ANZFA
Australia New Zealand Food Authority

TE MANA WHAKARITE KAI
MO AHITEREIRIA ME AOTEAROA

5 May 1999
12/99

EXPLANATORY NOTES

PROPOSAL P93

INFANT FORMULA PRODUCTS

The Australia New Zealand Food Authority (ANZFA) has before it a proposal (P93) to develop a revised standard for infant formula products. This proposal was originally prepared in 1993 to revise Australian *Food Standards Code* Standard R7 - Infant formula. A full assessment report was circulated in 1995 and public comment was received in the same year.

Following the Agreement which established ANZFA and the joint food standards setting system in 1996, it was decided that this proposal would be included within the Review of the food standards and that the previously prepared Full Assessment report would form the basis of the review of infant formula regulations.

A preliminary inquiry report is now being conducted to:

- modify the draft revised standard in accordance with the principles of the Review of food standards and the Government's obligations as a signatory to the World Trade Organization (WTO) taking into account received public comment; and
- provide formal opportunity for consultation in New Zealand.

OBJECTIVES

There is strong scientific evidence to show that human milk supplied through breast feeding is the superior form of nourishment for infants. However, infant formula can be the sole source of nutrition for some babies during the first four to six months of life. The objective of this proposal is to ensure that:

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

The approach taken to achieve objectives is to:

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

In response to the draft revised standard released in 1995, ANZFA received 29 submissions from infant formula manufacturers, pharmaceutical companies, health professionals, governments and individuals. Many were in broad support of the draft raised at Full Assessment. However a significant proportion of the submissions asserted that the draft standard was overly prescriptive, inconsistent with current regulatory practice and not harmonised with international standards. Following consideration of the public comments and an assessment against the objectives of the Review, draft Standard 2.9.1 has now been prepared as a joint ANZ standard for infant formulas.

SCOPE OF THE STANDARD

The joint ANZ standard for infant formula products includes provisions for different categories of infant formulas to cater for different ages and special purpose formulas intended for infants with specific diseases or disorders for whom breastfeeding is contraindicated.

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

Special purpose formulas are intended for infants who require specific modifications to suit specific diseases or disorders or who are pre-term infants. Formula categories are pre-term formulas, lactose free or low lactose formulas, formulated infant formula for metabolic and immunological conditions, including formulas based on protein substitutes. With the exception of formulas targeted to lactose intolerant infants, special purpose formulas are not suitable for general use and are to be labelled as such.

MAIN ELEMENTS OF THE STANDARD

The following elements proposed for this standard are that:

- The general composition is controlled by the definition of infant formula product and novel nutritional substances or sources of these substances for formulas should be assessed as safe and suitable in accordance with (draft) Standard 1.5.1 (Novel Foods) for infants before use in formulas in Australia or New Zealand.
- The total energy, total fat and essential fatty acids content is regulated to ensure infants who are formula fed receive sufficient but not excessive energy and fatty acid intakes. Fatty acids which are considered harmful to infants are restricted where necessary to protect infants from adverse

health consequences. Limits are recommended for *trans*- fatty acid and erucic acid contents of infant formula.

- The quality and quantity of the protein content of infant formulas is regulated and therefore it is not considered necessary to regulate the protein source. However, information about the source of protein should be declared on the label to assist carers make suitable product choices.
- The carbohydrate content of infant formula is indirectly controlled by the regulation of protein, fat and energy content. Sources of carbohydrate are no longer directly controlled as proposed at Full Assessment.
- Mandatory maximum levels of vitamins and minerals are only prescribed for those vitamins and minerals which are considered to pose a significant risk to infants if consumed in excess, whereas advisory maximum levels are recommended for other nutrients, whose risk characterisation is provisionally assessed as 'not of significance on the basis of current scientific knowledge'. A guideline accompanies the draft joint ANZ standard for infant formula products to guide manufacturers on these recommended maximum levels. These guidelines are expected to be implemented by Good Manufacturing Practice, but have no force of law. Refer to the later item on the vitamins and minerals policy.
- The potential renal solute load of follow-on formula and formulated infant formula for metabolic and immunological conditions is regulated to minimise the risk of dehydration illness from formulas with high protein and electrolyte contents.
- Specific long chain polyunsaturated fatty acids, specific nucleotides, carnitine, taurine, choline and inositol are permitted to be voluntarily added to infant formulas. The maximum permitted content of these substances in infant formula is regulated, as is the minimum claimable level.
- Limits for lead and aluminium contents are imposed to protect infants. Other potential contaminants are regulated by other mechanisms, such as water quality guidelines or do not pose a safety concern for infants. An advisory labelling statement to alert carers to seek specific health advice is proposed for formulas with unnecessarily high fluoride contents.
- It is considered that the risk to infants in Australia and New Zealand from potential gluten content of infant formulas is sufficient to prohibit gluten in formulas, although gluten is not specifically prohibited in the Codex standard.
- Microbiological criteria and the use of specific food additives are prescribed to ensure safety of infant formulas.
- Specific labelling is prescribed to advise carers to seek health advice before determining whether formula is the most appropriate method of feeding and if so whether the specific formula is the most appropriate formula for the individual infant. Labelling is also required to advise carers of the nutritional content of the formula and the safe preparation, storage, and use of the formula. The relevant labelling provisions of the WHO Code of Marketing Breast-milk Substitutes, which include a reference to breast

milk as the optimum source of nourishment for infants, are also adopted within the Standard.

- Specific labelling is also required to advise carers that infant formulas specially formulated for infants with metabolic or immunological needs are not for general use, should only be used under medical supervision and of the nature and purpose of the formulas' modification.

The Preliminary Inquiry concludes that a food standard for infant formulas which protects the health and safety of infants who are routinely fed substitutes for human milk is necessary and should be included in the joint ANZ Code. Infants are the most vulnerable group in the Australian and New Zealand population and may consume infant formula as the sole or principal source of nourishment. Therefore the proposed joint standard is justifiably more prescriptive than standards for other foods which form part of a varied diet.

The major differences between current Standard R7, NZ food regulation 242, and draft Standard 2.9.1 at Preliminary Inquiry are summarised and attached at Attachment 1.

GENERAL POLICY ISSUES

The regulation of maximum levels of vitamins and minerals in infant formulas

Because infant formula is intended as the sole source of nutrition for infants, vitamins and minerals used in excess can be harmful. Unlimited nutrient contents for infant formulas are not recommended as in the best interests of infant consumers. Therefore maximum levels of all vitamins and minerals should be contained. Although not all vitamins and minerals are toxic in large quantities, an excess of one nutrient can sometimes interact adversely with others. Human milk has a self limiting level for all vitamins and minerals and the setting of maximum levels mimic this natural protective factor. However, concerns were expressed at full assessment by industry in relation to the criteria used for the setting of nutrient levels, the lack of harmonisation with international standards, the need for overages, compliance difficulties and special requirements for special purpose formula. To eliminate unnecessary cost for industry, the Authority reviewed known health and safety concerns for vitamin and mineral intakes by infants. The risk to infants of excess intakes of individual vitamins and minerals was classified into 'significant' or 'probably not significant on the basis of current scientific knowledge' according to reports of toxicity or nutrient-nutrient interactions and with reference to potential intakes by infants.

High or unlimited intakes of vitamin A, vitamin D, vitamin E, vitamin B_6, calcium, chloride, copper, iron, iodine, magnesium, manganese, potassium, phosphorus, selenium, sodium and zinc were considered to pose a significant risk to infants. Therefore, mandatory maximum levels are prescribed for the joint ANZ standard for infant formula for these nutrients. Levels are the same for soy-based and milk-based formulas and apply to infant formula products for infants from birth to 12 months.

