**13 March 2002**
**08/02**

# PROPOSAL P93 - REVIEW OF INFANT FORMULA

## SUPPLEMENTARY FINAL ASSESSMENT (INQUIRY – s.24)

## STATEMENT OF REASONS

## AND

## DRAFT VARIATIONS TO VOLUME 1 AND VOLUME 2 OF THE *FOOD STANDARDS CODE*

## PROPOSAL P93 – FOR RECOMMENDING A STANDARD FOR INFANT FORMULA PRODUCTS

The Australia New Zealand Food Authority (ANZFA) has before it Proposal P93 to develop a draft standard for infant formula products for inclusion in Volume 2 of the *Food Standards Code* and a draft variation to Standard A11 in Volume 1 and Standard 1.3.4 in Volume 2 of the *Food Standards Code*.

## STATEMENT OF REASONS

ANZFA recommends the adoption of the draft Standard and draft variations, as amended, for the following reasons:

1. to protect the health and safety of formula-fed infants, who are the most vulnerable group in the Australian and New Zealand population and who may consume infant formula products as the sole or principal source of nourishment;

2. to ensure carers have adequate information about infant formula products to enable them to make appropriate choices in feeding their infant and in the safe use of products;

3. to ensure that food regulations reflect contemporary scientific knowledge about breast milk substitutes and infant nutritional requirements to protect the health of infant consumers;

4. to ensure that innovation in the infant formula industry that would benefit infant health is not hindered; and

5. to harmonise the food regulations applying to infant formula products in Australia and New Zealand.

Following consideration of public comments and an assessment against the objectives of the *Australia New Zealand Food Authority Act 1991 (ANZFA Act)*, a draft standard for Infant Formula Products has now been prepared, for Volume 2, with draft variations recommended for Standard A11 (Volume 1) and Standard 1.3.4 (Volume 2) of the *Food Standards Code*.

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

The proposed provisions are generally aligned internationally except where necessary to protect the health of infants in Australia and New Zealand. The following elements have been incorporated into the proposed standard -

- The quality and quantity of the protein content of infant formula products are regulated but it was considered not necessary to regulate the protein source. However, information about the source of protein will be declared on the label to assist carers make suitable product selection.

- The total energy, total fat, and essential and long chain polyunsaturated fatty acid contents are regulated to ensure infants who are formula fed receive sufficient but not excess energy and fatty acid intakes. Fatty acids that are considered harmful to infants are restricted where necessary to protect infants from adverse health consequences.

- 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 formula products represented as human milk substitutes are not recommended as in the best interests of infants, and maximum levels of these nutrients have been imposed. To eliminate unnecessary cost for industry, mandatory maximum levels are prescribed only 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'. Guidelines are included to provide manufacturers with guidance as to these recommended maximum levels and the implementation of these guidelines is expected to occur by Good Manufacturing Practice.

- The potential renal solute load of follow-on formula and infant formula for metabolic, immunological renal, hepatic or malabsorptive conditions is regulated to minimise the risk of dehydration illness from formula with high protein and electrolyte contents.

- Permission is given to voluntarily add carnitine, taurine, choline, inositol and specific nucleotides to infant formula. The maximum permitted content of these substances in infant formula is regulated, as is the minimum claimable level.

- Novel ingredients, nutrients, nutritive substances or novel sources of these are required to be assessed as safe and suitable for infants (under Standard 1.5.1 – Novel Foods) prior to approval being given for their use in infant formula products.

- Limits for lead and aluminium contents are imposed to protect infants. The limit for lead is controlled within Standard 1.4.1 – Contaminants and Natural Toxicants. An advisory labelling statement to alert carers to seek specific health advice is proposed for formula with unnecessarily high fluoride contents as sold.

- The risk to infants in Australia and New Zealand from potential gluten content of infant formula is such that gluten is directly prohibited in infant formula products.

- ANZFA supports the use of soy-based infant formula by infants for whom human milk or a modified cow's milk formula is contraindicated. 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.

- Microbiological criteria and the use of specific food additives are recommended to ensure safety of infant formula. The microbiological criteria are contained within the Standard 1.6.1 - Microbiological Limits for Foods and Standard 1.3.1 - Food Additives provides specific permissions on food additives in infant formula.

- Specific labelling is required 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 most appropriate 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 infant formula products can be informed of the full range of feeding options.

The specific provisions in the drafting prepared after Full Assessment (1995), Preliminary Inquiry (May 1999), Inquiry (November 1999) and Supplementary Final Assessment (Inquiry - s24) (Feb 2002) have been amended for the following reasons:

**Purpose**

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

- Reference to Standards that contain requirements pertaining to Standard 2.9.1 have been included.

- The term 'added nutrients' has been included in reference to Standard 1.3.4 containing specifications for certain oils used as sources of long chain polyunsaturated fatty acids.

**Clause 1 - Definitions**

- Inclusion of definitions from clauses 1 and 2 of Standard 1.2.8 as this standard does not apply to infant formula products unless specified.

- The definitions for infant formula product, infant formula, follow-on formula, lactose-free and low lactose, and pre-term 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, when those over 6 months of age 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 then intent of the draft Codex standard. The new definition is:

    *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*.

- 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 breast milk 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 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*.

- The definition of lactose free and low lactose formula has been changed to be consistent with other definitions in the standard. The new definition is:

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

- 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 represented as being suitable as the principal source of food for infants born prematurely or of low birth weight*.

- The definition for protein equivalent has been removed, as there is no reference made to this definition in the standard.

**Clause 4 – Calculation of protein**

- This clause has been re-formatted for general consistency with Volume 2 of the *Food Standards Code*.

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

- The calculation of PRSL has been modified to exclude the unavailable phosphorus content of formula from the estimation of PRSL. The calculation has also been modified to calculate PRSL using nitrogen rather than 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.

- This clause has been re-formatted for general consistency with Volume 2 of the *Food Standards Code*.

**Clause 6 – Calculation of amino acid score**

- This clause has been removed and the table to Clause 6 transferred to Clauses 22 and 32 as calculation of amino acid score is no longer required.

**The removal of Clause 6 has reduced the clause numbering by one from that proposed at Preliminary Inquiry (May 99) and the tables to Clauses have been re-numbered accordingly.**

**Clause 8 – Permitted nutritive substances (Now Clause 7)**

- The title of this clause has been changed from 'permitted optional nutritional substances' to 'permitted nutritive substances' to be generally consistent with Volume 2 of the *Food Standards Code*.

