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MO AHITEREIRIA ME AOTEAROA

Development of Joint Australia New Zealand Food Standards

**As part of the process of the Review of the
*Food Standards Code***

INFANT FORMULA

Preliminary Inquiry Report

Proposal P93

MAY 1999

The Authority should receive written submissions
no later than **16 JUNE 1999**

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The Authority appreciates the knowledge and expertise contributed by the above people, and acknowledges that the views contained in this paper do not necessarily represent the views of the individuals or their organisations.

The Australian Consumers Association was invited to provide nominees but was unable to do so.

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EXECUTIVE SUMMARY

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

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

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

The approach taken to achieve 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 full assessment standard released in 1995, ANZFA received 29 submissions from infant formula manufacturers, pharmaceutical companies, health professionals, governments and individuals. Following consideration of the public comments and an assessment against the objectives of the Review, a draft joint ANZ standard for infant formulas has now been prepared.

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

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

Special purpose formulas cover the same age ranges but are intended for infants who require specific modifications to suit specific diseases or disorders or are for preterm infants. Categories are pre-term formulas, lactose free or low lactose formulas, formulated infant formula for metabolic 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.

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

- The quality and quantity of the protein content of infant formulas is regulated but it is not considered necessary to regulate the protein source. However, information about the source of protein should be declared on the label to assist carers make suitable product selection.
- The total energy, total fat and essential fatty acids content is regulated to ensure infants who are formula fed receive sufficient but not excessive energy and fatty acid intakes. Fatty acids which are considered harmful to infants are restricted where necessary to protect infants from adverse health consequences. Limits are recommended for *trans*- fatty acid and erucic acid contents of infant formula.
- The carbohydrate content of infant formula is indirectly controlled by the regulations on protein, fat and energy content.
- Unlimited vitamin and mineral contents for infant formulas represented as human milk substitutes are not recommended as in the best interests of infant consumers, and maximum levels of these nutrients should be contained. To eliminate unnecessary cost for industry, mandatory maximum levels are only prescribed for those vitamins and minerals which are considered to pose a significant risk to infants if consumed in excess, whilst advisory maximum levels are recommended for other nutrients, whose risk characterisation is provisionally assessed as 'not of significance on the basis of current scientific knowledge'. A guideline will accompany the joint ANZ standard for infant formula to provide manufacturers with guidance as to these recommended maximum levels. These guidelines are expected to be implemented by Good Manufacturing Practice.
- 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.
- Novel nutrient or nutritional substances or novel sources of these for formulas should be assessed as safe and suitable for infants before use in formulas in Australia or New Zealand.
- Limits for lead and aluminium contents are imposed to protect infants. Other potential contaminants are regulated by other mechanisms, such as water quality guidelines or do not pose a safety concern for infants. An advisory labelling statement to alert carers to seek specific health advice is proposed for formulas with unnecessarily high fluoride contents.
- It is considered the risk to infants in Australia and New Zealand from potential gluten content of infant formulas is such that a prohibition on gluten inclusion in formulas is required, although not specifically prohibited in the Codex standard.
- Microbiological criteria and the use of specific food additives are recommended to ensure safety of infant formulas.
- Specific labelling is recommended to inform carers to seek health advice to determine whether formula is the most appropriate method of feeding and if so whether the specific formula is the most appropriate formula for the individual infant. Labelling is also required to ensure carers have advice as to 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 are also reflected within the Standard. These include a reference to breast milk as the optimum source of nourishment for infants so that potential purchasers of formula products can be informed of the full range of feeding options.

It is recommended that soy-based formula for infants be consumed only by infants for whom human milk or a modified cow's milk formula is contraindicated. The Authority is considering strategies in a separate project to reduce the incidence of inappropriate soy-based formula consumption in Australia and New Zealand to the level necessary on medical grounds.

Conclusion:

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

Executive summary from the Full Assessment Report (1995)

At NFA14, as a consequence of one of the recommendations made in the review of special infant formula (P49), the Authority prepared a proposal (P93), to review Standard R7 - Infant Formula. Ms Nancy Palmer, a paediatric nutritionist, was employed by the Authority to progress the revision of Standard R7 towards full assessment and subsequently additional consultants were appointed to advise on compositional aspects.

Standard R7 was originally gazetted in 1988 but needed revision because it is: out-of-date with current scientific knowledge and opinion; not harmonised with the infant formula standards of overseas organisations such as Codex, the US Food and Drug Administration, the European Community and New Zealand; and difficult to interpret, especially the definition of infant formula. In addition, there are some types of infant formula in the Australian marketplace which are not regulated by Standard R7.

Other aspects of Standard R7 which the Authority has considered include: permitted forms of the various nutrients; labelling and advertising requirements; contaminant levels (aluminium and fluoride); possible additional regulatory procedures, such as pre-market clearance; and the basis for permitting some substances as "optional" ingredients.

At NFA26, the Authority agreed to the establishment of an Expert Panel to assist the project team in its decision-making on the issues of "optional" ingredients and fluoride levels. The Panel met in February and March 1995. The Panel's assessment of these issues and the rationale for their decisions was included in the Full Assessment Report.

At NFA29, the Authority agreed to the appointment of a consultant to advise on the appropriate composition of formula based on modified protein, fat and carbohydrate. Her recommendations formed the basis for a new category, "proximate-modified" human milk substitute, now contained in the draft revised Standard R7. The consultant's report was also included in the Full Assessment Report.

The draft revised Standard R7 - Human Milk Substitutes, prescribed in detail the compositional, microbiological and labelling requirements for infant formula, follow-on formula, and human milk substitutes for special dietary use (including pre-term, lactose free and low lactose and proximate-modified human milk substitutes). Limits on aluminium and fluoride were introduced and consequential amendments were also made to regulate claims, provide specifications or references to specifications for substances not previously permitted, list new additives together with their food additive code numbers in the appropriate schedule and ensure that ranges specified for "selenium" in Standard R7 were the only ones applicable to human milk substitutes.

Previous Authority consideration

The full assessment report for the review of infant formula Standard R7 was gazetted in August 1995.

ISSUES RAISED AT PRELIMINARY INQUIRY

MAJOR ISSUE

The full assessment report was circulated in Australia for public comment, but not in New Zealand as it was published before the 1996 agreement between Australia and New Zealand came into force which established the Australia New Zealand Food Authority (ANZFA) and a system for developing joint food standards and an Australia New Zealand Food Standards Code. Twenty-nine submissions were received in response to gazettal.

Although work was undertaken on the Inquiry Report in 1996, resource constraints at the Authority since that time curtailed the progress of this draft standard. Since 1995 there have been some major developments that have impacted on the way in which the Authority conducts regulatory reviews.

The policy basis for food standards setting in Australia has changed since the full assessment report was prepared. The review of the infant formula standard now needs to be consistent with competition policy agreements adopted by the Council of Australian Governments and with the draft Code of Good Regulatory Practice in New Zealand. Additionally, the standard needs to be consistent with the Government's obligations as a signatory to the World Trade Organization (WTO) and the Agreement between Australia and New Zealand that established the ANZFA. These changes have meant that the project will develop one standard for the regulation of infant formula in Australia and New Zealand, and that the revision will be undertaken with greater attention being paid to international food standards. The report prepared at full assessment will form the basis for this new joint Australia and New Zealand standard for infant formula (joint ANZ standard).

Submissions were made by industry, professional and consumer groups and individuals in response to the full assessment report published in 1995. 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.

Significant issues identified in submissions to the draft standard prepared at Full Assessment:

1. **Lack of harmonisation with international standards**
2. **Regulations for special purpose infant formulas**
3. **Nutritional compositional issues**
 - a) **Energy levels and calculation factors**
 - b) **Protein requirements**
 - Sources of protein and declaration of sources of protein.
 - Protein quality
 - Calculation of protein content
 - Range of and maximum levels of protein
 - c) **Fat**
 - Sources of fat
 - Total fat content
 - Essential fatty acid content, including the ratio of linoleic to alpha linolenic acid and minimum levels of alpha linolenic acid.
 - Fat profile for non- essential fatty acids
 - Minimum levels of *trans*- fatty acids,
 - Medium chain triglycerides (MCT's); prohibition on MCT's, use in modified formulas
 - d) **Carbohydrate**
 - Level of carbohydrate
 - Types and sources of carbohydrate
 - Lactose free and low lactose infant formulas
 - Proposed warning statement for infants with galactosaemia
 - e) **Vitamins and Minerals**
 - Maximum levels for vitamins and minerals
 - Range set for some vitamins
 - Ratio of zinc to copper
 - Permitted forms of nutrients
 - f) **Other ingredients**
 - Maximum levels of inositol, taurine, nucleotides, carnitine, choline
 - Permissions for nucleotides to infant formula
 - Permitted forms of nutrients
 - g) **Osmolality value**

- 4. Food Additives**
 - a) Permission for food additives
 - b) Prohibition on carrageenan
- 5. Safety of Soy Formulas**
- 6. Contaminants**
 - a) Levels of aluminium, fluoride
 - b) Other contaminants
- 7. Microbiological requirements**
- 8. Labelling Requirements**
 - a) Print size, form and content of mandatory statements, including the statement containing advice to introduce other foods and the statement on the preparation of bottles
 - b) Nutrition Information Table entries
 - c) Feeding guide form and content
 - d) Date marking and storage
- 9. Title and scope of the proposed draft revised Standard R7**
 - a) Title
 - b) Scope
- 10. Definitions and terminology**
- 11. Advertising**

ASSESSMENT OF ISSUES RAISED

1. LACK OF HARMONISATION WITH INTERNATIONAL STANDARDS

The standard prepared at full assessment was seen as further from harmonisation with international standards than the current Standard R7. However harmonisation with Codex has assumed greater importance in recent times and preliminary inquiry will address many of these concerns.