Advisory maximum levels are recommended for other nutrients, whose risk characterisation is provisionally assessed as 'not of significance on the basis of current scientific knowledge'. A guideline accompanies the joint ANZ

standard for infant formula to guide manufacturers on these recommended maximum levels . This guideline is expected to be implemented by Good Manufacturing Practice and does not have the 'force of law' as do levels prescribed in the standard. However, it is recommended compliance with guideline levels of nutrients be monitored to evaluate the effectiveness of the policy of issuing guidelines in protecting the health and safety of infants.

The Australian infant formula industry representative on the ANZFA external team objected to the decisions in relation to chromium, molybdenum and the zinc: copper ratio as this would require the reformulation of some formulas.

Ed note: The EC has adopted (1999/21/EC of 25/3/99) a Directive on dietary foods for special medical purposes. This directive provides *inter alia* for infant formula products, except preterm formulas, prepared for infants with medical disorders and thus overlaps with categories of some of the modified formulas to be regulated by this standard. The directive includes rules for the vitamin and mineral content of these formulas and stipulates mandatory minimum and maximum levels for all 13 vitamins and all 15 minerals. In many cases the range proposed for vitamin and mineral levels for these special purpose formulas is narrower than those proposed for formulas for healthy infants. In the light of this recent development, submissions are sought on the suitability of applying the wider range of nutrients proposed for formulas for healthy infants to formulas designed for infants with medical disorders.

Provision for special purpose formulas

The removal of current Standard R7 clause 2(b) from the draft proposed at Full Assessment caused concern with industry and health professionals. This particular clause permitted infant formula to be specifically formulated to satisfy particular well recognised dietary requirements that are a result of a specific physical or physiological condition, disease or disorder.

There are some infants with metabolic or immunological diseases or disorders for whom breast feeding or standard milk-based formulas are unsuitable. Highly specialised formulas are required by these infants. These modified formulas are not recommended for general consumption and longer term, a separate standard or part of standard may be developed to regulate these specialised formulas in Australia and New Zealand. However, unless the permissions in the joint ANZ standard for infant formula in the joint ANZ standard are sufficiently broad to incorporate specialised formulas such as those based solely upon amino acids mixtures, these formula would be without regulatory status in both countries.

Use of the term, physiological

It is not proposed to include the term 'physiological' in these permissions as there are current concerns in relation to the marketing of anti-reflux formulas.

Regurgitation after a feed is common in infants, including by those who are breastfed and is usually not serious. Concern has been expressed by health professionals that the recent general marketing of thickened formulas as 'anti-reflux formulas' may influence carers to cease breastfeeding and instead to use these formulas. Special purpose formulas, including thickened formulas should not be fed to infants without prior medical advice and the current marketing situation of thickened formulas is considered problematic by the

Advisory Panel on the Marketing in Australia of Infant Formula. The cost differential between special purpose formulas and 'standard' infant formula products will usually deter carers from unwarranted use. However, thickened formulas are marketed in supermarkets at a similar price to 'standard' infant formula products. Such marketing increases the risk of carers using these formulas without due cause and particularly increases the risk of carers switching their infants from breastfeeding to thickened formulas to 'treat' regurgitation.

Therefore it is proposed not to provide specific permission for claims in relation to physiological conditions until evidence is presented to show that such formulas are not detrimental to breastfeeding rates in Australia and New Zealand.

Soy-based formulas

A number of professional and regulatory bodies have recently released documents which caution against the unnecessary use of soy-based formulas for infants.

The Authority has undertaken an assessment of the risks to infants from the phytoestrogen content of soy-based infant formulas. The document, 'Phytoestrogens, An assessment of the potential risks to infants associated with exposure to soy-based infant formula' (1999) is available from the Authority upon request.

It is concluded that although the currently available data is poor, there may be a potential risk from the phytoestrogen content of some soy-based formula for infants. At this time it is not proposed to require warning statements on the product labels of soy-based formulas. However, potential strategies to reduce the level of unnecessary soy-based infant formula consumption depend upon the future consumption levels.

The New Zealand Ministry of Health has recently released a public statement 'Soy Based Infant Formulas' which advises carers that breast milk is the best food for babies and dairy-based infant formulas are the next best choice. The New Zealand Ministry of Health has also provided more detailed information for health professionals and highlighted that any alternative to human or dairy-based milk should be discussed with a health professional.

DATA REQUIRED FOR THE INQUIRY OF DRAFT STANDARD 2.9.1

The Authority seeks additional information to complete its Inquiry into the standard for infant formulas on the following issues:

1. Medium chain triglycerides (MCTs) and pre-term formulas

At Full Assessment it was proposed to prohibit MCTs in formulas for healthy infants and for pre-term infants because they are not normally present in human milk; the long term effects of infants consuming a high percentage of saturated fats are unknown; and there is no convincing evidence that the inclusion of MCTs in formula has conferred any benefit to infants.

Submission was made that pre-term formulas containing high levels of MCTs are already in use in Australia, New Zealand and overseas and this prohibition would disadvantage pre-term infants as some forms of formula would not continue to be available.

Consideration

Historically, MCT's have been added to pre-term formula with the aim of improving the digestion and absorption of formulas, particularly the fat content, for very small infants with immature physiological systems. However, clinical studies have not confirmed a benefit for MCTs and there may be adverse health consequences from the currently high levels.

It is believed that many manufacturers are reducing the MCT content of pre-term formulas. The Authority requires additional data to resolve the requirements for MCT content of pre-term formulas.

Therefore, submission is sought on:

(i) the current MCT content in formulas, particularly pre-term formulas; and
(ii) evidence that shows MCTs at currently used levels are safe and efficacious.

Data provided at Inquiry will be used to determine a potential MCT content of formulas prepared for pre-term infants. The drafting now provides for MCT content which is the natural constituent of the milk-based ingredient of formulas.

2. Long chain polyunsaturated fatty acids (LCPUFAs)

LCPUFAs are fats derived from the essential fatty acids (linoleic and alpha-linolenic acid (ALA)). It was proposed at full assessment to regulate the maximum level for the total content and three individual LCPUFA content of infant formulas. The EC and UK standards are the only known standards which currently regulate the maximum levels of LCPUFAs.

There is no consensus that the addition of LCPUFA to infant formula with adequate linoleic and ALA is beneficial and there are concerns that the metabolic and nutritional effects of these LCPUFAs have not yet been adequately addressed. Disquiet has also been expressed that these nutrients may be sourced from 'novel sources' and purity needs to be assessed prior to use in infant formulas.

The Authority proposes three options for the voluntary addition of LCPUFAs to formulas.

Option 1: Do not provide express permission

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

Levels could be included in the guideline proposed to accompany the draft Standard.

Option 2: Amend express permission proposed at Full Assessment to align with the EC and UK

There is emerging evidence that some LCPUFAs may be beneficial for visual and neurodevelopment of infants. However, there is also evidence to suggest that different LCPUFAs of the 3- , 6-, and 9- series may interfere with each others' metabolism to varying extents. Therefore it is proposed as at Full Assessment to give a broad permission for a LCPUFA content similar to that found in human milk, sourced from food ingredients (subject to the novel food standard requirements) rather than individual fatty acids and to control the maximum levels as per the EC and UK since these are currently in force.

The permissions proposed in this option are:

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

If long chain polyunsaturated fatty acids are added to the formula then the eicosapentanoic acid (20:5 n-3) content shall not exceed the docosahexanoic acid (22:6 n-3) content.

Option 3: Amend express permission proposed at Full Assessment to align with the EC and UK but require a series 6 to series 3 ratio of 2 as in human milk.

As proposed at option 2 but the ratio of series 6 to series 3 LCPUFAs should be regulated at the level it is reported to be in human milk ie 2.

The permissions proposed in this option are as listed at option 2 plus:

If long chain polyunsaturated fatty acids are added to the formula the total long chain omega 6 series fatty acids (C>= 20) should be double the total long chain omega 3 series fatty acids (C>= 20).