- 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 maximum values are 0.8 mg/100 kJ for carnitine, 7.1 mg/100 kJ for choline and 9.5 mg/100 kJ 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 ingredient. This has arisen over some concerns about the setting of a maximum level for <u>added</u> carnitine, which some groups claimed was lower than the level of carnitine naturally present in milk.

**Clause 9 – Limit on nucleotide 5'-monophosphates (Now Clause 8)**

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

**Clause 11 – Food additives (Transferred to Standard 1.3.1)**

- 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.
- This clause has been moved to the Standard 1.3.1 – Food Additives.

**The transfer of Clauses 11 and 12 to Standard 1.3.1 – Food Additives has reduced the clause numbering by another two from that proposed at Preliminary Inquiry (May 99) and the tables to Clauses have been re-numbered accordingly.**

**Clause 10 – Lactic acid cultures (Now Clause 9)**

- The drafting of the this clause has been has been slightly amended by the removal of "*subject to Standard 1.6.1*" as Standard 1.6.1 has general application and reference to lactic acid cultures should automatically required compliance with Standard 1.6.1.

**Clause 11 – Limit on Aluminium (Now Clause 10)**

- Clause 14 (previously Limit on lead) as been removed and replaced with an editorial note referring to Standard 1.4.1 - Contaminants and Natural Toxicants that now contains the limits on lead. This editorial note to Clause 11 has been changed to '*The maximum level*

*(ML) of lead in infant formula products is specified in Standard 1.4.1*" to better reflect terminology used in Standard 1.4.1.

**Clause 14 – Requirement for a measuring scoop (Now Clause 13)**

- 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 facilitate the use of infant formula products in accordance with the directions contained in the label on the package.

**Clause 15 – Composition of lactose-free and low-lactose formulas (Now Clause 29)**

- This clause has been moved to Part 3, Division 2 – Infant formula products formulated for metabolic, immunological, renal and malabsorptive conditions as it is more appropriately situated in this part of the Standard.
- The clause has been amended to specify that low lactose formula must contain no more than 0.3 g lactose per 100 mL of infant formula product to be consistent with the new limit imposed for general purpose foods.

**Clause 15 – Required statements (Now Clause 14)**

- It was proposed at Preliminary Inquiry that manufacturers place a statement on the label that contained information about the superiority of breast milk 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:

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

  Clause 14 (3) has been added to exclude products for metabolic, immunological, renal, hepatic or malabsorptive conditions from requiring this statement as it is considered not appropriate for these products.

- It was proposed in subclause (1) to require the statement 'Inappropriate use or preparation can make your baby very ill'. This statement has been amended to 'Incorrect preparation can make your baby very ill' on the advice of stakeholders.

- the wording to subclause (3)(e) has also been amended to clarify the intent.

**Clause 16 – Print and package size (Now Clause 15)**

- The drafting of this clause has been amended to classify a small package as 500g 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 1 kg, as the majority of packages of infant formula products are less than 1 kg.

**Clause 17 – Declaration of nutrition information (Now Clause 16)**

- This clause has been amended to require nutrient declaration only per 100 mL as consumed and to require the declaration of the weight of product per scoop and proportion of solution on a weight/volume basis for the product to reduce the amount of label space required to provide nutrient information.
- This clause has been re-formatted to improve clarity.

**Clause 18 – Date marking and storage instructions (Now Clause 17)**

- This title of this clause has been amended to be consistent with Standard 1.2.5 - Date Marking of Packaged Foods.
- A subclause has been included to ensure compliance with Standard 1.2.5
- The editorial note to Clause 18 has been simplified to "*The appropriate storage instructions should be valid for the full range of climatic conditions that exist in Australia and New Zealand*"

**Clause 19 – Statement of protein source (Now Clause 18)**

- This clause has been amended to clarify that the declaration of source, or sources, of protein should be specific rather than as class names.

**Clauses 23 and 33 – Protein (Now Clause 22 and 32)**

- This clause has been amended to reflect the change in expression of protein quality to mg/100 kJ as at Clause 6. Due to this change the requirement for an amino acid score of 0.8 has been deleted. The Table to clause 6 has been transferred into clauses 23 and 33 and provides the minimum essential amino acid values /100 kJ.

- The table to Clauses 22 and 32 has been modified to permit the summation of cysteine and methionine; and phenylalanine and tyrosine as originally proposed at Full Assessment (Schedule 1). The units of expression have been modified from amino acid per protein content (g/100 g) to a per energy value (mg/100 kJ). The amino acid values from Schedule 1 (FAO/WHO 1991) have been converted to mg/100 kJ.

- Human milk is cysteine-rich and methionine-poor but infant formula products are made from cow's milk proteins that are poor in cysteine but rich in methionine, therefore summation assists to overcome this difficulty. To ensure that some cysteine is present in infant formulas for very young infants, an absolute minimum cysteine content (6 mg/100 kJ) has been prescribed. Additionally for a similar reason a minimum value for phenylalanine (17 mg/100 kJ) has also been included.

- A subclause has been included to allow addition of amino acids for the sole purpose of improving protein quality.

**Clause 24 – Minimum percentage alpha linolenic acid (Now Clause 23)**

- The table to this clause has been amended to reduce the minimum percentage alpha linolenic acid (1.1%) consistent with recent research that shows this level is safe.

**Clause 27 – Microbiological standards (Transferred to Standard 1.6.1)**

- The microbiological standards for infant formula products are regulated in Standard 1.6.1 – Microbiological Limits for Foods. This clause has therefore been deleted.

**Clause 30 – Fat (Now Clause 23)**

- 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.

- An Editorial Note has been included to provide reference of specifications for certain oils as sources of long chain polyunsaturated fatty acids in Standard 1.3.4 – Identity and Purity. These oils were assessed as safe for use in infant formula during the review of infant formula, and the safety assessment is included in the Supplementary Final Assessment (Inquiry) Report.