2. REGULATIONS FOR SPECIAL PURPOSE FORMULAS

The removal of current Standard R7 clause 2(b) from the draft proposed at full assessment has caused concern with industry and health professionals. Clause 2(b) states that:

'infant formula may be specifically formulated to satisfy particular well recognised dietary requirements that are a result of a specific physical or physiological condition, disease or disorder, but in all other respects shall comply with this Standard. All deviations from the requirements of this Standard necessary to suit the condition, disease or disorder shall be declared on or attached to a package containing the food'.

Codex does not specifically provide for formula specialised for infants with special medical needs. This provision is considered in the Preliminary Inquiry into the nutritional compositions of infant formula at Appendix 1.

There are some infants for whom breast feeding or standard milk- based formulas are unsuitable. These infants need specialised formulas. Longer term a separate standard or part of standard may be developed to regulate these specialised formulas. However, unless the permissions in the new 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 Australia and New Zealand. It is recommended that a modified version of this provision be included in the joint ANZ standard for infant formula to cover infants with highly specialised needs.

However, it is considered a potential risk to the health of infants to include the term 'physiological' within this provision. Therefore, the following provision similar to the previous Standard R7- clause 2(b) is recommended to provide temporary regulatory status and control for these special purpose infant formulas:

'Infant formula may be specifically formulated to satisfy particular metabolic or immunological conditions, but in all other respects shall comply with this Standard.'

The inclusion of this clause is intended to provide for formula for infants who are not able to tolerate human milk or the infant formula manufactured for healthy infants. Labelling requirements for these specialised formulas have been redrafted to reduce

prescription and to increase the amount of information provided to carers about the specific use of the product and the products nutritional composition.

However, such formulas may be unsafe for infants who do not need the special modifications in the formula. Therefore an advisory statement alerting carers to use the formula only under medical supervision is recommended. Also a statement targeted to the carers of infants for whom the special modifications are inappropriate which advises that the product is not for general use.

3. NUTRITIONAL COMPOSITIONAL ISSUES

A full preliminary inquiry into the nutritional compositional requirements for infant formula is included in Appendix 1.

A less prescriptive and less restrictive standard for infant formula can be achieved by the provision of a statement of essential composition such as 'Infant formula is a product based on milk or other edible constituents of animal or plant origin, suitable for infant feeding and intended to be the principal source of nourishment for infants'. Such a statement increases the scope of permitted ingredients for infant formula manufacture and eliminates the need for specific prohibitions on unsafe ingredients benefiting both infants who consume formula and the infant formula industry. However, infant formula should be required to be 'gluten free' as this affords an additional measure of protection by reducing the risk of coeliac disease to infants in Australia and New Zealand.

3A) ENERGY LEVELS AND ENERGY VALUE FOR CARBOHYDRATE

Comparison of levels proposed at full assessment and preliminary inquiry:

	Infant formula kJ/litre	Follow-on formula kJ/litre
PROPOSED AT FULL ASSESSMENT FOR INFANT FORMULAS FOR HEALTHY INFANTS	2700 - 3000	2700 - 3000
PROPOSED AT FULL ASSESSMENT FOR PRE- TERM INFANT FORMULAS	2720 - 3556	Not applicable
PROPOSED AT FULL ASSESSMENT FOR PROXIMATE MODIFIED INFANT FORMULAS *	2700 - 3000	Not applicable
PROPOSED AT PRELIMINARY INQUIRY FOR INFANT FORMULAS INCLUDING FORMULAS FOR METABOLIC AND IMMUNOLOGICAL CONDITIONS	2500 - 3150	2500 -3550
PROPOSED AT PRELIMINARY INQUIRY FOR PRE-TERM FORMULAS	as per full assessment	Not applicable

* the term 'proximate modified' was proposed at full assessment but it is proposed at preliminary inquiry to use the terms 'infant formula for metabolic and immunological conditions' or 'infant formula based upon protein substitutes for specific dietary use'.

A full text of the preliminary inquiry into the energy content of infant formula is included in Appendix 1.

Energy levels

The energy ranges proposed at full assessment were not consistent with ranges proposed in other regulations, including the Codex standards for infant formula and follow-on formula.

There is no public health contraindication to widening the permitted energy value range for infant formula to be consistent with the range currently included in the Codex standard or being considered for inclusion in the revised Codex standard. In the interest of harmonisation with Codex, it is recommended that the energy range of infant formula be adjusted to 2500kJ/L to 3150kJ/L and for follow-on formula to 2500kJ/L to 3550 kJ/L. The range for modified formulas for special dietary use should be consistent with those for infant formulas for healthy infants.

Energy value for carbohydrate

Industry submissions all argued against an energy conversion factor for carbohydrate of 16kJ as was proposed at full assessment. Codex and the EC both quote 17 kJ/g as the energy factor for carbohydrate. Although a carbohydrate

energy factor of 16 kJ/g is considered more accurate for formula where the predominant form of carbohydrate is disaccharide, the Authority is willing to amend the factor to 17 kJ/g in the interest of harmonization even though this may lead to a relative overestimation of the energy content of infant formula, and a concomitant reduction in carbohydrate content.

Under the review of general nutrition labelling, it is proposed to revise the definition of carbohydrate by difference to exclude unavailable carbohydrate, and for the energy factor of 17 kJ/g to be applied to the revised carbohydrate by difference, and a new factor of 8 kJ/g to be applied to unavailable carbohydrate. This will have the most impact on plant based formulas because of the presence of fibre components.

3 B) PROTEIN REQUIREMENTS

A full preliminary inquiry into the protein requirements for infant formula is included in Appendix 1.

The protein content and the protein quality of infant formulas should be regulated as recommended below to protect Australian and New Zealand infant consumers.

Sources of protein and declaration of sources of protein.

The specification of protein source for the infant formula varieties proposed at full assessment was more restrictive than Codex and the draft Codex standard. Specification of protein source is unnecessary if protein content and quality are regulated as recommended. However, information about the source of protein should be required to be included on the label of the formula 'immediately adjacent to the name of the food' to enable carers to make appropriate food choices for their infant.

Protein quality

Submissions in response to the full assessment were generally supportive for the introduction of a measure of protein quality for infant formula. However the dual approach of different measures of protein quality for milk-based and soy-based formulas proposed at full assessment was not supported.

The interrelationship between protein content and protein quality is significant for infant health and safety. The lower the protein content of a formula the more important the quality of that protein becomes for infant health.

The minimum protein content proposed for infant formula has been set sufficiently high to enable the protein quality to be regulated at a minimum of 0.8. This level which is consistent with the requirement in the EC Directive for infant formula and follow-on formula is recommended for inclusion in the joint ANZ standard for infant formula.

Reference amino acid composition of human milk

It is proposed to include the references to the amino acid composition of human milk at g/100g protein in the joint ANZ standard for infant formula as proposed at full assessment.

Calculation of protein content

The calculation factors for protein determination which were proposed at full assessment did not cover all potential mammalian milks, and did not provide sufficiently for partial protein hydrolysates or specialised formula which may be based solely upon amino acid mixtures.

The following calculation factor is recommended for calculating the protein content from amino acids: amino acid nitrogen x 6.25. For mixtures of amino acids and protein hydrolysates, the proportion of these components in the formula will need to be provided for in the calculation. However, the same calculation factor of 6.25 is required for soy based proteins. Therefore it is recommended the provision for calculation from soy based proteins be generalised to cover all other foods and the following factors which are consistent with the Codex factors are recommended:

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

Protein content = nitrogen content x 6.38

- (b) In all other cases

Protein content = nitrogen content x 6.25

Range and maximum levels of protein

Comparison of levels proposed at full assessment and preliminary inquiry:

	infant formula g/100 kJ	follow-on formula g/100 kJ	pre-term formula g/100 kJ	proximate modified formula g/100 kJ
PROPOSED AT FULL ASSESSMENT	0.45 - 0.7	0.7 - 1.0	<u>for < 1kg weight</u> 0.72 - 0.76 <u>for ≥ or = 1kg weight</u> 0.6 - 0.72	0.45 -1.4
PROPOSED AT PRELIMINARY INQUIRY	0.45 -0.7	0.45- 1.3	0.6-0.76	0.45-1.4 may be in the form of protein equivalents

There was general support in submissions for the protein concentrations proposed at full assessment for infant formula. However, some issues were raised about the levels proposed for follow-on formula, pre-term formula and the proposed proximate modified formula.

Protein content and protein quality are interrelated in determining the biological use of a food protein source. As the protein content of an infant formula is a significant contributor to the load on the infant's kidneys, the recommendation to increase the maximum protein content of follow-on formula to that set in the Codex standard should be conditional upon inclusion of a prescribed measure of renal solute load (RSL) value.

The sole difference between the regulation for pre-term formula for the two body weight categories was the variation in proposed protein contents. The protein ranges proposed at full assessment were narrow. Preterm infants would be under the care of specialist medical officers who would regularly evaluate the appropriateness of the food by monitoring the infant's weight change and other parameters. Therefore, preterm infants would not be likely to be placed at risk by combining the two levels of protein as medical attendants would be monitoring the infants' growth rate.

The maximum permitted protein content of the 'proximate modified formulas¹' is higher than that proposed for infant formulas for healthy infants. Infants who consume these formulas are expected to be under medical supervision when likely risks for the potentially higher protein intake from these formulas can be monitored and appropriate adjustments to treatment regime can be made. Therefore it is recommended that the levels proposed at full assessment be included in the joint ANZ standard for infant formula.

In conclusion, it is recommended that the protein levels proposed at full assessment be included in the joint ANZ standard for infant formula. However, the maximum permitted protein content for follow-on formula should be increased to 1.3 g/100kJ provided the RSL of the formula is regulated to protect infants from the risk of kidney damage, and the protein content of pre-term formulas should be prescribed at 0.60 - 0.76 g/ 100 kJ.