Preferred Option

The Authority's preferred option is option 3 as this is consistent with known international regulations but affords an extra safety measure of aligning the series 6 to series 3 LCPUFAs ratio to that in human milk.

3. Safety requirements for novel foods and novels ingredients

The current international and local regulatory systems for infant formulas has led to the addition of some ingredients to formulas without rigorous, objective safety assessments which are required for other food ingredients eg, food additives. Some constituents are added at unregulated levels or as unpurified forms with associated uncharacterised constituents and the safety of such ingredients may be of concern. There is disquiet that nutrients and other nutritive substances from 'novel sources' are now being added to formulas overseas and that these formulas may be marketed in Australia and New Zealand without there being an opportunity for an Australian and New Zealand assessment of safety. For example when LCPUFAs are added to some formulas, they may be added as an extract from herbal or marine preparations

rather than as pure fatty acids; the associated constituents need to be assessed as suitable for ingestion by infants. Therefore it is proposed that such novel foods are assessed for safety before use in infant formulas in Australia and New Zealand by virtue of the proposed Standard A19 - Novel Foods (draft Standard 1.5.1).

Information is required to identify the use of potential novel foods or ingredients from novel sources.

4. Purity specifications for optional ingredients

Concern has been expressed at the use of unpurified constituents in infant formulas, particularly for the addition of LCPUFAs and nucleotides.

4a) LCPUFAs

LCPUFAs derived from algal or fungal sources are used in infant formulas in some countries. LCPUFAs used in some infant formulas are claimed to be sourced from botanicals which are not permitted to be added to foods in Australia eg borage. These are 'novel' sources of nutrients for formulas and the Authority would require these to be assessed as safe and suitable for infants before use in formulas in Australia or New Zealand. Permission is currently included in the draft joint ANZ standard for the inclusion of LCPUFAs. Submission is sought on suitable purity specifications for these LCPUFAs.

4b) Nucleotides

Specifications for nucleotides for use in infant formulas are not readily available. Specifications for the five nucleotides currently being considered as optional ingredients have been supplied by industry for the preliminary inquiry. These are now proposed to be included in draft Standard 1.3.4. Submission is sought on the appropriateness of these specifications for inclusion in the joint ANZ Food Standards Code.

5. Permitted forms of nutrients

The permitted forms of nutrients proposed at Full Assessment, plus chromium sulphate and molybdenum sulphate which have been assessed as suitable for use in special purpose infant formulas, will be included in the draft joint ANZ standard for infant formula. NZFR provide permission for additional forms of nutrients. Submissions should assist with the identification of those considered necessary in the joint standard.

The use of additional forms of nutrients not currently permitted by the NZFR would require assessment to ensure these forms are safe for consumption by infants. Therefore requests at Inquiry to extend this list should be accompanied by data suitable for safety assessment of requested additional forms or a full application should be made after the joint standard is gazetted.

Submission has been made for the inclusion of sodium selenate as a permitted form of nutrient. Data on the bioavailability of sodium selenate compared to that of sodium selenite is required for assessment of this request at Inquiry.

PROPOSED JOINT AUSTRALIA NEW ZEALAND FOOD STANDARD - Standard 2.9.1

See Attachment 2.

REGULATORY IMPACT ANALYSIS

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community which includes the consumers, food industry and governments in both countries. The regulatory impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the Australian *Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice.*

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of the regulatory impact statement. Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

BACKGROUND

World Health Organization International Code of Marketing of Breast-milk Substitutes

The International Code of Marketing of Breast Milk Substitutes (WHO Code) was adopted at the 34th Session of the World Health Assembly, 20 May 1981. The aim of this Code is to "contribute to the provision of safe and adequate nutrition for infants by ... ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution". Many countries are signatories to this agreement and have taken action to effect the principles and aims of the WHO Code. Both Australia and New Zealand are signatories to the WHO Code.

Implementation of the WHO Code in Australia and New Zealand

The Australian and New Zealand governments have taken a number of different steps in support of their international commitments to the WHO, by incorporating the relevant articles into food standards and as voluntary Codes of Practice. The composition and labelling of infant formulas are regulated by food standards in both countries. Marketing aspects of the WHO Code are implemented in Australia through an authorised agreement under the Trade Practices Act 1974 (the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (May, 1992)(MAIF Agreement). The MAIF Agreement has been adopted by the Infant Formula Manufacturers as their Code of Conduct. The MAIF Agreement is monitored by the Advisory Panel for the Marketing in Australia of Infant Formula (APMAIF), a major function of which is to ensure that information supplied by manufacturers and marketers is 'scientific and factual'. The members of APMAIF are appointed by government and industry. A revised and updated agreement is currently being prepared to replace the 1992 MAIF Agreement.

Marketing aspects of the WHO Code are implemented in New Zealand through an industry Code of Practice (1997) which is monitored by the New Zealand Infant Formula Marketers' Association (NZIFMA).

These agreements, place certain limitations on the advertising and promotion of infant formulas, in particular the advertising and promotion of infant formulas to the general public is restricted.

PROBLEMS

Breastfeeding rates are lower than Australian and New Zealand government public health recommendations.

There is significant international trade in infant formula products. The current regulatory requirements limit access of consumers to some ingredients which may be of potential benefit to their health and may impede trade in infant formulas.

Lack of clarity in the current Standard may expose infants to an unacceptable risk from toxic levels of nutrients, contaminants or additives. One clause in the Australian Standard is interpreted by manufacturers as giving permission to introduce new constituents to infant formulas, such as nucleotides and long chain polyunsaturated fatty acids. The content of these is not prescribed by the current standard and thus application of the Standard potentially fails to control the safety, quantity and purity of certain special ingredients. Additionally, consumers are not able to interpret the value of these unfamiliar ingredients when claims are made about their content.

PUBLIC CONSULTATION

Consultation took place with representatives of industry, health professionals and consumer groups. The consultation was in the form of a panel of experts in infant health, an external project review team and material in submissions in response to the draft revised Standard. Submissions were received from industry, the Dietitians Association of Australia, a paediatric research dietitian, various departments of health in the Commonwealth, States and Territories and New Zealand. Most submissions raised a broad range of issues.

Further public consultation will be undertaken throughout New Zealand and Australia when the Preliminary Inquiry Report is released for comment.

REGULATORY OPTIONS

Option 1 – **to maintain the status quo**
Option 2 – **to regulate infant formula products as proposed at preliminary inquiry**
Option 3 – **no regulation of infant formula products in the FSC**

Option 1 – to maintain the status quo

Standard R7 in the Australian *Food Standards Code* and Regulation 242 in the New Zealand *Food Regulations 1984* regulate the composition and labelling of infant formula products in Australia and New Zealand. Neither regulation specifically includes provisions for formulas for pre-term infants or infants who require modified formulas. These standards vary from each other and

many of the compositional requirements vary from those in the Codex standard (international standard).

Advertising and promotion of infant formula products to the general public is limited by voluntary Codes of Practice in Australia and New Zealand as the public benefit of this restriction outweighs the cost to industry of the restriction. The Authority believes the Codes of Practice adopted in Australia and New Zealand are currently generally effective in limiting the advertising of infant formula products to the general public. Therefore it is proposed to rely on the current situation of voluntary Codes of Practice and not to include advertising restrictions in the food standard.

Option 2 – to regulate using the proposed revised Standard, the Codes of Practice to limit advertising to the general public and guidelines for good manufacturing practice for some nutrients.

This option regulates the composition and labelling of infant formula products for healthy infants, pre-term infant formulas and formulas modified for a limited range of other special conditions where necessary to protect the health of infants.

