessed this revised regulation impact statement as adequate.

6.2 International and World Trade Organization obligations

Australia and New Zealand are members of the World Trade Organization (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 Treaty between the Governments of Australia and New Zealand on joint 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).

Following Preliminary Inquiry (May 1999), this matter was notified to the WTO as a technical barrier to trade matter as the proposed revisions to the existing infant formula standards are more prescriptive than other standards internationally. One submission from the United States of America was received on this matter.

6.3 Transition Arrangements

Proposal P252 currently at Draft Assessment, proposes a 2-year transition period from the commencement of Standard 2.9.1, which involves concurrent operation of the existing regulations (Standard R7) as Transitional Standard 1.1A.1 Infant Formula Products and Standard 2.9.1. When Standard 2.9.1 becomes the sole standard, the proposed general stock-in-trade provisions (Proposal P248) will apply for a further 12 months.

7. CONCLUSION

This Supplementary Final Assessment (Inquiry – s.24) Report (Feb 2002) has assessed all issues raised since Preliminary Inquiry (May 1999) and made recommendations on the draft standard to address stakeholder concerns.

Therefore, ANZFA having undertaken a long and comprehensive review of infant formula, recommends to ANZFSC that draft Standard 2.9.1 – Infant Formula Products, as proposed in this Supplementary Final Assessment (Inquiry – s.24) Report (Attachment 4), be adopted in Volume 2 of the *Food Standards Code* (Volume 2) and that Standard 1.3.4 (Volume 2) and Standard A11 (Volume 1) be amended to include specifications for DHASCO and ARASCO oils.

8. ATTACHMENTS

1. Assessment of issues raised following Preliminary Inquiry (May 1999)
2. Safety assessment report - DHASCO and ARASCO as sources of long-chain polyunsaturated fatty acids in infant formula.
3. Revised regulation impact statement
4. Proposed draft Standard 2.9.1 - Infant Formula Products and amendments to Standard 1.3.4 – Identity and Purity, and to Standard A11, Volume1
5. Statement of Reasons
6. Summary of issues raised in Industry submission following Inquiry (Nov 1999)
7. Summary of Submissions following Preliminary Inquiry (May 1999)