**Clause 31 – Vitamins and minerals (Now Clause 24)**

- The selenium values proposed at Preliminary Inquiry (0.36-0.9 mcg/100 kJ) have been modified to 0.25-1.19 mcg/100 kJ. The maximum level is consistent with the maximum level of selenium recommended by LSRO based upon the upper limits of selenium in breast milk. 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- tocopherol succinate as a source of vitamin E
    - Phytylmenoquinone as a source of vitamin K
    - Sodium chloride iodised as a source of sodium
    - Cupric citrate as a source of copper
    - Manganese carbonate and manganese citrate as sources of manganese
    - Sodium selenate as a source of selenium
    - Pyridoxine-5'-phosphate.

- The maximum zinc: copper ratio has been raised to 15:1 for formulas for infants less than 6 months of age and 20:1 for formulas intended for infants over 6 months of age to meet the manufacturing concerns of industry.

**Clauses 32-35 – Pre-term formula (Now Clause 25)**

- 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: "*Infant formula product may be specifically formulated to satisfy the particular needs of premature infants or infants born low in birth weight and must comply with all the other requirements of this Standard that are not inconsistent with Division"*.

- ANZFA will raise a separate proposal to develop specific provisions for pre-term formula within 5 years of this Standard 2.9.1 coming into effect.

**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 accommodate formulas for these conditions and has the effect of excluding anti-reflux formulas from being described as such.

An exemption from the compositional requirements for these products is provided for a period of 5 years to guarantee supply of specialised products. A Proposal to develop a standard for Foods for Special Medical Purposes (P242) is under development and these products may be covered by this new standard. These products are also exempted from the requirement to label *' Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'* as breast milk may not be appropriate for these babies and the advice of a doctor will already be being sought.

**Clause 38 – Additional labelling (Now Clause 28)**

- 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 (i.e. products for metabolic, immunological, renal, hepatic and malabsorptive conditions).

**Clause 42 – Other permitted additions (Now Clause 34)**

- 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.
- The table to this clause has been moved to the Standard 1.3.1 – Food Additives and therefore the title of the clause has be amended to "Additional permitted triglycerides"

**Specifications**

- As noted at Preliminary Inquiry, the specifications for nucleotides are moved to Standard 1.3.4 – Identity and Purity.

- Specifications for certain oils as sources of long chain polyunsaturated fatty acids have been included in 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.

## REGULATION IMPACT

In meeting the objectives of this proposal, ANZFA has assessed 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. However, 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.

The revised regulation impact statement has recommended that the review of regulations for infant formula is of potential benefit to infant health. The Office of Regulation Review has assessed this revised regulation impact statement as adequate.

## WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

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.

## FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries.

It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

## FURTHER INFORMATION

### Submissions

No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia New Zealand Food Standards Council for consideration.

### Further Information

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:


Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
email: slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
email: anzfa.nz@anzfa.gov.au


Assessment reports are available for viewing and downloading from the ANZFA website www.anzfa.gov.au or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.

**DRAFT VARIATIONS TO VOLUME 1 AND VOLUME 2 OF THE *FOOD STANDARDS CODE***

**To commence: on gazettal**

***The Food Standards Code*** *is varied by –*

**[1]** ***Standard A11*** *of Volume 1 is varied by –*

[1.1] *inserting in the* Schedule *to A11 into* Column 1 *and* Column 2 *respectively, after the entry for* Divinylbenzene copolymer –

| | |
|---|---|
| Docosahexaenoic acid (DHA) – rich oil derived from the algae *Crypthecodinium cohnii* | Addendum 17 |

[1.2] *inserting in the* Schedule *to A11 into* Column 1 *and* Column 2 *respectively, after the entry for* Anthocyanins –

| | |
|---|---|
| Arachidonic acid (ARA) – rich oil derived from the fungus *Mortierella alpina* | Addendum 18 |

[1.3] *inserting following* ADDENDUM 16 –

**ADDENDUM 17**

**SPECIFICATION FOR DOCOSAHEXAENOIC ACID (DHA) - RICH OIL DERIVED FROM THE ALGAE *CRYPTHECODINIUM COHNII***

| | |
|---|---|
| Full chemical name for DHA | 4,7,10,13,16,19-docosahexaenoic acid (22:6n-3) |
| Appearance | Free flowing oil |
| Colour | Yellow to orange |
| Odour | Characteristic |
| DHA (%) | min. 40 max. 45 |
| Dodecanoic acid 12:0 (%) | min. 0 max. 6 |
| Tetradecanoic acid 14:0 (%) | min. 10 max. 20 |
| Hexadecanoic acid 16:0 (%) | min. 10 max. 20 |
| Octadecenoic acid 18:1 (%) | min. 10 max. 30 |
| Peroxide value (meq/kg) | max. 5 |
| Moisture and volatiles (%) | max. 0.01 |
| Non-saponifiables (%) | max. 3.5 |
| Trans fatty acids (%) | max. 1.0 |
| Free fatty acid (%) | max. 0.4 |
| Lead (ppm) | max. 0.2 |
| Arsenic (ppm) | max. 0.5 |
| Copper (ppm) | max. 0.1 |
| Iron (ppm) | max. 0.5 |
| Mercury (ppm) | max. 0.2 |
| Hexane (ppm) | max. 0.3 |

## ADDENDUM 18

## SPECIFICATIONS FOR ARACHIDONIC ACID (ARA) – RICH OIL DERIVED FROM THE FUNGUS *MORTIERELLA ALPINA*

| | | |
|---|---|---|
| Full chemical name for ARA | 5,8,11,14-eicosatetraenoic acid (20:4n-6) | |
| Appearance | Free flowing oil | |
| Colour | Yellow | |
| Odour | Characteristic | |
| ARA (%) | min. 38 | max. 44 |
| Hexadecanoic acid 16:0 (%) | min. 3 | max. 15 |
| Octadecanoic acid 18:0 (%) | min. 5 | max. 20 |
| Octadecenoic acid 18:1 (%) | min. 5 | max. 38 |
| Octadecadienoic acid 18:2 (%) | min. 4 | max. 15 |
| Peroxide value (meq/kg) | max. 5 | |
| Moisture and volatiles (%) | max. 0.05 | |
| Non-saponifiables (%) | max. 3.5 | |
| Trans fatty acids (%) | max. 1.0 | |
| Free fatty acid (%) | max. 0.4 | |
| Lead (ppm) | max. 0.2 | |
| Arsenic (ppm) | max. 0.5 | |
| Copper (ppm) | max. 0.1 | |
| Iron (ppm) | max. 0.5 | |
| Mercury (ppm) | max. 0.2 | |
| Hexane (ppm) | max. 0.3 | |