Such an approach addresses public health and safety issues by prescribing compositional requirements, such as setting upper limits on the addition of nutrients, and mandates these limits where there is known risk to infant health of excessive intake. The proposed standard has addressed particular labelling and consumer information needs as well as permitting certain claims to be made.

As noted above for option 1 the advertising and promotion of infant formula products to the general public are restricted by voluntary Codes of Practice. Therefore it is proposed to retain the current situation of voluntary Codes of Practice and it is not proposed to include these restrictions in the food standard.

Option 3 – no regulation

Option 3 would result in no food standard for infant formula in the Food Standards Code and the onus would be on manufacturers to maintain an acceptable standard. Application of good manufacturing practice would be expected to produce products free from contamination and of satisfactory microbiological profile. The formulary of infant formula would not be subject to government control and there is the potential for unsafe use or levels of specific ingredients, thus the health and safety of infants may be put at risk. Additionally, information for carers would become complex and confusing due to the possible variations in labelling.

AFFECTED PARTIES

- Government – Commonwealth (ANZFA, AQIS), New Zealand, State, Territory and Local.
- Industry – Manufacturers and importers of Infant Formula.
- Consumers / community – carers and consumers of Infant Formula and health professionals who advise them.

EVALUATION

Option 1 is not considered to be a viable option because of the obsolete nature of the current regulation. There are costs for all and no obvious benefit is apparent for stakeholders.

Option 2 is preferred because it reduces the cost to government and allows government to meet its obligations to protect public health and safety. It also provides assurance and protection for carers / consumers giving the healthy growth and development of infants first priority. Option 2 increases costs to industry but no more than compliance with formulated foods standards elsewhere in the Food Standards Code. The proposed new standard is harmonised with international standards other than for health or safety reasons and therefore reduces potential trade barriers.

Option 3 is not considered a viable option because of the possible risks to the safety of consumers and the increased costs to government and the community.

Consideration of the Regulatory Impact for this proposal concludes that government action is needed and the proposed revised Standard is the preferred option for containment of costs and the pursuit of public health and safety objectives.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

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

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

Matters relating to public health and safety are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

This matter will be notified to the WTO as a Sanitary/Phytosanitary notification because standards are proposed for pre-term formulas and infant formula formulated for metabolic and immunological conditions for which there are no Codex standards.
Additionally, to protect infants in Australia and New Zealand from potential risk of developing coeliac disease, the proposed standards for infant formula products will not permit a gluten content.

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. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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 the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984*.
- Food imported into Australia other than from New Zealand must comply solely with the Australian *Food Standards Code*.
- Food imported into New Zealand from Australia must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both.
- Food imported into Australia from New Zealand must comply with the Australian *Food Standards Code*. 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 for most products comply solely with the Australian *Food Standards Code*.

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*.

INVITATION FOR PUBLIC SUBMISSIONS

The Authority has completed a preliminary inquiry of the proposal, developed a new joint Australia New Zealand food standard and will now conduct an inquiry to consider the new draft standard and its regulatory impact.

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Proposal P93** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by **16 June 1999.**

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.

Attachments:

1. Major differences between current Standard R7, NZ regulation 242, and draft Standard 2.9.1 at Preliminary Inquiry

2. Proposed Drafting

Major differences between current Standard R7, NZ regulation 242, and draft Standard 2.9.1 at Preliminary Inquiry

Element	Current Standard R7	Current NZ Regulation 242	Draft Standard 2.9.1 compared to Std R7)
Purpose	Covers all types infant formula-products by virtue of clause 2(b)	Covers all types infant formula products by virtue of regulation 237	Covers those types of infant formulas that are nutritionally complete. Temporarily includes amended form of clause 2(b) to cover special infant formulas until development of separate regulation
Definitions	Covers only 'infant' and 'energy value'	Covers only 'infant' (reg 237); infant formula, follow-on formula	Expanded to cover various types of formula, and particular nutritional constituents
Novel foods and ingredients	Permitted by virtue of clause 2(a). Standard A19 - Novel foods would apply to Std R7 when in effect	No controls on source of base ingredients	Define infant formula product; introduce explicit link to Standard 1.5.1- Novel foods
Cereal proteins	Prohibit cereal proteins in formula described as suitable from birth	None	Prohibit gluten in all formulas
Energy factors	Carbohydrate as monosaccharides 16 kJ/g	Regulation 2(3)(c) carbohydrate 17 kJ/g	Amended carbohydrate to 17 kJ/g to apply to available carbohydrate; Adopt general factor of 8kJ/g for unavailable carbohydrate
Osmolality/ Potential Renal Solute Load	Osmolality	None specified	Change parameter to potential renal solute load, and introduce method of calculation
Energy and macro-nutrient content		None specified	Expanded range of contents for energy, protein. Increased minimum amount of fat
Amino acids	Specific minimum milligram content; permission for addition of L-amino acids	No control on content; permission for addition of L-methionine, taurine	Calculation according to amino acid score, min score 0.8 for all formulas; permission for addition of L-amino acids to achieve min score Permission for specialised formulas where protein content is based solely upon amino acids

Element	Current Standard R7	Current NZ Regulation 242	Draft Standard 2.9.1 compared to Std R7)
Medium chain triglycerides (MCT)	Permitted in all types of formula by virtue of clause 2(a)	No controls on source of base ingredients	Restricted to MCTs naturally provided from milk ingredients, except for specific dietary use formulas to which addition is permitted. Public comment sought on prohibition of addition to other formulas
Prohibition of specific oils	Prohibition on sesame and cottonseed oil	No controls on source of base ingredients	
Fatty acids	Trans ≤ 8%	No limit given	Trans ≤ 4% total fatty acids
			Maximum limit on erucic fatty acid content
	Max amounts 12:0 and 14:0	No limit given	No limit 12:0 and 14:0
	Min amounts 18:2	No limit given	Min and max amounts 18:2 and 18:3; new ratio range of 18:2 to 18:3
			Voluntary addition of LCPUFAs, max limits on omega 6. Omega 3, 20:4. New ratio for omega 6 to omega 3
Vitamins	13 vitamins; min and max for vits A, D; min only for remainder	13 vitamins listed in column 2, Schedule 13A; no specified min or max	Decreased min for vits B12, C, E, A; increased min for folate, niacin; increased max for vits A and D; new max for vits E, B6
			New advisory max guideline for remainder
Minerals and electrolytes	11 minerals (not selenium, chromium, molybdenum); min and max for K, Cl, P, Mg, Fe, I; min only for Na, Ca, Cu, Mn, Zn; no permission for added Se	11 minerals (not chloride) listed in column 2, Schedule 13A; no specified min or max	Decreased min for Cl, Mg, Mn; increased min for Fe; new min for Se; increased max for Mg, Fe; new max for Na, Cu, Zn, Mn, Se.
			New advisory max guideline for remainder, + Cr, Mb
			New ratio Zn:Cu, Vit E: 18:2

Element	Current Standard R7	Current NZ Regulation 242	Draft Standard 2.9.1 compared to Std R7)
Optional nutritive substances: - choline - inositol - taurine - L-carnitine - 5 nucleotides	No limits by virtue clause 2(a) except for Min taurine Min L-carnitine	No controls on source of base ingredients - permission for choline - permission for L-carnitine if not provided by protein sources	Min and max amounts apply for each, including 5 individual nucleotides as well as max total of nucleotides
Lactic acid (cultures)	L(+) lactic acid permitted	L(+) lactic acid and cultures permitted	L(+) lactic acid; lactic acid producing cultures
Food additives	Several permitted but not anti oxidants; imposed max; carrageenan only in liquid formulas	Several permitted including carrageenan; no imposed max; 2 anti oxidants permitted with max	Expanded range
		Prohibition on carryover	Permission for carryover from ingredients
Limit on contam-inants	None specified	None specified in reg 242	Max for Al, Pb Specific labelling for formulas with high fluoride content
Microbiolog-ical requirements	Indirectly prohibit lactic acid cultures	Permits lactic acid producing cultures	Accommodates lactic acid cultures
Permitted forms vitamins and minerals	66 in Schedule (none repeated), no selenium, choline	129 in Schedule 13A (several repeats), no chloride or choline	Considerably extended range of R7, includes chloride, choline; net 18 less than NZ schedule 13A
Formulas other than infant formula for normal use, and follow-on formula	Compositional deviations to suit purpose permitted by virtue of clause 2(b)	Compositional deviations to suit purpose permitted by virtue of reg 237	Relevant compositional parameters for formulas for pre-term, lactose free/low lactose, designed for metabolic and immunological conditions
			Min and max Cr, Mb
			Temporarily includes amended form of clause 2(b) to cover special infant formulas until development of separate regulation
	No permission for declaration of condition for which formula is designed	No permission for declaration of condition for which formula is designed other than amino acid modified foods (NZFR 237)	Requirement of declaration of condition for which formula is designed