3C) FAT CONTENT OF INFANT FORMULAS

Many submissions commented on the proposed provisions for the fat content of infant formula.

Lack of harmonisation

¹now proposed to be 'Infant formula formulated for metabolic and immunological conditions'.

Submissions noted variations between the levels proposed at full assessment and levels recommended by other international agencies.

At full assessment it was proposed to regulate total fat content, limit total saturated fat and specifically lauric, myristic and > C=18 fatty acids, require a monounsaturated, linoleic and alpha - linolenic acid content (ALA) and permit omega 3 and omega 6 series fatty acids. The levels were generally opposed by industry as being 'too tight'. In addition industry warned of the consequences to the physical state of the product of changes in the proportion of saturated fat to polyunsaturated fat.

The current Codex standards for infant formula and follow up formula only regulate total fat and require a certain linoleic acid content.

There is international recognition that the current Codex standard is not completely in line with current scientific knowledge about the nutritional needs of infants. This is reflected in the increased level of regulation currently being considered by Codex. The individual fats proposed for regulation at full assessment have been reassessed in the context of current review policy and international provisions. Regulations considered necessary to protect the health and safety of infants are recommended for inclusion in the joint ANZ standard.

Refer Appendix 1 for a detailed review of the fat content of infant formula

Source of fatty acids, including prohibitions on specific sources of fat

There is concern that nutrients 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 Australia and New Zealand assessment of safety. Therefore novel foods are to be assessed for safety before use in infant formulas in Australia and New Zealand by virtue of the proposed Standard A19 - Novel Foods. Therefore no specific prohibitions for individual fatty acids or sources of fatty acids are currently considered necessary in the joint ANZ standard for infant formula. However, it is recommended that a generic prohibition on novel foods or novel ingredients not assessed as safe be included in the infant formula standard.

Total fat content

Comparison of levels proposed at full assessment and preliminary inquiry:

	Infant formula g/100 kJ	Follow-on formula g/100 kJ
PROPOSED AT FULL ASSESSMENT	1.1 - 1.4 (pre-term formula: 1.1 - 1.4) (proximate modified formula: 0.93-1.4)	0.9 - 1.4
PROPOSED AT PRELIMINARY INQUIRY	1.05 - 1.5 (pre-term formula: 1.05 -1.5) (proximate modified formula: 0.93 -1.5)	1.05 - 1.5

The level of fat proposed for infant formula at full assessment was not consistent with levels in international regulations. There is no known health or safety contraindication to widening the range for fat to 1.05 - 1.5 g/100 kJ to harmonise with the international standards and recommendations.

However, the fat content of some specialised formulas for infants with chronic diseases is occasionally necessarily lower than that proposed for infant formula for healthy infants. Infants who consume these formulas are expected to be under medical supervision when any adverse symptoms can be monitored and appropriate adjustments to feeding regime can be made. Therefore it is recommended that the fat levels proposed at full assessment for formulas for then classified 'proximate modified formulas' be included in the joint standard for infant formula in the category 'infant formula formulated for metabolic and immunological conditions'.

Essential fatty acid content, including the ratio of linoleic to alpha linolenic acid (ALA) and minimum levels of ALA.

Ratio of linoleic to linolenic acid

Industry argued against the tightening of the tolerance for the ratio of linoleic to ALA and in favour of the ratio used in the EC which is 5:1-15:1.

The metabolic pathways for linoleic acid and ALA appear to use some enzymes in common and therefore the ratio between the two sets of fatty acids is important in determining the metabolic outcomes of these fatty acids and therefore important for the health of infants.

It is recommended that the ratio 5:1-15:1 be included in the joint ANZ infant formula standard to ensure there is no interference with infant production of either of the longer chain fats of the omega-3 and omega-6 fatty acid series and other potential adverse health consequences.

Linoleic acid (as glycerides)

Comparison of levels proposed at full assessment and preliminary inquiry:

	Infant formula	Follow-on formula
PROPOSED AT FULL ASSESSMENT	8-20 % total fatty acids	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	9-26% total fatty acids	as per infant formula

Human milk typically provides 8-17% total fatty acids as linoleic acid. Linoleic acid is essential as mammalian cells cannot synthesise this fat. The level of linoleic acid together with ALA is a key determinant of arachadonic acid synthesis. It is recommended that the minimum linoleic acid content of infant formula be 9% total fatty acids and the maximum linoleic acid content be 26% total fatty acids to accommodate the increased minimum and maximum for the linoleic: ALA ratio of 5:1 - 15:1. These levels align internationally for the minimum and are more liberal for the maximum and accommodate the current known market levels.

Alpha- Linolenic acid (ALA)

Comparison of levels proposed at full assessment and preliminary inquiry:

	Infant formula	Follow-on formula
PROPOSED AT FULL ASSESSMENT	2 - 4% total fatty acids	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	1.75 - 4.0 % total fatty acids	as per infant formula

The levels of ALA proposed at full assessment are not consistent with the revised ratio of linoleic acid to ALA. Human milk typically provides 0.5-1.0 % total fatty acids as ALA with varying contents of other polyunsaturated fatty acids (PUFA).

ALA is a precursor for the long chain polyunsaturated fatty acids (LCPUFA) of the omega 3 series, particularly docosahexanoic acid (DHA). Insufficient intake of ALA has resulted in infants becoming deficient in omega 3 LCPUFA, particularly DHA despite adequate intakes of linoleic acid. It is reported formula with inadequate ALA contents may be associated with delayed development of visual function and possibly lower levels of DHA in the brain. A formula ALA content of 1.75% to 4% total fatty acids has been recommended by health authorities and these level are recommended for inclusion in the joint ANZ standard for infant formulas.

3d) LONG CHAIN POLYUNSATURATED FATTY ACIDS (LCPUFA)

Issues

LCPUFA's 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 and three specific individual LCPUFA content of infant formulas. The EC and UK standards are the only known international 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 fatty acids 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.

There is currently insufficient data to finalise a recommendation about the addition of LCPUFAs to infant formulas. Three options are proposed for the addition of LCPUFAs to formulas.

Option 1: Do not provide express permission

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

Levels could be included in the guideline proposed to be provide with the standard.

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

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

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

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

The permissions proposed in this option are:

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

If Long chain polyunsaturated fatty acids are added to the formula then:

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

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.

Fat profile for non- essential fatty acids

Total saturated fatty acid content and *cis*-monounsaturated fatty acid content

It was proposed at full assessment to limit total saturated fatty acids to a maximum of 50% total fatty acids and to require a *cis*-monounsaturated fatty acid content of 30 to 60% total fatty acids. There are no international regulations which expressly control the total saturated fatty acid or *cis*-monounsaturated fatty acid content of infant formula. Therefore the limitation on saturated fatty acids and the requirement for *cis*-monounsaturated fatty acids as proposed in the draft are more restrictive than Codex and constitute a barrier to trade. The health and safety of infants is protected by the proposed regulation of total fat content and the requirement for the essential fatty acid content. Therefore it is not proposed to retain these restrictions in the joint ANZ infant formula standard.

Lauric acid and Myristic acid

The lauric acid and myristic acid content of infant formula was proposed to be restricted at full assessment but Codex neither has nor proposes to restrict these fats in infant formula.

No express permission is proposed to be granted for addition of these two substances to infant formula, therefore the lauric and myristic acid content of infant formula will be that which results from the ingredients used to manufacture the formula. Therefore, no regulation is required in the joint ANZ standard for infant formula.

Erucic acid

The EC limits the erucic acid content of infant formula to not more than 1% of the total fat content and Codex is considering limiting the erucic acid content of infant formula to not more than 1% of the total fat content in the revised standard. No limit on erucic acid was proposed at full assessment.

Erucic acid is unsafe for humans as it causes fatty infiltration of the heart muscle. Erucic acid in some seed varieties can be the major fat type in the seed oil. With the potential liberalising of permissions for use of other foods in infant formula, it may be prudent to include a regulation on the erucic acid content and align with the EC provision.

It is recommended that the maximum erucic acid content of infant formula be limited to not more than 1% of the total fat content.

Maximum levels of *Trans*- Fatty Acids

Comparison of levels proposed at full assessment and preliminary inquiry:

	Infant formula % total fatty acids	Follow-on formula % total fatty acids
PROPOSED AT FULL ASSESSMENT	8 (including 6 for <i>trans</i> -monounsaturated fatty acids)	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	4	as per infant formula

Submission was received to increase the proposed maximum level of *trans*- fatty acids from 8 to 12-15%.

Trans- fatty acids originate primarily from hydrogenation of unsaturated vegetable oils during processing but small amounts are present in animal fats. There is no known nutritional function and many adverse actions attributed to *trans*- fatty acids, including that *trans*-fatty acids may inhibit the metabolism of PUFA and cholesterol in infants.

A recent major review of infant formula nutrient contents commissioned by the FDA has recommended that due to the potential long term and short term harmful effects of *trans*- fatty acids and the absence of any nutritional benefit from them, that hydrogenated oils not be used in infant formula as these oils are the major source of *trans*- fatty acids.

It was proposed at full assessment to limit *trans*- fats to a maximum of 8% total fatty acids, of which 6% were permitted to be *trans*- monounsaturated fatty acids. The proposed permission is higher than levels reported for human milk and higher than that in the EC directives for infant formula and follow up formula (maximum 4%). It does not appear to be in the interests of infants to increase the maximum permission for *trans*- fatty acids and it would appear prudent to align with the EC and limit the maximum permission to 4% of the total fatty acids.

Medium chain triglycerides (MCTs)

The definition of 'fat modified' proposed at Full Assessment as meaning that the food contains medium chain triglycerides (MCT's) was challenged by industry. Similarly industry required clarification in relation to the definition of MCT's and also challenged the prohibition on a MCT content for infant formulas, particularly pre-term formulas.