**[2]** ***Standard 1.1.1*** *of Volume 2 is varied by omitting from clause 2, in the definition for* warning statement *subclause* (d) –

*substituting*

(d) subclauses 14(1), 14(3) and 26(1) of Standard 2.9.1; and

**[3]** ***Standard 1.3.4*** *of Volume 2 is varied by inserting in the* Schedule *immediately after the* Specification for tall oil phytosterols derived from tall oils *the following* -

**Specification for docosahexaenoic acid (DHA) – rich oil derived from the algae *Crypthecodinium cohnii***

| | | |
|---|---|---|
| Full chemical name for DHA | 4,7,10,13,16,19-docosahexaenoic acid (22:6n-3) | |
| Appearance | Free flowing oil | |
| Colour | Yellow to orange | |
| Odour | Characteristic | |
| DHA (%) | min. 40 | max. 45 |
| Dodecanoic acid 12:0 (%) | min. 0 | max. 6 |
| Tetradecanoic acid 14:0 (%) | min. 10 | max. 20 |
| Hexadecanoic acid 16:0 (%) | min. 10 | max. 20 |
| Octadecenoic acid 18:1 (%) | min. 10 | max. 30 |
| Peroxide value (meq/kg) | max. 5 | |
| Moisture and volatiles (%) | max. 0.01 | |

| | |
|---|---|
| Non-saponifiables (%) | max. 3.5 |
| Trans fatty acids (%) | max. 1.0 |
| Free fatty acid (%) | max. 0.4 |
| Lead (ppm) | max. 0.2 |
| Arsenic (ppm) | max. 0.5 |
| Copper (ppm) | max. 0.1 |
| Iron (ppm) | max. 0.5 |
| Mercury (ppm) | max. 0.2 |
| Hexane (ppm) | max. 0.3 |

**Specification for arachidonic acid (ARA) – rich oil derived from the fungus *Mortierella alpina***

| | |
|---|---|
| Full chemical name for ARA | 5,8,11,14-eicosatetraenoic acid (20:4n-6) |
| Appearance | Free flowing oil |
| Colour | Yellow |
| Odour | Characteristic |
| ARA (%) | min. 38 max. 44 |
| Hexadecanoic acid 16:0 (%) | min. 3 max. 15 |
| Octadecanoic acid 18:0 (%) | min. 5 max. 20 |
| Octadecenoic acid 18:1 (%) | min. 5 max. 38 |
| Octadecadienoic acid 18:2 (%) | min. 4 max. 15 |
| Peroxide value (meq/kg) | max. 5 |
| Moisture and volatiles (%) | max. 0.05 |
| Non-saponifiables (%) | max. 3.5 |
| Trans fatty acids (%) | max. 1.0 |
| Free fatty acid (%) | max. 0.4 |
| Lead (ppm) | max. 0.2 |
| Arsenic (ppm) | max. 0.5 |
| Copper (ppm) | max. 0.1 |
| Iron (ppm) | max. 0.5 |
| Mercury (ppm) | max. 0.2 |
| Hexane (ppm) | max. 0.3 |

**[4]** ***Standard 2.9.1*** *of Volume 2 is varied by* -

[4.1] *omitting* Standard 2.9.1 *and substituting* -

## *STANDARD 2.9.1*

## *INFANT FORMULA PRODUCTS*

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**Purpose**

This Standard provides for the compositional, and labelling requirements for foods intended or represented for use as a substitute for breast milk, herein referred to as 'infant formula products'. This Standard applies to all infant formula products whether in powder, liquid concentrate or 'ready to drink' forms.

This Standard also provides for infant formula products intended for infants with special nutritional requirements.

Additionally, recommended guidelines regarding vitamins and minerals are contained at the end of this Standard. Standard 1.3.1 contains provisions relating to the food additives permitted in infant formula products. Standard 1.6.1 contains the microbiological limits in relation to infant formula products. Standard 1.3.4 contains specifications for permitted nucleotides and added nutrients. Standard 1.1.1 defines nutritive substances for the purposes of this Code.

**Table of Provisions**

# Division 1

## Subdivision 1 – Interpretation

### 1 Definitions

(1) The definitions in clauses 1 and 2 of Standard 1.2.8 apply to this Standard.

(2) In this Code –

**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** means a person under the age of 12 months.

**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.

**Editorial note**:

A reference to infant formula product may include a reference to infant formula but the converse does not apply.

**infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

**Editorial note:**

The intent of this definition is to limit the addition of ingredients to infant formula product to ingredients that would be considered to be foods. The addition of an ingredient that is not considered to be a food is prohibited unless specifically permitted elsewhere in this Standard.

Standard 1.5.1 contains prohibitions and restrictions relating to novel foods and novel food ingredients. Nothing contained in this Standard permits infant formula products to contain novel foods or novel food ingredients that are not permitted in Standard 1.5.1.

**lactose free formula** and **low lactose formula** means infant formula products which satisfy the needs of lactose intolerant infants.

**medium chain triglycerides** means triacylglycerols which contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

**pre-term formula** means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.

**protein substitute** means L-amino acids and/or the hydrolysate of one or more of the proteins on which infant formula product is normally based.

**soy-based formula** means an infant formula product in which soy protein isolate is the sole source of protein.

### 2 Interpretation

A reference to any infant formula product in the compositional provisions of this Standard is a reference to –

(a) a powdered or concentrated form of infant formula product which has been reconstituted with water according to directions; or
(b) an infant formula product in 'ready to drink' form.

## Subdivision 2 – Calculations

### 3 Calculation of energy

The energy content of infant formula product, expressed in kilojoules (kJ), must be calculated using –

(a) only the energy value contributions of the fat, protein and carbohydrate ingredients of the infant formula product; and
(b) the relevant energy factors set out in Standard 1.2.8.

**4 Calculation of protein**

The prescribed formula for the calculation of the protein content of infant formula product for the purposes of this Standard is -

| Formula |
| --- |
| For milk proteins and their partial protein hydrolysates - |
| Protein content = nitrogen content x 6.38; or |
| In any other case - |
| Protein content = nitrogen content x 6.25. |

**5 Calculation of potential renal solute load**

The prescribed formula for the calculation of the potential renal solute load for the purposes of this Standard is -

| Formula |
| --- |
| 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/100kJ) /28)]. |
| In this formula |
| $P_{avail}$ = P of milk-based formula + 2/3 of P of soy-based formulas. |

## Subdivision 3 - General compositional requirements

**6 Restrictions and prohibitions**

(1) A vitamin, mineral, food additive or nutritive substance must not be added to infant formula product unless -

(a) expressly permitted by this Code; or
(b) it is naturally present in an ingredient of the infant formula product.