Element	Current Standard R7	Current NZ Regulation 242	Draft Standard 2.9.1 compared to Std R7)
Labelling - prescribed names	None, although prescribed text for 'infant formula'	Infant formula; follow-on formula or other appropriate designation	Infant formula; follow-on formula
Labelling - prescribed statements	Prescribed text on: - breast milk best - consult doctor before deciding to use - correct proportions, follow instructions - weaning - use of scoop - discourage additional vit or min intake - suitability from birth or over 6 months	Prescribed text on: - discourage additional vit or min intake	Prescribed text on: - correct proportions, follow instructions. - for pre-term only, use under specialist medical supervision
	Advisory text on: - preparation and use - storage instructions - source of protein	Advisory text on: - preparation and use - storage instructions - date mark	Advisory text on: - breast milk best - use on advice doctor or health worker - preparation and use - weaning - use of scoop - suitability from birth - date marking and storage instructions - source of protein immediately adjacent to name of product - formulas with high fluoride content : advice to seek specific advice to min. risk of dental fluorosis
Labelling - feeding table	Prescribed format	Not explicitly required, but general requirement for clear directions for use	Not explicitly required, but general requirement for full directions for use relevant to age of infant

Element	Current Standard R7	Current NZ Regulation 242	Draft Standard 2.9.1 compared to Std R7)
Labelling - nutrient composition	Requirement as appropriate for declaration of composition after reconstitution (ready to feed)	Requirement for declaration of composition as sold and after reconstitution (ready to feed)	Requirement as appropriate for declaration of composition before and after reconstitution (ready to feed)
	Prescribed format and list of nutrients		Advisory format and list of nutrients /optional ingredients
	No specific guidance as to representation of nutrient content eg average, minimum etc However, A1(13) requires use of 'average'	No guidance in reg 242 as to representation of nutrient content eg average, minimum etc	Average representation of content
Labelling - guideline statements	None	None	Discourage additional vit or min intake

DRAFT REVISED STANDARD R7 - INFANT FORMULAS

1. The Food Standards Code is amended by inserting

"STANDARD 2.9.1 - Infant formula products

PURPOSE

This Standard provides for the compositional, microbiological and labelling requirements of foods intended or represented for use as a substitute for human milk, herein referred to as 'infant formula products'. 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.

Drafting Note:

This draft Standard will be reformatted to be consistent with the structure of the revised Code.

TABLE OF PROVISIONS

SCHEDULE

Permitted forms of vitamins and minerals

PART 1 - GENERAL PROVISIONS

Division 1 - Interpretation

Definitions

1. (1) In 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.

'infant' means a child under the age of 12 months.

'infant formula' means an infant formula product that is represented as being suitable as the principal source of food for infants.

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

an **'infant formula product'** is a product based on milk or other edible food constituents of animal or plant origin and which is intended to be, and is suitable for use as, the principal source of nourishment for infants.

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

'lactose free formula' and **'low lactose formula'** mean infant formula products represented as being the principal source of food for lactose intolerant infants.

'medium chain triglycerides' in this Standard means triacylglycerols which contain predominantly the saturated fatty acids 8:0 and 10:0.

'pre-term formula' means infant formula product represented as being suitable as the principal source of food for infants of less than 37 weeks gestation.

'protein equivalent' means the amount of nitrogen from hydrolysates and/or L-amino acids expressed as protein.

'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 infant formula product in which soy protein isolate is the sole source of protein.

Interpretation

2. In the compositional requirements of this Standard a reference to any '**infant formula product**' 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.

Division 2 – Calculations

Calculation of energy

3. 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.

Calculation of protein

4. The protein content of infant formula product, must be calculated as follows:

(a) For milk proteins and their partial protein hydrolysates:

Protein content = nitrogen content x 6.38; or

(b) In any other case:

Protein content = nitrogen content x 6.25.

Calculation of Potential Renal Solute Load

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

Potential renal solute load in mOsm/100 kJ
= [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [P(mg/100 kJ)/31] + [protein (mg/100 kJ)/175].

Calculation of amino acid score

6. 'amino acid score' means the lowest of the ratios between the quantity in the infant formula product of the L-amino acid listed in column 1 of the Table to this clause and the quantity of the corresponding L-amino acid listed in column 2 of the Table to this clause.

TABLE TO CLAUSE 6

Column 1	Column 2
L-Amino Acid	per 100 g of protein
Histidine	2.60 g
Isoleucine	4.60 g
Leucine	9.30 g
Lysine	6.60 g
Cystine	2.45 g
Methionine	1.27 g
Phenylalanine	4.19 g
Tyrosine	4.75 g
Threonine	4.30 g
Tryptophan	1.70 g
Valine	5.50 g

Division 3 - General Compositional Requirements

Restrictions and prohibitions

7. (1) A vitamin, mineral, food additive or nutritional substance must not be added to infant formula product unless:

(a) expressly permitted by this Standard; or

(b) it is included in the infant formula as naturally present in an ingredient of the infant formula product.

(2) Infant formula product must not contain any detectable gluten.

Editorial Note: Infant formula product must not contain novel foods or novel food ingredients which are not permitted under Standard 1.5.1.

Permitted optional nutritional substances

8. (1) Any nutritional substance listed in column 1 of the Table to this clause may be added to infant formula product provided that:

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

(b) the total amount of the nutritional substance in the infant formula product is not more than the amount specified in column 4 of the Table to this clause.

(2) Infant formula product must not be labelled with words indicating, or any other indication, that the product contains an ingredient specified in column 1 or in column 2 of the Table to this clause unless the total amount of the nutrient in the food is not less than the amount specified in column 3 of the Table to this clause.

Editorial Note: The Australia New Zealand Food Authority has issued a guideline on the use and format of nutrient information tables.

TABLE TO CLAUSE 8

Column 1 Nutritional Substance	Column 2 Permitted Forms	Column 3 Minimum Amount for Claim per 100 kJ	Column 4 Maximum Permitted Amount per 100 kJ
Choline	Choline chloride Choline bitartrate	1.7 mg	5.4 mg
Inositol	Inositol	1.0 mg	5.4 mg
Taurine	Taurine	0.8 mg	3 mg
L-carnitine	L-carnitine	0.21 mg	0.42 mg
Cytidine 5′-monophosphate	Cytidine 5′-monophosphate Cytidine 5′-monophosphate sodium salt	0.22 mg	0.6 mg
Uridine 5′-monophosphate	Uridine 5′-monophosphate Uridine 5′-monophosphate sodium salt	0.13 mg	0.42 mg
Adenosine 5′-monophosphate	Adenosine 5′-monophosphate Adenosine 5′-monophosphate sodium salt	0.14 mg	0.38 mg
Guanosine 5′-monophosphate	Guanosine 5′-monophosphate Guanosine 5′-monophosphate sodium salt	0.04 mg	0.12 mg
Inosine 5′-monophosphate	Inosine 5′-monophosphate Inosine 5′-monophosphate sodium salt	0.08 mg	0.24 mg

Limit on nucleotide 5′-monophosphates

9. Infant formula product must not contain more than a total amount of 1.2 mg of nucleotide 5′-monophosphates per 100 kJ.