MCT's are defined as by Francis as 'triglycerides containing fatty acids with 8-10 carbon atoms' although Health Canada defines MCTs as semi-synthetic triglycerides which contain predominantly the saturated fatty acids 8:0 and 10:0.

The main metabolic pathway for MCTs in infants is catabolism to acetyl CoA. Therefore there is a potential concern for high intakes of MCTs as the concentration of serum ketones and the excretion of carboxylic acids increases linearly with intake. Whilst there needs to be permission for the low innate levels of MCTs in milk based ingredients, there is no justification for the further addition of MCTs to formula for healthy term infants. However, some infants suffering malabsorption or liver disorders may benefit from special dietary formulas with MCTs. Therefore, it is recommended that no provision be made for MCT oil use as an ingredient in the manufacture of infant formula for healthy infants, but that a permission be given for use of MCT's in specialised formulas for infants with immunological and metabolic conditions.

MCT use in Pre-term formulas

At full assessment it was proposed to prohibit MCTs in Pre-term formula. However, some pre-term formulas currently available internationally, including in Australia and NZ contain high levels of MCTs. Adoption of this regulation will cause some products to be lost from the market.

Preliminary science that the use of MCTs in pre-term formulas would be of benefit to the growth and development of these infants is not supported by current evidence. In 1995, Health Canada in its review of the compositions of pre-term formulas noted 'there is clear evidence of abnormal fatty acid metabolism' from the use of MCTs in formulas; although Health Canada did not at that time recommend a prohibition on MCT inclusion in pre-term formulas.

It is recommended that provision be made for the innate MCT content of the milk-based ingredients used in infant formula manufacture but to continue the Authority's position *pro tempore* on a prohibition of added MCT to all infant formulas other than those specialised formulas for infants with immunological and metabolic conditions. However, to complete the inquiry into the MCT content of pre-term formulas, ANZFA requires data from industry as to:

- (i) the current MCT content in formulas, particularly preterm formulas;

(ii) evidence to show MCT at currently used levels are safe and efficacious; and

(iii) level of use in Australia and New Zealand of formulas with significant MCT content.

On behalf of the infant formula industry, the Australian industry representative on the Authority's external team objected to this decision, as this would require the reformulation of some pre-term formulas.

3D) CARBOHYDRATE CONTENT OF INFANT FORMULAS

Refer Appendix 1 for a detailed preliminary inquiry into the carbohydrate content of infant formulas.

The provisions proposed at full assessment are more prescriptive and restrictive than the Codex standards and proposed standard for the types of carbohydrates permitted in infant formula. It was also proposed that the carbohydrate content of infant formula should be at least 80% lactose which excluded formula based upon soya bean which usually contains sucrose as the carbohydrate of choice. Additionally the permitted sources of carbohydrate were not consistent from one formula type to another in the proposed standard.

Level of carbohydrate

It is proposed to regulate the protein, fat and energy contents of infant formula. Therefore the carbohydrate content is indirectly regulated as it is assumed that carbohydrate would be the third macro-nutrient to contribute to energy content. However, it is proposed to include a provision to clarify that it is carbohydrate and not organic acids for example, which are expected to make the remaining contribution to the energy content of infant formula.

Type or source of carbohydrate

Formula based upon mammalian milk will inherently contain lactose as the main carbohydrate unless specifically manufactured to lower the lactose content. Therefore prescription of the carbohydrate types may not be required as the generic requirement for all ingredients to 'be suitable for infant feeding' limits the use of unsafe constituents. As previously noted, formula based upon soy protein usually contains sucrose or glucose as the main carbohydrate source which is considered safe.

Therefore it is recommended the clauses proposed at full assessment which prescribe carbohydrate types not be included in the joint ANZ standard.

Lactose free and low lactose infant formulas

It was proposed at full assessment that lactose free infant formula must not contain any detectable lactose and low lactose infant formula must not contain more than 2.4 g/L of lactose if based on cows' milk protein or modified cows' milk protein; or 1.9 g/L of lactose if based on goats' milk protein. Submissions questioned the different maximum level of lactose for goat- and cow- milk based formula and requested a method of analysis for lactose be prescribed.

Codex has no specific standard for infant formula prepared for the lactose maldigesting infant. However, lactose maldigestion occurs secondary to gastroenteritis in infants and can be life threatening. Therefore provision for lactose free and low lactose infant formula is necessary to protect infants sick with a gastrointestinal disease.

The requirement for a lactose free food to contain 'no detectable lactose' regardless of method of analysis, affords infants the highest level of protection as it requires the most advanced method of analysis be used at all times. Therefore it is recommended that lactose free infant formula and lactose free follow-on formula should contain no detectable lactose. The onus is then on the manufacturer to select the most sensitive method with the lowest limit of detection.

It is proposed that low lactose formula regardless of base ingredient should not contain more than 2.4 g/L. This maximum level may be revised when Standard R1(5) is reviewed in the review of food standards to ensure consistency.

Low lactose formula should quantify the lactose content in the label to allow carers of infants who are intolerant to lactose to easily determine the lactose content of a formula. This will provide information to facilitate formula changes which may be necessary to protect the susceptible infant from adverse symptoms due to lactose intake.

Proposed Warning Statement for infants with galactosaemia

Galactosemia is a rare disease which is usually fatal if untreated.

Galactosemia is treated by the exclusion of galactose from the diet. The major dietary source of galactose is dietary lactose.

Declaration of galactose content on formula which claim a lower lactose content than usual

As lactose is the major dietary source of galactose information suggesting a reduction in lactose content may be misconstrued to imply a reduction in galactose content when this may not be true. Low lactose, reduced lactose and lactose free foods based upon milk, including infant formulas are therefore currently required to provide information about the galactose content of the food. This information enables carers

of children or infants with galactosemia to determine how much of the food, if any, is suitable for galactosemics. It is recommended that this provision be included in the joint ANZ standard for infant formula.

Warning statement for infants with galactosemia.

It was proposed at full assessment that lactose free and low lactose infant formulas in which the protein is milk protein include the following statement:

'NOT SUITABLE FOR INFANTS WITH GALACTOSEMIA'

International regulations do not make any provision for such a warning statement about unsuitability for galactosemics.

The value of this warning statement was questioned on the basis that galactosemia is often not diagnosed until later in infancy, the incidence of galactosemia is low and all infants with this disorder would be expected to be under specialist medical supervision. Therefore carers of infants with galactosemia would be provided with expert advice about which formula to purchase and therefore would not benefit from a warning statement as it is considered unlikely that they would be relying solely on label information when choosing formula.

Additionally, it is neither desirable nor necessary to require a such a warning statement on these formulas because the majority of infants using 'lactose-free' or 'low lactose' formula do not suffer from galactosemia.

3E) VITAMINS AND MINERALS

Maximum levels for vitamins and minerals, range set for some vitamins, and ratio of zinc to copper

It was proposed at full assessment to prescribe maximum levels for all vitamins and minerals in the standard. Whilst there was support for this approach from public health agencies, there was strong industry opposition to the mandatory maximum limits for vitamins and minerals other than where they were proposed for safety concerns.

Concerns were expressed 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. Industry submissions to the Authority state the medical, regulatory and economic implications of setting maximum levels for nutrients in infant formula which are not considered 'unsafe' for infants is high and not justified.

A risk assessment and full preliminary inquiry into the vitamin and mineral content of infant formula is included in Appendix 1.

The regulation of maximum levels of nutrients

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 represented as human milk substitutes 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.

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 B₆, 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 recommended for the joint ANZ standard for infant formula for these nutrients.

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'. It is recommended that a guideline accompany the joint ANZ standard for infant formula to provide manufacturers with guidance as to these recommended maximum levels and that these guidelines be implemented by Good Manufacturing Practice. Advisory levels do not have the 'force of law' as do levels prescribed in the standard.

Levels which are set on the basis of public health and safety should be the same for soy-based and milk-based formulas and the levels apply to infant formula products for infants from birth to 12 months.

Comparison of levels proposed at full assessment and preliminary inquiry:

Vitamins

Nutrient	Range proposed at Preliminary Inquiry		Range proposed at Full Assessment
	Range proposed for inclusion in the Joint ANZ standard /100 kJ	Advisory guideline /100 kJ	
Vitamin A	14 - 43 mcg*	-	17 - 54 mcg
Thiamin	10 mcg - no maximum level specified	maximum of 48 mcg	10 - 22 mcg
Riboflavin	14 mcg - no maximum level specified	maximum of 86 mcg	14 - 86 mcg
Preformed Niacin	130 mcg - no maximum level specified	maximum of 480 mcg	60 - 71 mcg
Folate	2.0 mcg - no maximum level specified	maximum of 8.0 mcg	1.7 - 7.9 mcg
Vitamin B ₁₂	0.025 mcg - no maximum level specified	maximum of 0.17 mcg	0.04 - 0.13 mcg
Vitamin C	1.7 mg - no maximum level specified	maximum of 5.4 mg	1.7 - 5.4 mg
Vitamin D	0.25 - 0.63 mcg	-	0.25 - 0.61 mcg
Vitamin K	1.0 mcg - no maximum level specified	maximum of 5.0 mcg	1.0 - 3.6 mcg
Pantothenic acid	70 mcg - no maximum level specified	maximum of 360 mcg	71 - 360 mcg
Biotin	0.36 mcg - no maximum level specified	maximum of 2.7 mcg	0.36 - 2.7 mcg
Vitamin B ₆	9 - 36 mcg	-	8.9 - 36 mcg
Vitamin E	0.5 mg/g linoleic acid; 0.11 - 1.1 mg	-	0.9 mg/g linoleic acid; 0.11 - 1.1 mg

* mcg refers to 'micrograms'