(2) Infant formula product must contain no detectable gluten.

**7 Permitted nutritive substances**

(1) Any nutritive substance listed in column 1 of the Table to this clause may be added to infant formula product provided that -

(a) the nutritive substance is in one or more of the forms specified in column 2 of the Table in relation to that substance; and

(b) the total amount of the nutritive substance in the infant formula product is no more than the amount specified in column 4 of the Table.

(2) The label on a package of infant formula product must not include any words indicating, or any other indication, that the product contains a nutritive substance specified in column 1 or in column 2 of the Table to this clause unless the total amount of the nutritive substance in the food is no less than the amount specified in column 3 of the Table.

**Editorial note:**

The intent of subclause 7(1) is that the maximum permitted amounts only apply when the substance is added, and in that case, it then applies to the sum of the naturally occurring and added nutritive substances.

This Standard contains guidelines on the use and format of nutrient information tables.

**Table to clause 7**

| Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|
| **Nutrititive substance** | **Permitted forms** | **Minimum amount for claim per 100 kJ** | **Maximum amount per 100 kJ** |
| Choline | Choline chloride<br>Choline bitartrate | 1.7 mg | 7.1 mg |
| Inositol | Inositol | 1.0 mg | 9.5 mg |
| Taurine | Taurine | 0.8 mg | 3 mg |
| L-carnitine | L-carnitine | 0.21 mg | 0.8 mg |
| Cytidine 5’-monophosphate | Cytidine 5’-monophosphate<br>Cytidine 5’-monophosphate sodium salt | 0.22 mg | 0.6 mg |
| Uridine 5’-monophosphate | Uridine 5’-monophosphate<br>Uridine 5’-monophosphate sodium salt | 0.13 mg | 0.42 mg |
| Adenosine 5’-monophosphate | Adenosine 5’-monophosphate<br>Adenosine 5’-monophosphate sodium salt | 0.14 mg | 0.38 mg |
| Guanosine 5’-monophosphate | Guanosine 5’-monophosphate<br>Guanosine 5’-monophosphate sodium salt | 0.04 mg | 0.12 mg |
| Inosine 5’-monophosphate | Inosine 5’-monophosphate<br>Inosine 5’-monophosphate sodium salt | 0.08 mg | 0.24 mg |

## 8 Limit on nucleotide 5’-monophosphates

Infant formula product must contain no more than 3.8 mg/100 kJ of nucleotide 5’-monophosphates.

**Editorial note:**

Standard 1.3.4 contains specifications for nucleotides.

### 9 Lactic acid cultures

L(+) producing lactic acid cultures may be added to infant formula product.

### 10 Limit on aluminium

(1) Infant formula product, other than a pre-term formula or soy-based formula product, must contain no more than 0.05 mg of aluminium per 100 mL.

(2) Pre-term formula must contain no more than 0.02 mg of aluminium per 100 mL.

(3) Soy-based formula must contain no more than 0.1 mg of aluminium per 100 mL.

**Editorial note:**

Standard 1.4.1 contains the maximum level (ML) of lead contaminant in infant formula products.

## Subdivision 4 - General labelling and packaging requirements

### 11 Representations of food as infant formula product

A food must not be represented as an infant formula product unless it complies with this Standard.

### 12 Prescribed names

**'**Infant Formula' and 'Follow-on Formula' are prescribed names.

### 13 Requirement for a measuring scoop

(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 of an infant formula product in a powdered form.

### 14 Required warnings, directions and statements

(1) The label on a package of infant formula product must include the following warning statement -

(a) in the case of infant formula product in powdered form -

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill'; and

(b) in the case of concentrated infant formula product -

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Incorrect preparation can make your baby very ill'; and

(c) in the case of 'ready to drink' infant formula product -

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this 'ready to drink' formula except on medical advice. Incorrect preparation can make your baby very ill'.

(2) The label on a package of infant formula product must include directions for the preparation and use of the infant formula product which include words and pictures instructing -

(a) that each bottle should be prepared individually; and
(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; and
(c) that potable, previously boiled water should be used; and
(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.

(3) Subject to subclause (4), the label on a package of infant formula product must contain the following warning 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 states –

'Important Notice' or any word or words having the same or similar effect.

(4) Subclause (3) does not apply to infant formula products for metabolic, immunological, renal, hepatic or malabsorptive conditions.

(5) The label on a package of 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; and
(b) the infant formula product should not be used for infants aged under 6 months in the case of follow-on formula; and
(c) except in the case of packages of pre-term formula, it is recommended that infants over the age of 6 months should be offered foods in addition to the infant formula product.

## 15 Print and package size

(1) Where an infant formula product is in a package having a net weight of more than 500g, the statements required by subclauses 14(1), (3) and 26(1) must be in size of type of no less than 3 mm.

(2) Where an infant formula product is in a package having a net weight of 500g or less the statements required by subclauses 14(1), (3) and 26(1) must be in size of type of no less than 1.5 mm.

## 16 Declaration of nutrition information

(1) The label on a 'ready to drink' infant formula product must include a statement, which may be in the form of a table, that contains the following information –

(a) the average energy content expressed in kJ per 100 mL; and
(b) the average amount of protein, fat and carbohydrate expressed in g per 100 mL; and
(c) the average amount of each vitamin, mineral and any other nutritive substance permitted by this Standard expressed in weight per 100 mL.

(2) The label on a powdered or concentrated form of infant formula product must include a statement, which may be in the form of a table that contains the following information -

(a) the average energy content expressed in kJ per 100 mL of infant formula product that has been reconstituted according to directions; and
(b) the average amount of protein, fat and carbohydrate expressed in g per 100 mL of infant formula product that has been reconstituted according to directions; and
(c) the average amount of each vitamin, mineral and any other nutritive substance permitted by this Standard expressed in weight per 100 mL of infant formula product that has been reconstituted according to directions; and
(d) a declaration –

(i) of the weight of one scoop in the case of powdered infant formula; and
(ii) of the proportion of powder or concentrate required to reconstitute the formula according to directions.