Editorial Note: Refer to Standard 1.3.4 Identification and Purity for specifications for nucleotides

Lactic acid cultures

10. L(+) producing lactic acid cultures may be added to infant formula product subject to subclause 27(b).

Food Additives

11. (1) Infant formula product may contain food additives specified in column 1 of the Table to this clause provided that the total amount of the food additive is not more than the amount specified in column 2 of the Table.

Editorial Note: The total amount of the food additive includes food additive that is present or naturally occurring in any ingredient in the infant formula product.

TABLE TO CLAUSE 11

Column 1 Food additive	Column 2 Maximum amount per 100 mL
Thickening agents	
Guar gum	0.1 g
Locust bean gum	0.1 g
Emulsifiers	
Lecithin	0.5 g
Mono- and diglycerides	0.4 g
pH-Adjusting agents	
Sodium hydroxide, Sodium hydrogen carbonate, Sodium carbonate	
Potassium hydroxide, Potassium hydrogen carbonate, Potassium carbonate	
Calcium hydroxide	
Sodium citrate	
Potassium citrate	
L(+) Lactic acid	
Citric acid	
Antioxidants	
Mixed tocopherols concentrate	1 mg
L-Ascorbyl palmitate	1 mg

Editorial Note: With the exception of L(+) lactic acid and citric acid, where no maximum is set for a substance in this Table, note that the quantity of this substance permitted in an infant formula product is limited by the maximums specified in the Table to Clause 31 in the case of infant formula and follow-on formula, and in the Table to Clause 35 in the case of pre-term formula. The maximum levels of L(+) lactic acid and citric acid should be determined by good manufacturing practice.

(2) Soy-based infant formula product must not contain:

(a) more than 0.5 g of distarch phosphate per 100 mL;

(b) more than 0.5 g, either singly or in combination, acetyl distarch phosphate, phosphated distarch phosphate or hydroxypropyl starch per 100 mL.

(3) Liquid infant formula product must not contain more than 0.03 g carrageenan per 100 mL.

Carry-over of food additives

12. Other than by direct addition, a food additive may be present in infant formula product as a result of carry-over from an ingredient, provided that:

(a) (i) it is a nutrient as specified in the Tables to clauses 31 and 35; or

(ii) it is a food additive specified in the Table to clause 11; and

(iii) the amount of the nutrient or food additive is not more than the maximum level stipulated in the relevant table; and

(b) the level of the food additive in the final food is not more than would be introduced by the use of the food additive under proper technological conditions and good manufacturing practice.

Limit on aluminium

13. (1) Infant formula product, other than a soy-based formula product or pre-term formula, must not contain more than 0.05 mg of aluminium per 100 mL.

(2) Pre-term formula must not contain more than 0.02 mg of aluminium per 100 mL.

(3) Soy-based formula must not contain more than 0.1 mg of aluminium per 100 mL.

Limit on lead

14. Infant formula product must not contain more than 2 μg of lead per 100 mL.

Composition of lactose free and low lactose formulas

15. (1) A lactose free or low lactose variety of infant formula product 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 not contain any detectable lactose.

(3) Low lactose formula must not contain more than 0.24 g per 100mL of lactose.

Division 4 - General Labelling and Packaging Requirements

Representations of food as infant formula product

16. A food must not be represented as being suitable as a sole or principal source of nutrition for infants unless it complies with this Standard.

Names

17. The names by which infant formula products are defined in this Standard are not prescribed names except for 'Infant Formula' and 'Follow-on Formula'.

Requirement for a measuring scoop

18. 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.

Required statements

19. (1) The label on an infant formula product must contain the following statements:

(a) in the case of powdered infant formula product
'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Inappropriate use or preparation can make your baby very ill';

(b) in the case of concentrate infant formula product
'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Inappropriate use or preparation can make your baby very ill';

(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 concentrate this ready to drink formula except on medical advice. Inappropriate use or preparation can make your baby very ill'.

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

(a) that each bottle should be prepared individually;

(b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours;

(c) that potable, previously boiled water should be used;

(d) where a package contains a measuring scoop, that only the enclosed scoop should be used;

(e) that formula left in the bottle after a feed must be discarded.

(3) Subject to subclause (4) the label on an infant formula product must contain statements indicating that:

(a) breast feeding is superior to the use of infant formula product in the feeding of infants;

(b) the infant formula product should only be used on the advice of a medical practitioner or health worker as to the need for its use and the proper method of its use;

(c) the infant formula product may be used from birth, in the case of infant formula;

(d) the infant formula product should not be used for infants aged under 6 months in the case of follow-on formula;

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

(4) The statements required by subclause (3) must occur under a heading that reads 'Important Notice' or any word or words having the same or similar effect.

Print and package size

20. (1) Where infant formula product is in a package having a net weight of more than 1 kg, the statements required by clauses 19(1) and 36(1) must be in size of type of not less than 3 mm.

(2) Where infant formula product is in a package having a net weight of 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.

Declaration of nutrition information

21. The label on an infant formula product must include a statement, which may be in the form of a table, that contains the following information:

(1) (a) the average energy content expressed in kJ per 100 mL in the case of ready to drink formula;

(b) in the case of powdered or concentrated infant formula product:

(i) the average energy content expressed in kJ per 100 mL of infant formula product that has been reconstituted according to directions; and

(ii) the average energy content expressed in kJ per 100 g of the infant formula product prior to reconstitution in the case of powdered infant formula product or kJ per 100 mL prior to reconstitution in the case of liquid concentrated infant formula product.

(2) (a) the average amount of each of protein, fat and carbohydrate expressed in g per 100 mL in the case of ready to drink formula;

(b) in the case of powdered or concentrated infant formula product:

(i) the average amount of each of protein, fat and carbohydrate expressed in g per 100 mL of infant formula product that has been reconstituted according to directions; and

(ii) the amount of each of protein, fat and carbohydrate expressed in g per 100 g of infant formula product prior to reconstitution in the case of powdered infant formula product or g per 100 mL prior to reconstitution in the case of liquid concentrated infant formula product.

(3) (a) the average amount for each vitamin, mineral and any other nutritional substance permitted by this standard expressed in weight per 100 mL in the case of ready to drink formula;

(b) in the case of powdered or concentrated infant formula product:

(i) the average amount for each vitamin, mineral and any other nutritional substance permitted by this Standard expressed in weight per 100 mL of infant formula product that has been reconstituted according to directions; and

(ii) the average amount for each vitamin, mineral and any other nutritional substance permitted by this Standard expressed in weight per 100 g prior to reconstitution in the case of powdered infant formula product or weight per 100 mL prior to reconstitution in the case of liquid concentrated infant formula product.

Date marking and storage instructions

22. (1) Notwithstanding the provisions in subclause 2(1) of Standard 1.2.5, the label on an infant formula product must include a statement of the best before date.

(2) A label on an 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.

Statement of protein source

23. The label on an infant formula product must contain a statement of the source 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 23 of this Standard applies only to the name as labelled on the product in accordance with the requirement in Standard 1.2.2.

Statement on dental fluorosis

24. (1) An infant formula product that:

(a) contains more than 17 µg of fluoride per 100 kJ prior to reconstitution, in the case of powdered or concentrated infant formula product; or

(b) contains more than 0.15 mg of fluoride per 100 mL, in the case of ready to drink formula;

must comply with subclause (2) of this clause.

(2) The label on an 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.

Labelling of lactose free and low lactose formulas

25. (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.