Minerals

Nutrient	Range proposed at Preliminary Inquiry		Range proposed at Full Assessment
	Range proposed for inclusion in the Joint ANZ standard /100 kJ	Advisory guideline /100 kJ	
Calcium	12 mg - no maximum level specified	maximum of 33 mg (controlled by Ca:P ratio)	12 mg - no maximum level specified (controlled by Ca:P ratio)
Phosphorus	6 - 25 mg	maximum of 22 mg	6 - 22 mg
Calcium: phosphorus ratio	1.2 - 2:1	-	1.1 - 2:1
Chloride	12 - 35 mg	-	14 -35 mg
Copper	14 - 43 mcg*	-	14 - 36 mcg (non soy- based) and 21 - 43 mcg (soy-based)
Zinc	0.12 - 0.43 mg	-	0.12 - 0.36 mg (non soy- based) and 0.18 - 0.43 mg (soy-based and follow- on formula)
Zinc: copper ratio	not > 12:1	-	not > 10:1
Chromium	For infant formula based upon protein substitutes only: 0.35 - 2.0 mcg	For infant formulas for normal use only: maximum of 2.0 mcg	not specified for infant formula but optional at 3.5 - 15 mcg for proximate modified formula
Molybdenum	For infant formula based upon protein substitutes only: 0.36 - 3.0 mcg	For infant formulas for normal use only: maximum of 3 mcg	not specified for infant formula but optional at 0.36 - 0.72 mg for proximate modified formula
Iodine	1.2 - 10 mcg	-	1.2-18 mcg
Iron	0.2 - 0.5 mg	-	0.2 - 0.5 mg
Magnesium	1.2 - 4.0 mg	-	1.4 - 3.6 mg
Manganese	0.24 - 24.0 mcg	maximum of 7.2 mcg for special purpose infant formulas	1.2 -13 mcg and 1.2 - 7.2 mcg for proximate modified formula
Potassium	20 - 50 mg	-	20 - 50 mg
Sodium	5 - 15 mg	-	5 -14 mg
Selenium	0.36 - 0.9 mcg	-	0.42 - 0.89 mcg (IF) 0.79 - 0.89 mcg(FOF) 0.53 - 0.89 mcg (proximate modified formula)

* mcg refers to 'micrograms'

On behalf of the infant formula industry, the Australian 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.

Comparison of levels proposed at full assessment and preliminary inquiry for Pre-term infant formula:

Nutrient	Range proposed for inclusion in the Joint ANZ standard (**) /100 kJ	Range proposed at Full Assessment /100 kJ
Vitamin A	as proposed at full assessment	20 - 36 mcg
Vitamin D	as proposed at full assessment	0.75 - 2.0 mcg
Vitamin C	as proposed at full assessment	3.5 - 9.6 mg
Thiamin	as proposed at full assessment	10 - 48mcg
Riboflavin	as proposed at full assessment	14 - 86 mcg
Preformed Niacin	as proposed at full assessment	0.18 - 0.89 mg
Vitamin B ₆	9.0 - 42 mcg	8.9 - 42 mcg
Folate	as proposed at full assessment	5.0 - 10 mcg
Pantothenic acid	0.24 - 0.36 mg	0.24 - 0.36(mcg in error)mg
Vitamin B ₁₂	as proposed at full assessment	0.04 - 0.13 mcg
Vitamin K	1.0 - 3.6 mcg	0.96 - 3.6 mcg
Biotin	0.36 - 2.7 mcg	0.37 - 2.7 mcg
Vitamin E	as proposed at full assessment	0.18 - 1.6 mg (0.9 mg of Vit E per g of linoleic acid)
Minerals		
Sodium	9.0 - 14 mg	9.1 - 14 mg
Potassium	as proposed at full assessment	20 - 36 mg
Chloride	as proposed at full assessment	14 - 22 mg
Calcium	as proposed at full assessment	17 - 34 mg
Phosphorus	as proposed at full assessment	12 - 22 mg
Ca:P	1.4 - 2.0 :1	1.4- 2.0 :1
Magnesium	as proposed at full assessment	1.5 - 3.6 mg
Iron	as proposed at full assessment	0.01 - 0.4 mg
Iodine	2.4 - 10 mcg	2.4 - 11 mcg
Copper	as proposed at full assessment	23 - 30 mcg
Zinc	0.12 - 0.36 mg	0.13 - 0.36 mg
Zn:Cu	< 12:1	< 10:1
Manganese	as proposed at full assessment	1.2 - 1.8 mcg
Selenium	0.5 - 0.9 mcg	0.53 - 0.89 mcg

* mcg refers to 'micrograms'

** minor adjustments made to align with the levels infant formula for term infants where there is no health or safety contraindication.

Permitted forms of nutrients

The permitted forms of nutrients proposed at full assessment will be included in the joint ANZ standard for infant formula. A toxicological evaluation of chromium sulphate and molybdenum sulphate indicates these forms of chromium and molybdenum are acceptable for use in special purpose infant formulas based upon protein substitutes. Therefore these forms will be added to the permitted forms of nutrients for use in special purpose infant formulas based upon protein substitutes.

The use of additional forms of nutrients 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 justification of safe use for infants or a full application should be made after the joint standard is gazetted.

3F) OPTIONAL NUTRITIONAL SUBSTANCES Nutritional substances other than the macronutrients (protein, fat carbohydrate), vitamins and minerals require clearer definition in the joint ANZ Food Standards Code as these may be added to foods but are not currently considered 'food additives' and are not 'foods'. The definition of 'nutritional substance' (or alternative term) will be considered by the P166 - review of vitamins and minerals for the purposes of the development of a joint ANZ Food Standards Code. For the purposes of the development of a joint infant formula standard, the term 'nutritional substances' will be used for substances which are not: foods, food additives, macronutrients, vitamins or minerals (including electrolytes).

Levels of inositol, taurine, nucleotides, carnitine and choline

Comparison of levels proposed at full assessment and preliminary inquiry:

Nutrient	Range proposed for inclusion in the Joint ANZ standard	Proposed minimum level for claim	Range proposed at Full Assessment (Minimum for claim)
Carnitine	0 - 0.8 mg/100 kJ	0.21 mg/100 kJ	0 - 0.42 mg/100 kJ (0.21 mg/100kJ)
Choline	0 - 7.1 mg/100 kJ	1.7 mg/100kJ	0 - 5.4 mg/100 kJ (1.7 mg/100kJ)
Taurine	0 - 3 mg/100 kJ	0.8 mg/100 kJ	0 - 3 mg/100 kJ (0.8 mg/100kJ)
Inositol	0 - 9.5 mg/100 kJ	1.0 mg/100 kJ	0 - 5.4 mg/100 kJ (1.0 mg/100kJ)
Total Nucleotides	0 - 1.2 mg/100kJ	-	as per recommendation at Preliminary Inquiry
Nucleotide: CMP	0 - 0.6 mg/100kJ	0.22 mg/100kJ	as per recommendation at Preliminary Inquiry
Nucleotide: UMP	0 - 0.42 mg/100kJ	0.13 mg/100kJ	as per recommendation at Preliminary Inquiry
Nucleotide: AMP	0 - 0.38 mg/100kJ	0.14 mg/100kJ	as per recommendation at Preliminary Inquiry
Nucleotide: GMP	0 - 0.12 mg/100kJ	0.04 mg/100kJ	as per recommendation at Preliminary Inquiry
Nucleotide: IMP	0 - 0.24 mg/100kJ	0.08 mg/100kJ	as per recommendation at Preliminary Inquiry

A full preliminary inquiry into the optional nutrient content of infant formula is included in Appendix 1.

Some nutrients which, although not essential nutrients, may be of benefit to infants are permitted to be added to infant formula. These nutrients are carnitine, choline, taurine, inositol and five specific nucleotides. However, the maximum levels of these ingredients are recommended to be regulated to protect infants from excessive intakes. These nutrients must be present in the formula to the level in human milk for a declaration of nutrient content to ensure carers of infants are provided with appropriate information. The recommended maximum levels and minimum level required for a claim are given in the above table.

3G) OSMOLALITY VALUE

The renal solute load (RSL) of a formula is a more suitable measure of the risk to infants of dehydration illness from formula than is the osmolality of a feed. The RSL is the amount of metabolic waste products that must be excreted by the kidney. Protein, sodium, potassium, phosphorus and chloride are the main dietary contributors to RSL. The safety of formula for infants is influenced by the potential renal solute load (PRSL) of the formula.

The PRSL can be calculated easily from the formula composition with the assumption that all dietary nitrogen is converted to urea as follows:

<p style="text-align: center;">Potential Renal Solute Load (PRSL) in mOsmol/100 kJ</p> $= [\text{Na (mg)} / 23^*] + [\text{Cl (mg)} / 35^*] + [\text{K (mg)} / 39^*] + [\text{P (mg)} / 31^*] + [\text{protein (mg)} / 175^{**}]$
--

* conversion factor for nutrient from mg to mmol

** PRSL from protein is protein (mg)/175 where PRSL from nitrogen content of the diet is 14 (atomic weight of N) * 2 as urea contains 2 atoms of N = N / 28. However, there are 6.25 mg protein / 100 mg nitrogen .

Dehydration is life threatening and the risk of dehydration can be minimised by avoiding highly concentrated feeds with high renal solute loads and limited water intake and also by delaying the introduction of solids until 4-6 months. Evidence indicates a PRSL of 3 times the level in human milk contributes significantly to the incidence of infant hypernatremic dehydration.