## 17 Date marking and storage instructions

(1) Paragraphs 2(1)(c) and (d) of Standard 1.2.5 do not apply to this Standard.

(2) A label on a package of infant formula product must contain storage instructions covering the period after it is opened.

**Editorial note:**

The appropriate storage instructions should be valid for the full range of climatic conditions that exist in Australia and New Zealand.

**18 Statement of protein source**

The label on a package of infant formula product must contain a statement of the specific source, or sources, of protein in the infant formula product immediately adjacent to the name of the infant formula product.

**Editorial note:**

Standard 1.2.2 requires that all food be labelled with its name. The requirement in clause 18 of this Standard applies only to the name on the label on the product in accordance with the requirement in Standard 1.2.2.

**19 Statement on dental fluorosis**

(1) An infant formula product must comply with subclause (2) where it contains -

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

(2) The label on a package of infant formula product referred to in subclause (1) must contain statements -

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

**20 Prohibited representations**

The label on a package of infant formula product must not contain -

(a) a picture of an infant; or
(b) a picture that idealises the use of infant formula product; or
(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or
(d) words claiming that the formula is suitable for all infants; or
(e) information relating to the nutritional content of human milk; or
(f) subject to clause 28, 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 a low lactose formula; or
(ii) a statement of ingredients; or
(iii) a nutrition information statement; or

(g) subject to Division 3, a representation that the food is suitable for a particular condition, disease or disorder.

**Editorial Note:**

Division 3 relates to Infant Formula Products for Special Dietary Use. Clause 28 permits labelling which varies from this clause.

## Division 2 – Infant Formula and Follow-on Formula

### 21 Composition

(1) Infant formula and follow-on formula must -

(a) have an energy content of no less than 2500 kJ/L and no more than 3150 kJ/L in the case of infant formula, and no less than 2500 kJ/L and no more than 3550 kJ/L in the case of follow-on formula; and

(b) contain an amount of each nutrient specified in column 1 of the Table to this clause which is no less than the amount specified in column 2 of the Table and no more than the amount specified in column 3 of the Table.

**Table to clause 21**

| Column 1 | Column 2 | Column 3 |
|---|---|---|
| **Nutrient** | **Minimum amount per 100 kJ** | **Maximum amount per 100 kJ** |
| Protein | 0.45 g | 0.7 g for infant formula<br>1.3 g for follow-on formula |
| Fat | 1.05 g | 1.5 g |

(2) Follow-on formula must have a potential renal solute load value of no more than 8 mOsm/100 kJ.

### 22 Protein

(1) The L-amino acids listed in column 1 of the Table to this clause must be present in infant formula and follow-on formula at the minimum level specified in column 2 of the Table, subject to subclause 2 and 3.

**Table to clause 22**

| Column 1 | Column 2 |
|---|---|
| **L-Amino Acid** | **Minimum amount per 100 kJ** |
| Histidine | 12 mg |
| Isoleucine | 21 mg |
| Leucine | 42 mg |
| Lysine | 30 mg |
| Cysteine & Methionine | 19 mg |
| Phenylalanine & Tyrosine | 32 mg |

| | |
|---|---|
| Threonine | 19 mg |
| Tryptophan | 7 mg |
| Valine | 25 mg |

(2) Infant formula or follow-on formula must provide no less than -

(a) 6 mg cysteine per 100 kJ; and
(b) 17 mg phenylalanine per 100 kJ.

(3) L-amino acids listed in the Table to this clause must be added to infant formula or follow-on formula only in an amount necessary to improve protein quality.

**23 Fat**

The fats in infant formula and follow-on formula must -

(a) not contain medium chain triglycerides except where a medium chain triglyceride is present in a particular infant formula or follow-on formula as the result of being a natural constituent of a milk-based ingredient of that particular infant formula or follow-on formula; and
(b) have a ratio of linoleic acid to α–linolenic acid of no less than 5 to 1 and no more than 15 to 1; and
(c) if specified in column 1 of the Table to this clause, comply with the limits, if any, specified in columns 2 and 3 of the Table; and
(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 approximately 2 in an infant formula or follow-on formula which contains those fatty acids; and
(e) where long chain polyunsaturated fatty acids are present in an infant formula or follow-on formula, an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content.

**Table to clause 23**

| **Column 1** | **Column 2** | **Column 3** |
|---|---|---|
| **Fatty acids** | **Minimum % total fatty acids** | **Maximum % total fatty acids** |
| **Essential fatty acids** | | |
| Linoleic acid (18:2) | 9 | 26 |
| α-Linolenic acid (18:3) | 1.1 | 4 |
| **Long chain polyunsaturated 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 |
| **Total *trans* fatty acids** | | 4 |
| **Erucic acid** (22:1) | | 1 |

**Editorial note:**

Standard 1.3.4 contains specifications for Docosahexaenoic acid (DHA) rich oil derived from the algae *Crypthecodinium cohnii* and Arachidonic acid (ARA) rich oil derived from the fungus *Mortierella alpina*.

## 24 Vitamins and minerals

(1) Infant formula and follow-on formula must contain the vitamins and minerals specified in column 1 of the Table to this subclause provided that, in relation to each vitamin or mineral -

(a) the added vitamin or mineral is in a permitted form as listed in Schedule 1; and

(b) the infant formula or follow-on formula contains no less than the amount specified in column 2 of the Table; and

(c) the infant formula or follow-on formula contains no more than the amount specified in column 3 of the Table, if any.

**Table to clause 24(1)**

| Column 1 | Column 2 | Column 3 |
|---|---|---|
| **Nutrient** | **Minimum amount per 100 kJ** | **Maximum amount per 100 kJ** |
| **Vitamins** | | |
| Vitamin A | 14 µg | 43 µg |
| Vitamin D | 0.25 µg | 0.63 µg |
| Vitamin C | 1.7 mg | |
| Thiamin | 10 µg | |
| Riboflavin | 14 µg | |
| Preformed Niacin | 130 µg | |
| Vitamin $B_6$ | 9 µg | 36 µg |
| Folate | 2.0 µg | |
| Pantothenic acid | 70 µg | |
| Vitamin $B_{12}$ | 0.025 µg | |
| Biotin | 0.36 µg | |
| Vitamin E | 0.11 mg | 1.1 mg |
| Vitamin K | 1.0 µg | |
| | | |
| **Minerals** | | |
| Sodium | 5 mg | 15 mg |
| Potassium | 20 mg | 50 mg |
| Chloride | 12 mg | 35 mg |
| Calcium | 12 mg | |
| Phosphorus | 6 mg | 25 mg |
| Magnesium | 1.2 mg | 4.0 mg |
| Iron | 0.2 mg | 0.5 mg |
| Iodine | 1.2 µg | 10 µg |
| Copper | 14 µg | 43 µg |
| Zinc | 0.12 mg | 0.43 mg |
| Manganese | 0.24 µg | 24.0 µg |
| Selenium | 0.25 µg | 1.19 µg |

(2) Infant formula and follow-on formula must contain no less than 0.5 mg of Vitamin E per g of polyunsaturated fatty acids.