Prohibited representations

26. The label on a package containing infant formula product must not contain:

(a) a picture of an infant;

(b) a picture that idealises the use of infant formula product;

(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect;

(d) words claiming that the formula is suitable for all infants;

(e) information relating to the nutritional content of human milk;

(f) subject to subclause 38(2) a reference to the presence of any nutrient or nutritional substance, except for a reference to a nutrient or nutritional substance in:
(i) the name of a lactose free formula or a low lactose formula
(ii) a statement of ingredients or
(iii) a nutrition information statement;

(g) subject to Part 3, Division 2 representation that the food is suitable for a particular condition, disease or disorder.

Editorial Note: Part 3, Division 2 relates to infant formula product formulated for metabolic or immunological conditions. Clause 38 permits labelling which varies from this clause.

Division 5 - General Microbiological Requirements

Microbiological standards

27. Infant formula product:

(a) in powdered form, must:

(i) have a standard plate count of not more than 1000 micro-organisms per g;
(ii) be free from coliforms in 1 g;
(iii) be free from coagulase-positive staphylococci in 0.1g;
(iv) be free from *Salmonella* in 25 g;
(v) have a *Bacillus cereus* count of not more than 100 micro-organisms per g;

(b) in powdered form with added L(+) producing lactic acid cultures, must:

(i) be free from coliforms in 1 g;
(ii) be free from coagulase-positive staphylococci in 0.1g;
(iii) be free from *Salmonella* in 25 g;

(iv) have a *Bacillus cereus* count of not more than 100 micro-organisms per g;

(v) have prior to the addition of L(+) producing lactic acid cultures a standard plate count of not more than 1000 micro-organisms per g;

(c) in liquid concentrate form or ready to drink form must not exhibit any detectable microbial growth.

PART 2 - INFANT FORMULA AND FOLLOW-ON FORMULA

Composition

28. (1) Infant formula and follow-on formula must:

(a) have an energy content of not less than 2500 kJ/L and not more than 3150 kJ/L in the case of infant formula, and not less than 2500 kJ/L and not more than 3550 kJ/L in the case of follow-on formula;

(b) must contain an amount of each nutrient specified in column 1 of the Table to this clause which is not less than the amount specified in column 2 of the Table and not more than the amount specified in column 3 of the Table.

TABLE TO CLAUSE 28

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 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 not more than 8 mOsm/100 kJ.

Protein

29. (1) The protein in infant formula and follow-on formula must have an amino acid score of not less than 0.8.

(2) L-amino acids may be added solely for the purpose of achieving the amino acid score specified in subclause (1).

Fat

30. 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;

(b) have a ratio of linoleic acid to α–linolenic acid of not less than 5 to 1 and not more than 15 to 1;

(c) if specified in column 1 of the Table to this clause, must comply with the limits, if any, specified in columns 2 and 3 of the Table;

(d) have a ratio of total long chain omega 6 series fatty acids (C>= 20) to total long chain omega 3 series fatty acids (C>= 20) of 2 in an infant formula or follow-on formula which contains those fatty acids; and

(e) where long chain polyunsaturated fatty acids are present in an infant formula or follow-formula, the eicosapentanoic acid (20:5 n-3) content of not more than the docosahexanoic acid (22:6 n-3) content.

TABLE TO CLAUSE 30

Column 1 Fatty Acids	Column 2 Minimum % total fatty acids	Column 3 Maximum % total fatty acids
Essential fatty acids		
Linoleic acid (18:2)	9	26
α-Linolenic acid (18:3)	1.75	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

Vitamins and minerals

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

(a) the added vitamin or mineral is in a form specified in the Schedule;

(b) the infant formula or follow-on formula contains not less than the quantity specified in column 2 of the Table; and

(c) the infant formula or follow-on formula contains not more than the quantity specified in column 3 of the Table, if any.

TABLE TO CLAUSE 31

Column 1 Nutrient	Column 2 Minimum per 100 kJ	Column 3 Maximum 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	0.36 µg	0.9 µg

(2) Infant formula and follow-on formula must contain not 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 not less than 1.2 to 1 and not more than 2 to 1.

(4) The ratio of zinc to copper in infant formula and follow-on formula must not be more than 12 to 1.

Editorial Note: 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 for levels of vitamins and minerals that as a matter of good practice should not be exceeded.

PART 3 - INFANT FORMULAS FOR SPECIAL DIETARY USE

Division 1 - Pre-term formula

Composition

32. Pre-term formula must:

(a) have an energy content of not less than 2720 kJ/L and not more than 3556 kJ/L;

(b) contain an amount of each nutrient specified in column 1 of the Table to this clause which is not less than the amount specified in column 2 of the Table and not more than the amount specified in column 3 of the Table.

TABLE TO CLAUSE 32

Column 1	Column 2	Column 3
Nutrient	Minimum amount per 100 kJ	Maximum amount per 100 kJ
Protein	0.6 g	0.76 g
Fat	1.05 g	1.5 g

Protein

33. (1) The protein in pre-term infant formula must have an amino acid score not less than 0.8.

(2) L-amino acids may be added solely for the purpose of achieving the amino acid score specified in subclause (1).

Fat

34. The fats in pre-term infant formula must comply with the provisions of clause 30 as if pre-term formula were infant formula or follow-on formula.

Vitamins and minerals

35. (1) Pre-term formula must contain the vitamins and minerals specified in column 1 of the Table to this clause provided that, in relation to each vitamin or mineral:

(a) the added vitamin or mineral is in a form specified in the Schedule;

(b) the formula contains not less than the amount specified in column 2 of the Table to this clause; and

(c) the formula contains not more than the amount specified in column 3 of the Table to this clause.

TABLE TO CLAUSE 35

Column 1 Nutrient	Column 2 Minimum per 100 kJ	Column 3 Maximum per 100 kJ
Vitamins		
Vitamin A	20 µg	36 µg
Vitamin D	0.75 µg	2.0 µg
Vitamin C	3.5 mg	9.6 mg
Preformed Thiamin	10 µg	48 µg
Riboflavin	14 µg	86 µg
Preformed Niacin	0.18 mg	0.89 mg
Vitamin B_6	9.0 µg	42 µg
Folate	5.0 µg	10 µg
Pantothenic acid	0.24 mg	0.36 mg
Vitamin B_{12}	0.04 µg	0.13 µg
Vitamin K	1.0 µg	3.6 µg
Biotin	0.36 µg	2.7 µg
Vitamin E	0.18 mg	1.6 mg
Minerals		
Sodium	9.0 mg	14 mg
Potassium	20 mg	36 mg
Chloride	14 mg	22 mg
Calcium	17 mg	34 mg
Phosphorus	12 mg	22 mg
Magnesium	1.5 mg	3.6 mg
Iron	0.01 mg	0.4 mg
Iodine	2.4 µg	10 µg
Copper	23 µg	30 µg
Zinc	0.12 mg	0.36 mg
Manganese	1.2 µg	1.8 µg
Selenium	0.50 µg	0.9 µg

(2) A pre-term infant formula must contain not less than 0.9 mg of Vitamin E per g of polyunsaturated fatty acid.

(3) The ratio of calcium to phosphorus in pre-term formula must be not less than 1.4 to 1 and not more than 2.0 to 1.

(4) The ratio of zinc to copper in pre-term formula must be not more than 12 to 1.

Labelling

36. (1) The label on a package containing pre-term formula must include the statement:

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

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

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

Composition

37. Infant formula product may be specifically formulated to satisfy particular metabolic or immunological conditions and must comply with:

(a) this Division; and

(b) with all the other requirements of this Standard that are not inconsistent with this Division.

Additional Labelling

38. (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.