Modelling indicates the protein and electrolyte permissions granted at full assessment to follow-on formula and 'infant formula based upon protein substitutes for specific dietary use' could create unacceptably high PRSLs which may increase the risk of dehydration for infants. Whilst the kidneys of older infants are more capable of handling high PRSLs, the introduction of solid foods which have a very high PRSL and low water content necessitates a limitation on PRSL for formulas prepared for older infants. Therefore it is recommended the regulation for the osmolality of follow-on formula be replaced by a regulation for PRSL as this is more critical to the health of infants. The PRSL of infant formula and preterm infant formula is controlled to safe levels by the permitted protein and electrolyte levels and it is not necessary to prescribe a PRSL for infant formula or preterm infant formula. However, there is a need to regulate the maximum PRSL of follow-on formula and infant formula based upon protein substitutes for specific dietary use to protect the health of infants. It is recommended that to reduce the risk of dehydration in infants the maximum PRSL of formulas be restricted to 2.5 times PRSL of human milk or 8 mOsmol/100 kJ.

4. FOOD ADDITIVES

4A) PERMISSION FOR FOOD ADDITIVES

Industry has asked for an increased selection of additives for infant formulas and harmonisation with Codex. The Codex provisions for food additive use in infant formulas are recommended for inclusion in the joint ANZ standard for infant formula with adjustment for the recommendations by the European Commission's Scientific Committee for Foods, particularly for special purpose formulas based upon hydrolysed protein or amino acid based formulas.

Refer to Food Technology Report at Appendix 2.

4B) PROHIBITION ON CARRAGEENAN

An assessment of the potential toxicity of carrageenan in liquid formula has concluded there is not sufficient evidence of potential adverse effects of carrageenan to restrict its use in liquid infant formulas. Therefore provision has been made for the use of carrageenan in liquid infant formulas.

Refer to toxicology report at Appendix 3 Part B.

5. SAFETY OF SOY FORMULAS

Concern has been expressed about the safety for infants of formula based upon soy, particularly because of its phytoestrogen content. Industry submissions claimed soy formulas had a long history of use and were therefore safe. Other submissions suggested there were health concerns for soy consumption by infants and special measures were called for to reduce the prevalence of soy-based infant formula consumption. The special measures suggested in submissions were the requirement for a specific 'warning' statement on the product label or restriction on the sale of the product.

Assessment

The NZ Ministry of Health has recently released a public statement 'Soy Based Infant Formulas' as a pamphlet for parents which advises that breast milk is the best food for babies and dairy-based infant formulas are the next best choice. The pamphlet also highlights that any alternative to human or dairy based milk should be discussed with a health professional. The Ministry notes the long term effects of the phytoestrogen content in soy-based formula as an infant's main food source are not known and that this area is the subject of on-going international research. Previously regulatory bodies in the UK and Switzerland and the Australian College of Pediatrics have all issued statements which suggest soy-based formulas should only be used if there are contraindications for breast milk or cow's milk-based formulas.

An assessment of the risks to infants from the phytoestrogen content of soy based formulas was undertaken by the Authority. The Authority document, 'Phytoestrogens: An assessment of the potential risks to infants associated with exposure to soy-based infant formula' (1999) is available upon request. It is concluded in this assessment that currently available information suggests while phytoestrogen at the levels found in soy-based infant formula have the potential to cause adverse effects, there is no evidence that exposure of healthy infants to soy-based infant formula over some 30 years of use has been associated with any demonstrated harm.

However, because there are no case-controlled or longitudinal human studies designed to examine any long-term effects on humans exposed to phytoestrogens in infancy, a precautionary approach would suggest that while some of the concerns about the use of soy-based infant formula remain unresolved, it would be prudent to aim to limit its use.

Strategies to deter the use of soy-based infant formula will be considered by the Authority. These strategies could include targeted education initiatives based upon a public health policy that infants should be breast fed where possible, and that where breast feeding is not an option, modified cow's milk formulas would be recommended as the preferred feeding choice. Soy-based formulas should only be used on the advice of a health professional and for infants who have a special medical requirement which precludes breast feeding or modified cow's milk formulas.

Other strategies associated with an education initiative could include specific advisory labelling of the product or a reduction of the unrestricted access to soy-based infant formula. At this time it is not proposed to require warning statements on the product labels but potential strategies are dependent upon the future levels of unnecessary consumption of soy-based infant formulas.

6. LEVELS OF CONTAMINANTS

Contaminants in infant formula

There are some compelling reasons why a more cautious approach to the control of contaminants should be taken for infant formula than for general purpose foods, namely that,

1. infant formula is usually the sole source of nutrition for the infant in many cases;
2. the tolerable daily intake (TDI) for contaminants is not considered to be applicable to infants under 3 months of age;
3. the normal functions of the gastrointestinal tract and the metabolic processes of the liver are not fully developed in infants and, therefore, the fate of contaminants in the diet is unknown;
4. it is unlikely that data will become available to establish safe levels of exposure for many contaminants in infants.

A toxicological assessment was undertaken for the following specific potential contaminants of infant formula.

Fluoride

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

However, due to the possibility of dental fluorosis from the use of some formulas, the Authority is proposing that products with high fluoride contents should have an advisory statement on the label to advise carers of this potential risk. The advisory statement should recommend carers to specifically discuss the risk of dental fluorosis associated with the use of the product with a Doctor or health professional. This statement is proposed for infant formula powders containing fluoride levels >0.5 mg/L when reconstituted with fluorine free water (formulas with approx 17 microgram fluoride /100kJ) and ready-to-drink formulas containing fluoride > 1.5 mg/litre.

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

Refer to toxicology report at appendix 3 Part A.

Cadmium

The toxicology assessment concludes given that the toxicity associated with cadmium is the result of long-term exposure, there is no immediate health concern for infants from exposure to low levels of cadmium via infant formula. Only low levels of cadmium are likely to occur in the raw materials used to prepare infant formula and, therefore, there is no reason to specifically restrict the level of cadmium in infant formula.

Refer to toxicology report at appendix 3 Part A.

Lead

The risk assessment undertaken by the Authority has concluded that there is cause for concern about exposure to lead, even at very low levels particularly for susceptible groups such as infants and children. This is supported by the fact that lead is ubiquitous in nature, is cumulative and the effects may not be reversible in children. It is proposed that a maximum limit of 0.02 mg/kg for lead in infant formulas be set. This is consistent with the proposed Codex level.

Refer to toxicology report at appendix 3 Part A.

Nitrates

Refer to toxicology report at Appendix 3 Part A.

The toxicology report concluded that infants below the age of 3 months are more vulnerable to the toxicity of nitrite than adults. Nitrite is formed following endogenous conversion from nitrate in the diet. There is some evidence that this conversion is more likely to occur in infants because of their low production of gastric acids. The Authority considers that restriction of the level of nitrate in infant formula is essential and is being addressed in the current NHMRC water quality guidelines.

Pesticides

The Toxicology report noted a recent Australian analysis of foods for levels of 70 different pesticides detected none above the level of detection in infant formula. Therefore, the Authority does not consider there is a need to have specific upper levels for pesticides in infant formula.

Refer to toxicology report at appendix 3 Part A.

Aluminium

There was widespread support for the setting of a maximum level for aluminium in infant formula, although submissions considered there were no grounds to have different maximum permissions for non-soy and soy based formulae as the level should be determined on health and safety grounds.

It is recommended that the maximum level set at full assessment for non- soy- formulae be increased to 0.5 mg/L. However, the level should remain at 0.2 mg/L for pre-term infants as they may be at particular risk of aluminium toxicity because of their immature gastro-intestinal tracts and limited ability to excrete aluminium through normal renal clearance.

There are safety concerns with the use of soy-based formula and it is now recommended these formulas should only be used by infants who have a medical reason which precludes breast feeding or milk-based foods. The level of 1.0 mg/L for soy based formula is to be retained as it may not be currently possible to attain the lower limit possible for non-soy based formula. The risk of higher aluminium intake for infants for whom there is a well justified reason for recommending that they be fed soy-based infant formula, is considered to be probably less than the risk of consumption of a milk based formula by these infants. However, doctors and health professionals may not be aware of the potential higher aluminium content in soy-based formulas. Therefore it may be prudent to provide education for the reference groups on this issue.

Refer to toxicology report at appendix 3 Part A.

7 MICROBIOLOGICAL REQUIREMENTS

As infants are more susceptible to food poisoning than adults, very stringent microbiological criteria are required and provided for in the draft standard.

Refer to Risk assessment for microbiological safety of infant formula at Appendix 4.

8. LABELLING REQUIREMENTS

These issues have been reviewed in detail at Appendix 5 - Preliminary inquiry into labelling provisions.

8 A) PRINT SIZE, FORM AND CONTENT OF MANDATORY STATEMENTS, INCLUDING THE STATEMENT CONTAINING ADVICE TO INTRODUCE OTHER FOODS AND THE STATEMENT ON THE PREPARATION OF BOTTLES.

Issues raised in submissions were the print size and print quality requirements; the prescription of the wording for required information; and the difficulty of providing the required labelling on small packages.

The review of labelling provisions has indicated the need for the following labelling issues and provisions to be included in the joint ANZ standard for infant formula:

Printing style

Mandatory information must be clear, legible and noticeable, warning statements required on infant formula products should be in 3mm standard type or in the case of packages of less than 1kg, 1.5mm standard type. When the joint FSC comes into force 'standard type' will no longer be specified and legibility will be the key criteria.

Prescription of wording

Where a statement is considered necessary because there is a potential life threatening risk to the infant or a specific group of infants in the community, it is classified as a warning statement and the exact wording of the statement is prescribed in the joint ANZ standard for infant formula.

However, if the statement is considered to be advisory in nature and the risk to infants is not life threatening, then only the intent of the statement is prescribed. Manufacturers may then use their own words to convey the required intent.

Mandatory information

It is recommended that:

- each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- (a) the words “important notice” or their equivalent;
- (b) a statement of the superiority of breast feeding;
- (c) a statement that the product should only be used on advice of a medical practitioner or health worker as to the need for its use and the proper method of use;
- the following warning statement should appear in the label of infant formula in type of 3 mm.