(3) The ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1.2 to 1 and no more than 2 to 1.

(4) 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.

**Editorial note:**

This Standard contains guidelines setting out the recommended levels of vitamins and minerals that as a matter of good practice should not be exceeded.

## Division 3 - Infant Formula Products for Special Dietary Use

## Subdivision 1 – Infant formula products formulated for premature or low birthweight infants

### 25 Composition and labelling

Infant formula products may be specifically formulated for premature or low birthweight infants provided that in all other respects they comply with this Standard.

### 26 Additional labelling

(1) The label on a package of pre-term formula must include the warning statement -

'Suitable only for pre-term infants under specialist medical supervision'.

(2) The words 'pre-term' must appear as part of the name of a food standardised in this subdivision.

## Subdivision 2 - Infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions

### 27 Composition

(1) Subject to subclause (2), infant formula products may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic 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.

(3) Subclause (2) takes effect 5 years after the commencement of this Standard.

**28 Claims**

Where a label contains a claim that the infant formula product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, then the label on a package of 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; and
(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.

**29 Composition of lactose free and low lactose formulas**

(1) A lactose free formula or low lactose formula must, except for the lactose content, comply with the compositional and labelling requirements which apply to the infant formula product of which they are a variety.

(2) Lactose free formula must contain no detectable lactose.

(3) Low lactose formula must contain no more than 0.3 g lactose per 100 mL of infant formula product.

**30 Claims relating to lactose free and low lactose formulas**

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.

## Subdivision 3 - Infant formula products for specific dietary use based upon protein substitutes

**31 Composition**

An infant formula product for specific dietary use based upon protein substitutes must -

(a) have an energy content of no less than 2500 kJ/L and no more than 3150 kJ/L in the case of infant formula, and no less than 2500 kJ/L and no more than 3550 kJ/L in the case of follow-on formula; and

(b) have a potential renal solute load of no more than 8 mOsm per 100 kJ; and

(c) contain an amount of each nutrient specified in column 1 of the Table to this clause which is no less than the amount specified in column 2 of the Table and no more than the amount specified in column 3 of the Table.

**Table to clause 31**

| Column 1 | Column 2 | Column 3 |
|---|---|---|
| **Nutrient** | **Minimum amount per 100 kJ** | **Maximum amount per 100 kJ** |
| Protein | 0.45 g | 1.4 g |
| Fat | 0.93 g | 1.5 g |

## 32 Protein

(1) The protein content of an infant formula product for specific dietary use based upon protein substitutes may be in the form of protein substitute.

(2) The L-amino acids listed in column 1 of the Table to this clause must be present in infant formula product for special dietary use at the minimum level specified in column 2 of the Table, subject to subclause 3 and 4.

**Table to clause 32**

| Column 1 | Column 2 |
|---|---|
| **L-Amino Acid** | **Min amount per 100 kJ** |
| Histidine | 12 mg |
| Isoleucine | 21 mg |
| Leucine | 42 mg |
| Lysine | 30 mg |
| Cysteine & Methionine | 19 mg |
| Phenylalanine & Tyrosine | 32 mg |
| Threonine | 19 mg |
| Tryptophan | 7 mg |
| Valine | 25 mg |

(3) Infant formula product for specific dietary use based upon protein substitutes must provide no less than -

(a) 6 mg cysteine per 100 kJ; and

(b) 17 mg phenylalanine per 100 kJ.

(4) L-amino acids listed in the Table to this clause must be added to infant formula product for specific dietary use base upon protein substitutes only in an amount necessary to improve protein quality.

## 33 Vitamins and minerals

An infant formula product for specific dietary use based upon protein substitutes must contain -

(a) chromium in an amount of no less than 0.35 μg per 100 kJ and no more than 2.0 μg per 100 kJ; and

(b) molybdenum in an amount of no less than 0.36 μg per 100 kJ and no more than 3.0 μg per 100 kJ.

**Editorial note:**

The provisions of clause 24 of this Standard also apply in respect of the vitamins and minerals permitted in an infant formula product for specific dietary use based upon protein substitutes.

## 34 Additional permitted triglycerides

An infant formula product for specific dietary use based upon protein substitutes may contain added medium chain triglycerides.

## SCHEDULE 1

## PERMITTED FORMS OF VITAMINS AND MINERALS IN INFANT FORMULA PRODUCTS

| **Column 1**<br>**Vitamins or minerals** | **Column 2**<br>**Permitted Forms** |
|---|---|
| Vitamin A | Retinol Forms<br>vitamin A (retinol)<br>vitamin A acetate<br>(retinyl acetate)<br>vitamin A palmitate (retinyl palmitate)<br>retinyl propionate<br>Carotenoid Forms<br>beta-carotene |
| Vitamin C | L-ascorbic acid<br>L-ascorbyl palmitate<br>calcium ascorbate<br>potassium ascorbate<br>sodium ascorbate |
| Vitamin D | vitamin $D_2$ (ergocalciferol)<br>vitamin $D_3$ (cholecalciferol)<br>vitamin D (cholecalciferol-cholesterol) |
| Thiamin | thiamin hydrochloride<br>thiamin mononitrate |
| Riboflavin | riboflavin<br>riboflavin-5'-phosphate, sodium |
| Niacin | niacinamide (nicotinamide) |
| Vitamin $B_6$ | pyridoxine hydrochloride<br>pyridoxine-5'-phosphate |
| Folate | folic acid |
| Pantothenic acid | calcium pantothenate<br>Dexpanthenol |