Subdivision 1 - Infant formula products for specific dietary use based upon protein substitutes

Composition

39. (1) An infant formula product for specific dietary use based upon protein substitutes must:

(a) have an energy content of not less than 2500 kJ/L and not more than 3150 kJ/L in the case of infant formula, and not less than 2500 kJ/L and not more than 3550 kJ/L in the case of follow-on formula;

(b) have a potential renal solute load of not more than 8 mOsm per 100 kJ; and

(c) must contain an amount of each nutrient specified in column 1 of the Table to this clause which is not less than the amount specified in column 2 of the Table and not more than the amount specified in column 3 of the Table.

TABLE TO CLAUSE 39

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

Protein

40. (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 protein in an infant formula product based upon protein substitutes must have an amino acid score of not less than 0.8.

Vitamins and minerals

41. An infant formula product for specific dietary use based upon protein substitutes must:

(a) contain chromium in an amount of not less than 0.35 µg per 100 kJ and not more than 2.0 µg per 100 kJ; and

(a) contain molybdenum in an amount of not less than 0.36 µg per 100 kJ and not more than 3.0 µg per 100 kJ.

Editorial Note: The provisions of clause 31 of this standard also applies in respect of the vitamins and minerals permitted in an infant formula product for specific dietary use based upon protein substitutes.

Additional permitted additions

42. An infant formula product based upon protein substitutes for specific dietary use may contain:

(a) added medium chain triglycerides;

(b) food additives specified in column 1 of the Table to this clause provided that the total amount of the food additive, including food additive that is present or naturally occurring in any food in the infant formula product, is not more than the amount specified in column 2.

TABLE TO CLAUSE 42

Column 1 Food additive	Column 2 Maximum amount per 100 mL
Thickening agents	
Distarch phosphate	2.5 g
Acetylated distarch phosphate Phosphated distarch phosphate Hydroxypropyl starch	2.5 g singly or in combination
Carrageenan	0.1 g
Mono- and diglycerides	0.5g
Diacetyl tartaric acid esters of mono and diglycerides (DATEM)	0.4g

SCHEDULE 1

PERMITTED FORMS OF VITAMINS AND MINERALS IN INFANT FORMULA PRODUCTS

Column 1	Column 2
Substance	
Vitamins	**Permitted Forms**
Vitamin A	Retinol Forms
	vitamin A (retinol)
	vitamin A acetate (retinyl acetate)
	vitamin A palmitate (retinyl palmitate)
	Carotenoid Forms
	beta-carotene
Vitamin D	vitamin D_2 (ergocalciferol)
	vitamin D_3 (cholecalciferol)
Vitamin C	ascorbic acid
	ascorbyl palmitate
	calcium ascorbate
	potassium ascorbate
	sodium ascorbate
Thiamin	thiamin hydrochloride
	thiamin mononitrate
Riboflavin	riboflavin
	riboflavin-5'-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
Folate	folic acid
Pantothenic acid	calcium pantothenate
	dexpanthenol
Vitamin B_{12}	cyanocobalamin
	hydroxocobalamin
Biotin	d-Biotin
Vitamin E	dl-α-tocopherol
	d-α-tocopherol concentrate
	tocopherols concentrate, mixed
	d-α-tocopheryl acetate
	dl-α-tocopheryl acetate
	d-α-tocopheryl acid succinate
Vitamin K	vitamin K_1, as phylloquinone (phytonadione)

Column 1	Column 2
Minerals	Permitted Forms
Sodium	sodium bicarbonate
	sodium carbonate
	sodium chloride
	sodium citrate
	sodium gluconate
	sodium hydroxide
	sodium iodide
	sodium lactate
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
	sodium sulphate
	sodium tartrate
Potassium	potassium bicarbonate
	potassium carbonate
	potassium chloride
	potassium citrate
	potassium glycerophosphate
	potassium gluconate
	potassium hydroxide
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
Chloride	calcium chloride
	magnesium chloride
	potassium chloride
	sodium chloride
Calcium	calcium carbonate
	calcium chloride
	calcium citrate
	calcium gluconate
	calcium glycerophosphate
	calcium hydroxide
	calcium lactate
	calcium oxide
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	calcium sulphate

Column 1	Column 2
Minerals	**Permitted Forms**
Phosphorus	calcium glycerophosphate
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	magnesium phosphate, dibasic
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
Magnesium	magnesium carbonate
	magnesium chloride
	magnesium gluconate
	magnesium oxide
	magnesium phosphate, dibasic
	magnesium phosphate, tribasic
	magnesium sulphate
Iron	ferric ammonium citrate
	ferric pyrophosphate
	ferrous citrate
	ferrous fumarate
	ferrous gluconate
	ferrous lactate
	ferrous succinate
	ferrous sulphate
Iodine	potassium iodate
	potassium iodide
	sodium iodide
Copper	copper gluconate
	cupric sulphate
Zinc	zinc acetate
	zinc chloride
	zinc gluconate
	zinc oxide
	zinc sulphate

Column 1	Column 2
Minerals	**Permitted Forms**
Manganese	manganese chloride
	manganese gluconate
	manganese sulphate
Selenium	sodium selenite
	seleno methionine
Chromium	chromium sulphate
Molybdenum	sodium molybdateVI dehydrate

"

2. Standard 1.3.4 is amended by inserting

"SPECIFICATIONS FOR NUCLEOTIDES

DESCRIPTION/ PHYSICAL CONSTRAINTS

Inosine - 5' monophosphate disodium salt (IMP)

1. Chemical nomenclature: C_{10} H_{11} N_4 Na_2 O_8 P· 7.5H_2 O
   In addition the compound must be of the 5 species, eg the disodium monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 527.25

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: 24 g is soluble in 100 g of water at 20°C; is stable in acid liquids under the identical conditions

Uridine - 5' monophosphate disodium salt (UMP)

1. Chemical nomenclature: C_9 $H_{11}N_2$ O_9 PNa_2
   In addition the compound must be of the 5 species, eg the disodium monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 368.15

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: Freely soluble in water; very slightly soluble in alcohol.

Adenosine- 5' monophosphate (AMP)

1. Chemical nomenclature: C_{10} $H_{14}N_5$ O_7 P
   In addition the compound must be of the 5 species, eg the monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 347.22

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic acidic taste.

4. Solubility: Very slightly soluble in water; practically insoluble in alcohol.

Cytidine - 5' monophosphate

1. Chemical nomenclature: $C_9 H_{14} N_3 O_8 P$
   In addition the compound must be of the 5 species, eg the monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 323.20

3. Structure/Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic slightly acidic taste.

4. Solubility: Very slightly soluble in water; practically insoluble in alcohol.

Guanosine - 5' monophosphate disodium salt

1. Chemical nomenclature: $C_{10} H_{12} N_5 Na_2 O_8 P \cdot 7.OH_2O$
   In addition the compound must be of the 5 species, eg the disodiummonophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 533.26

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: 20 g is soluble in 100g of water at 20°C; becomes gelatinous in acid liquids under the identical conditions

TESTING REQUIREMENTS FOR NUCLEOTIDES

1. Physical inspection: white crystals or crystalline powder

2. Identification:

   a) Ultraviolet absorbance: A1 in 12,500 solution of the powder in 0.01N hydrochloric acid exhibits an absorbance maximum at:

Absorbance	Nucleotide
250+- 2nm	Inosine - 5' monophosphate disodium salt
260+- 2nm	Uridine - 5' monophosphate disodium salt
257+- 2nm	Adenosine- 5' monophosphate
280+- 2nm	Cytidine - 5' monophosphate
256+- 2nm	Guanosine - 5' monophosphate disodium salt

   b) IMP, UMP and GMP must test positive for sodium phosphate

   c) IMP,UMP,AMP, CMP and GMP must test positive for organic phosphate

Nutrition information table

The nutrition information contained on the label on a package containing 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 as bought (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 nutritional 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 bought in ready to drink form