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

- there be a requirement for infant formula in a powdered or liquid concentrate form to contain words and pictures as to its appropriate use and preparation. The directions for preparation and use should include the following:
 - that each bottle of formula should be prepared individually;
 - if a bottle of made up formula is to be stored prior to use, it should be refrigerated and used within 24 hours;
 - that potable, previously boiled water should be used; and
 - that formula left in the bottle after a feed must be discarded.
- there should be a statement in the label indicating the infant formula product may be used from birth and if a follow-on formula is used it should not be introduced before the infant is 6 months or older'.
- an advisory statement should appear in the label of infant formula providing information that infants (over 6 months of age) should receive other foods in addition to the formula.
- a guideline recommending manufacturers indicate in the label that additional vitamin or mineral supplementation is not needed be incorporated into an attached guideline document.
- the instructions for use of powdered infant formula containing a measuring scoop, must provide advising information that only the enclosed scoop should be used.
- The label of a formulated infant formula for metabolic and immunological conditions should contain an advisory statement in the label indicating the:

- conditions, disease or disorder for which the food has been specially formulated;
 - nutrient modifications on which it is based; and
 - product should be used under medical supervision and that the product is unsuitable for general use'.
- The label of pre-term infant formula must include the statement, 'SUITABLE ONLY FOR PRETERM INFANTS UNDER SPECIALIST MEDICAL SUPERVISION'.

Other

It is proposed to retain the following labelling provisions proposed at full assessment.

- The label shall have no pictures of infants nor any other pictures or text which idealises the use of infant formula.
- The label may have graphics illustrating the method of preparation of the formula.
- The terms 'humanised', 'maternalised' or other similar terms should not appear in the label of infant formula.

8B) NUTRITION INFORMATION TABLE ENTRIES

Submissions requested the provision of nutritional information be harmonised with international requirements.

Harmonisation of type and style of nutritional information has been reviewed in detail at Appendix 5 - Preliminary inquiry into labelling provisions.

The requirement for the nutrition information table (NIT) proposed at full assessment differs from the Codex requirements in that it required minimum rather than average levels for nutrients be stated in the NIT; it made no allowances for optional ingredients to be included in the NIT; it required nutrient information only per 100 mL and there are differences in nutrient order of the tables and in the units of measurement.

It is recommended at preliminary inquiry that:

- the nutrient values in the NIT be average or typical nutrient values;
- that provision be made in the NIT to include other nutritional substances in its list so that all nutrients and nutritional substances in infant formula are listed in the NIT;

- the NIT include nutrients and nutritional substances as purchased as well as per 100 mL ready to consume formula; and
- the order of nutrients in the NIT be consistent throughout the standard.

However, the specification of the NIT format and order of nutrients is proposed to be included as a guideline, rather than a prescription.

8C) FEEDING GUIDE CONTENT

The purpose of a feeding guide on infant formula products is to require manufacturers to provide guidance to care givers on both the preparation of the formula and the recommended daily number of feeds. The draft proposed at full assessment includes a guideline that is quite detailed by age breakdown. There is no such precedent in Codex or in the NZFR.

It is recommended that the joint ANZ standard for infant formula require the provision of directions as to the preparation and use of the product but not to prescribe the format of those directions.

8D) DATE MARKING AND STORAGE INSTRUCTIONS AND DIRECTIONS FOR USE

It was submitted that, in the very hot areas of Australia, opened cans or packages deteriorate before the expiry date. Therefore it is recommended that provision be made in the joint ANZ standard for infant formula to require the manufacturer to provide storage instructions for the product after it is opened and date marking in accordance with date marking requirements for all infant formula products regardless of shelf life.

An editorial note should be included in the standard to advise manufacturers that the storage instructions must be valid for the full range of climatic conditions in Australia and New Zealand.

9. TITLE AND SCOPE OF DRAFT STANDARD R7

TITLE OF DRAFT STANDARD R7

There was general agreement in submissions that the Standard should be called Infant Formula and not Human Milk Substitutes although there was disagreement about justification for choice of title. Two submissions argued that the term 'human milk substitutes' had negative connotations while others argued that this term implied that the formulas are better than they actually are. Submission was made that the new name is not in the spirit of the World Health Organization's International Code of Marketing of Breastmilk Substitutes (WHO Code) since use of

the term 'may imply that the products within the Standard are of the same quality as human milk.'

The name 'infant formula' is used in the Codex, EC and FDA standards and therefore it is recommended that the title of the joint ANZ standard be 'infant formula products' to provide for the range of different products.

SCOPE OF THE DRAFT STANDARD

Submission was received supporting the creation of a Standard which contains reference to a range of complete formulas.

Codex has a standard for infant formula and a standard for follow-on formula. There is no Codex standard for pre-term formula. Preterm infants have different requirements for some nutrients than term infants. Therefore, some countries are preparing standards for pre-term formula.

The imposition of a standard where there is no Codex standard may be considered a technical barrier to trade, however it is justified as it provides for the health requirements of infants with special needs.

Size of Draft Standard R7

Comment was received that the draft proposed at full assessment is too long and it has been developed not for simplicity and brevity, but with prescriptive detail.

The draft proposed at full assessment has been reviewed in the preliminary inquiry to ensure consistency with review objectives and to reduce unnecessary prescription. Only those provisions which are necessary to protect the health of infant are included in the proposed joint ANZ standard provisions. The proposed standard is still lengthy but its length is justified as infant formula is intended as the sole source of food and nutrition for the first four to six months of life and thereafter it is the principal source of nutrition for infants. This makes it a special case.

10. DEFINITIONS AND TERMINOLOGY

CONSISTENCY OF TERMINOLOGY

Submission was made that 'fat' should be the term used throughout the Standard, rather than 'fat' in some places and 'lipid' in other places.

The Codex Standard, and draft proposed at full assessment use the term 'fat'. Fat is a term more easily understood by consumers. Therefore it is recommended that the term 'fat' should be used throughout the joint ANZ standard for infant formulas.

DEFINITIONS

Submission was made that some of the definitions were regarded as unnecessary or required change. The following issues concerning some definitions are specifically assessed for potential use in the joint ANZ standard.

Modified Cows Milk Protein

Submissions consider the term 'modified cows milk protein' to be unnecessary. Modified cows milk protein means cows milk protein in which the ratio of casein protein content to whey protein content is altered. Each of these types of protein has a different amino acid score as will mixtures of the two protein types. However, as the amino acid score is proposed to be regulated in the standard, these differences will become irrelevant. Therefore there is no need to define 'modified cows milk protein' in the standard.

It is recommended that the term 'cows milk protein' should replace 'modified' and 'unmodified' cows milk protein.

Principal Source

Roche requested a definition of the term 'principal source' which has been used mostly in the definitions of human milk substitute and infant formula. The definition for infant formula is, 'a food that is represented as being suitable as the principal source of food for infants'.

Common dictionaries define 'principal' in generic terms. Principal is defined by the:

- Macquarie Dictionary as *inter alia*:
 - 'first or highest in rank, importance, value';
 - 'something of principal or chief importance' and
- Concise Oxford Dictionary as *inter alia*:
 - 'first in rank, importance, chief'.

These generic definitions are therefore appropriate for legal determination and it is not proposed to define 'principal source' in the joint ANZ standard for infant formula.

Protein substitute

A definition of protein substitute is needed because individual sources of protein are not proposed to be specified in the joint ANZ standard for infant formula.

For the purposes of this draft standard a 'protein substitute' is defined as L-amino acids or the hydrolysate of one or more of the proteins on which infant formula is normally based.

Protein-modified

This term was defined as a food which contains either extensively or partially hydrolysed protein or synthetically produced amino acids. Submissions disagreed with the use of the term 'synthetic' for amino acids and considered the term was not necessary in the standard.

The reference to synthetically produced amino acids will be changed simply to L amino acids, leaving out the term 'synthetically'.

The proposed term 'proximate modified' was unpopular as submissions noted not many people would understand the term 'proximate'. Additionally, the term 'protein modified' was suggested as a likely term for some of the specialised formulas which are not necessarily prepared from extensively or partially hydrolysed protein or synthetically produced amino acids. The term 'protein substitute' is now proposed for formulas based on L- amino acids or protein hydrolysates. Therefore the definition 'protein modified' will not be included in the joint ANZ standard for infant formula.

11. ADVERTISING OF INFANT FORMULAS

The Australian and New Zealand governments are signatories to the World Health Organization's 'The International Code of Marketing Breast-milk Substitutes (WHO Code). As signatories to the WHO Code, both Australia and New Zealand have made a commitment to implement the provisions or articles of the WHO Code in their respective countries. Article 1 of the WHO Code is *'the aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information through appropriate marketing and distribution'*. The WHO Code includes the following restriction on advertising at Article 5.1 "There should be no advertising or other form of promotion to the general public of products within the scope of this Code".

In the light of Australia's and New Zealand's commitment to the WHO Code, the New Zealand Ministry of Health suggest that the advertising and promotion of infant formula be restricted by the inclusion of the following words or similar in the draft standard for infant formula:

'Infant formula may only be advertised in publications aimed specifically at health professionals'; and

'Promotional material relating to infant formula may only be distributed by health professionals'.

Assessment

Australia's and New Zealand's thorough commitment to the advertising component of the WHO Code is currently effected by separate voluntary Codes of Conduct in each country. The Authority believes these Codes of Conduct are in the main, effective in implementing the aim of the WHO Code. Unless there is evidence of systemic failure of these non-regulatory mechanisms in achieving the desired outcome, a restriction on advertising is inconsistent with the objectives of the review of food standards to reduce prescriptiveness in the standards. Therefore such a potential restriction is not warranted whilst Codes of Conduct can achieve the necessary outcome of prohibiting advertising or other form of promotion to the general public of infant formula products. Therefore, it is recommended a requirement to restrict the advertising of infant formula to publications for, or distributed by health professionals not be included in the joint ANZ standard for infant formulas.