| | |
|---|---|
| Vitamin $B_{12}$ | Cyanocobalamin<br>Hydroxocobalamin |
| Biotin | d-Biotin |
| Vitamin E | dl-α-tocopherol<br>d-α-tocopherol concentrate<br>tocopherols concentrate, mixed<br>d-α-tocopheryl acetate<br>dl-α-tocopheryl acetate<br>d-α-tocopheryl acid succinate<br>dl-α-tocopheryl succinate |
| Vitamin K | vitamin $K_1$, as phylloquinone<br>(phytonadione)<br>phytylmenoquinone |
| Calcium | calcium carbonate<br>calcium chloride<br>calcium citrate<br>calcium gluconate<br>calcium glycerophosphate<br>calcium hydroxide<br>calcium lactate<br>calcium oxide<br>calcium phosphate, dibasic<br>calcium phosphate, monobasic<br>calcium phosphate, tribasic<br>calcium sulphate |
| Chloride | calcium chloride<br>magnesium chloride<br>potassium chloride<br>sodium chloride |
| Chromium | chromium sulphate |
| Copper | copper gluconate<br>cupric sulphate<br>cupric citrate |
| Iodine | potassium iodate<br>potassium iodide<br>sodium iodide |
| Iron | ferric ammonium citrate ferric<br>pyrophosphate ferrous citrate<br>ferrous fumarate<br>ferrous gluconate<br>ferrous lactate<br>ferrous succinate<br>ferrous sulphate |
| Magnesium | magnesium carbonate<br>magnesium chloride<br>magnesium gluconate<br>magnesium oxide<br>magnesium phosphate, dibasic<br>magnesium phosphate, tribasic<br>magnesium sulphate |
| Manganese | manganese chloride<br>manganese gluconate<br>manganese sulphate<br>manganese carbonate<br>manganese citrate |
| Molybdenum | sodium molybdateVI dehydrate |

| | |
|---|---|
| Phosphorus | calcium glycerophosphate<br>calcium phosphate, dibasic<br>calcium phosphate, monobasic<br>calcium phosphate, tribasic<br>magnesium phosphate, dibasic<br>potassium phosphate, dibasic<br>potassium phosphate, monobasic<br>potassium phosphate, tribasic<br>sodium phosphate, dibasic<br>sodium phosphate, monobasic<br>sodium phosphate, tribasic |
| Potassium | potassium bicarbonate<br>potassium carbonate<br>potassium chloride<br>potassium citrate<br>potassium glycerophosphate<br>potassium gluconate<br>potassium hydroxide<br>potassium phosphate, dibasic<br>potassium phosphate, monobasic<br>potassium phosphate, tribasic |
| Selenium | sodium selenite<br>seleno methionine |
| Sodium | sodium bicarbonate<br>sodium carbonate<br>sodium chloride<br>sodium chloride iodised<br>sodium citrate<br>sodium gluconate<br>sodium hydroxide<br>sodium iodide<br>sodium lactate<br>sodium phosphate, dibasic<br>sodium phosphate, monobasic<br>sodium phosphate, tribasic<br>sodium sulphate<br>sodium tartrate |
| Zinc | zinc acetate<br>zinc chloride<br>zinc gluconate<br>zinc oxide<br>zinc sulphate |

# GUIDELINES FOR INFANT FORMULA PRODUCTS

**(These guidelines are not part of the legally binding Standard)**

## Guideline for maximum amount of vitamins and minerals in infant formula products

It is recommended that the quantities specified in the table below be observed as the maximum levels of vitamins and minerals in infant formula product.

| Nutrient | Recommended maximum amount per 100 kJ |
|---|---|
| **Vitamins** | |
| Vitamin C | 5.4 mg |
| Thiamin | 48 µg |
| Riboflavin | 86 µg |
| Preformed Niacin | 480 µg |
| Folate | 8.0 µg |
| Pantothenic acid | 360 µg |
| Vitamin $B_{12}$ | 0.17 µg |
| Vitamin K | 5.0 µg |
| Biotin | 2.7 µg |
| | |
| **Minerals** | |
| Calcium | 33 mg |
| Phosphorus | 22 mg |
| Manganese | 7.2 µg for infant formula products regulated by Division 3, Subdivision 2 only |
| Chromium | 2.0 µg |
| Molybdenum | 3 µg |

**Guideline on advice regarding additional vitamin and mineral supplementation**

Manufacturers are recommended to provide an advice in the label on a package of infant formula product to the effect that consumption of vitamin or mineral preparations are not necessary.

**Nutrition information table**

The nutrition information contained in the label on a package of infant formula product is recommended in the following format -

**NUTRITION INFORMATION**

| | **Average amount per 100 mL made up formula** *1 | **Average amount per 100 g of powder (or per 100 mL for liquid concentrate)** *2 |
|---|---|---|
| Energy | kJ | kJ |
| Protein | g | g |
| Fat | g | g |
| Carbohydrate | g | g |
| Vitamin A | µg | µg |
| Vitamin $B_6$ | µg | µg |
| Vitamin $B_{12}$ | µg | µg |
| Vitamin C | mg | mg |
| Vitamin D | µg | µg |
| Vitamin E | µg | µg |

| | | |
|---|---|---|
| Vitamin K | µg | µg |
| Biotin | µg | µg |
| Niacin | mg | mg |
| Folate | µg | µg |
| Pantothenic acid | µg | µg |
| Riboflavin | µg | µg |
| Thiamin | µg | µg |
| | | |
| Calcium | mg | mg |
| Copper | µg | µg |
| Iodine | µg | µg |
| Iron | mg | mg |
| Magnesium | mg | mg |
| Manganese | µg | µg |
| Phosphorus | mg | mg |
| Selenium | µg | µg |
| Zinc | mg | mg |
| | | |
| Chloride | mg | mg |
| Potassium | mg | mg |
| Sodium | mg | mg |
| | | |
| (insert any other nutritive substance to be declared) | g, mg, µg | g, mg, µg |

***1** – Delete the words 'made up formula' in the case of formulas sold in 'ready to drink' form.
***2** – Delete this column in the case of formulas sold in 'ready to drink' form.

Note: The information in column 2 is not mandatory.

**[5]** *omitting from the* Table of Contents *of Volume 2 the following –*

Standard 2.9.1 Reserved (Infant Formula Products)

*substituting –*

Standard 2.9.1 Infant Formula Products