12. OTHER

LEAD-IN TIME

Wyeth argued in 1996 that a one-year lead-in time was insufficient to implement such changes as reformulation and that stability studies take significant amounts of time. However, other infant formula manufacturers are keen to implement the revised standard as soon as possible.

The draft revised standard proposed for the joint ANZ standard is less prescriptive than previously proposed and industry is now keen to see a revised standard implemented as soon as possible.

Therefore it is proposed that the standard come into force on gazettal and that the current standard remains in force as an alternative for 12 months after gazettal.

MEASURING SCOOP SIZE AND DESIGN

Human Services and Health and Maureen Minchin requested a standardised scoop be required for use in infant formula preparation. Dorothy Francis pointed out that design is important and a deep scoop is more accurate than a shallow one.

Assessment

A standardised scoop size is not currently appropriate because of the different product densities. The Authority recognises the technical difficulties in setting a standard scoop size and so retains the requirement that the scoop must be suitable for use in accordance with the directions contained in the label on or attached to the package.

DRAFT REGULATORY IMPACT STATEMENT

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 each taken a number of different steps in support of their international commitments to the WHO, by incorporating the relevant articles into food standards and 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 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 restrictions on the advertising and promotion of infant formulas.

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 for 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.

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 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 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. Membership of the external project review team included ANZFA staff, paediatricians, a professor of biochemistry (human milk specialist), a representative from industry, an independent infant feeding consultant and a NZ government representative. Submissions were received from industry, the Dietitians Association of Australia, Dorothy Francis a paediatric research dietitian, various departments of health in the Commonwealth, States and Territories and New Zealand.

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 FSC and Regulation 242 in the NZFR regulate the composition and labelling of infant formula products in Australia and New Zealand. Neither regulation specifically includes provisions for formulas for preterm 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 effective in limiting the advertising of infant formula products to the general public. 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 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, preterm 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

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.

Advertising and promotion of infant formula products to the general public has the potential cause a decline in breast-feeding rates with adverse consequences for public health. Industry Codes of Practice currently restrict the advertising and promotion of infant formula products to the general public in Australia and New Zealand; the onus being on manufacturers to maintain acceptable practices which will not adversely affect the health of infants.

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.

STATEMENT OF COSTS AND BENEFITS OF EACH ALTERNATIVE

This statement of costs and benefits is based on the possible regulatory impacts on Australian governments, industry and consumers. It will be necessary, in the course of development of any enforcement agreement between Australia and New Zealand, and the development of a joint standard, to consider the impacts of various options on governments industry and consumers in both countries. Comment on any such impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of this statement of costs and benefits.

OPTION 1 – maintaining the status quo

BENEFITS

Government:

- The health and safety of infants is basically protected. However, there is some evidence that new constituents are being added to formulas without an appropriate public health assessment.
- Advertising to the general public remains voluntarily restricted, limiting adverse impacts on breast-feeding rates and thereby reducing community health costs.

Industry:

- No obvious benefit.

Consumers:

- Infant Formulas are safe, although formula fed infants do not have a potential health outcome as good as breast fed infants. There is a risk of addition of unsuitable ingredients or levels of ingredients with the current regulations. Carers of infants are not subjected to advertising pressure to use infant formulas instead of breast-feeding and new mothers are not supplied with free formulas in hospitals with consequent disruption to breast-feeding practice.

COSTS

Government

- There are costs to government in determining compliance of Infant Formulas produced and sold in an environment where the current Standard R7 is partly obsolete and yet allows new products with a partly uncontrolled composition.
- There may be costs to State, Territory and New Zealand Health Departments to monitor infant formula for any new additions.

Industry

- Ingredients permitted in formulas sold overseas are not permitted in formulas sold in Australia, necessitating reformulation for the Australian market and increased costs for industry.
- Some labelling provisions are different from those required by Codex and other countries which necessitates the relabelling of some formulas particularly those prepared for infants who need special purpose formulas.
- The composition and labelling provisions which differ from the international standard requirements are a potential barrier to trade.

Consumers

- Consumers are denied access to ingredients which may improve health. Some ingredients or levels of ingredients which may not be suitable for infants may be included in infant formulas.
- Carers of consumers incur higher costs as costs of reformulation and relabelling are passed on to the purchaser.

OPTION 2

BENEFITS

Government

- The regulatory basis for assessing infant formula whether imported or produced locally will be clear and unequivocal resulting in reduced costs.
- The government will be assisting in the promotion of fair trading through the provision of a harmonised regulatory framework.
- The government will be fulfilling its obligation to protect the public health and safety of infants because of the enhanced provisions of the draft revised Standard.
- Advertising to the general public remains voluntarily restricted, limiting adverse impacts on breast-feeding rates and thereby reducing community health costs.

Industry

- Infant formula industry has increased potential to use more nutrients/ingredients.
- Infant formula industry will have reduced costs from the proposed simpler and harmonised standard with sufficient flexibility to permit industry innovation consistent with the increased scientific knowledge about optimal composition.
- Decreased costs will occur with the reduction in prescriptiveness and increased flexibility proposed for mandatory labelling provisions.

Consumers

- The health of infants may benefit by access to a wider range of ingredients in the formulas consistent with the increased scientific knowledge about optimal composition.

- The health and safety of infants is greatly enhanced by proposing maximum levels for vitamins, minerals, and fatty acids in infant formulas.
- Carers will benefit from improved labelling allowing them to ensure appropriate use and to make a more informed choice.
- Costs of formula may reduce with increased competition in the market.
- Carers of infants are not subjected to advertising pressure to use infant formulas instead of breast-feeding and new mothers are not supplied with free formulas in hospitals with consequent disruption to breast-feeding practice.

COSTS

Government

- Potential cost to government of enforcing the regulation.

Industry

- Extra costs are associated with the maximum levels proposed for additional vitamins and minerals and other compositional restrictions. Industry will need to analyse formulas to ensure prescribed maximum levels are not exceeded.

Consumers

- Increased costs to industry of reformulation may be passed on to consumers.

OPTION 3

BENEFITS

Government

- No obvious benefit

Industry

- This would be of benefit to industry. There would be no limitation on ingredients, no tolerances to meet and there may be product innovation. Various claims, albeit substantiated or unsubstantiated may be able to be made to obtain a marketing advantage subject only to Trade Practices law.

Consumers

- No obvious benefit as a whole. There may be particular products suitable for special applications. However confusion may result in inappropriate products being fed to infants which may be an unacceptable risk.

COSTS

Government

- Government would bear the brunt of costs in protecting the public from potentially unsafe and confusing formulations. Government would be the only organisation with the means to test products to ascertain actual composition in order to protect consumers. This would be far more expensive than monitoring product which was regulated.

The government may be perceived by consumers as placing industry profits and deregulation ahead of the health and safety of infants.

Trade Practice law may not be an appropriate mechanism to enforce potential claims about nutritional substances where there is not yet scientific consensus of nutritional efficacy or safety. With no regulation the industry would be free to make claims about nutritional constituents to the confusion of consumers and with no measurement available to validate that the claims are accurate. There would also be no requirement that other information would be accurate. Competition would ensure proliferation of claims and counterclaims. Increased costs would be incurred to educate the public to ensure informed choice is possible, for claims about unfamiliar nutritional or potential nutritional constituents.

- Health costs of infants adversely affected by unsafe or inappropriate ingredients or level of constituents in formulas would be borne by government and the community.

Industry

- Industry may find that keeping up with competitors in an unregulated market may be more expensive than competing in a regulated market.

Consumers

- Carers / consumers would bear the cost of coping with competing and conflicting advice and a potential increase in health costs for their infants.

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 any potential trade barriers.

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

REGULATORY IMPACT CONCLUSION

Government action is seen to be needed and the proposed revised Standard is the preferred option for containment of costs and the pursuit of public health and safety objectives.

CONCLUSION

The draft revised infant formula standard proposed at full assessment was not consistent with current regulatory policy as it was overly prescriptive and lacked consistency with current international standards. A detailed review of those proposed provisions indicates a less prescriptive standard can be achieved whilst still providing for safe and healthy formulas.

In order to satisfy the health and safety requirements for infants, the standard should stipulate the nutritional composition of infant formulas to provide fully for the nutritional needs of infants at all stages of growth and development. For nutrients considered as essential, a range of contents within minimum and maximum levels is recommended to ensure that the amounts of nutrients available from formula products are both safe and adequate to support health.

It is necessary that the quality and quantity of the protein content of infant formulas be regulated and hence it is not considered necessary to regulate the protein source. However, to provide carers with information to assist with formula choice, information about the source of protein should be declared on the label. The total energy, total fat and essential fatty acids content is recommended to be 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 recommended to be restricted where necessary to protect infants from adverse health consequences.

Human milk has a self limiting level for all vitamins and minerals and the setting of maximum levels mimic this natural protective factor. Although not all vitamins and minerals are toxic in large quantities, an excess of one nutrient can interact adversely with others. Therefore, maximum levels of all vitamins and minerals should be contained, as unlimited nutrient contents for infant formulas represented as human milk substitutes are not recommended as in the best interests of infant consumers.-

To eliminate unnecessary cost for industry, it is recommended that mandatory maximum levels be set 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'. It is recommended that a guideline accompany the joint ANZ standard for infant formula to provide manufacturers with guidance as to these recommended maximum levels and that these guidelines be implemented by Good Manufacturing Practice.

Where there is sufficient evidence of a sustainable health benefit from consumption of infant formulas containing other nutritional factors found in human milk, these factors are considered as optional additions to formula products and are permitted to be added up to a specified maximum level. For example, some LCPUFA are currently considered to assist in infant neurodevelopment. Sufficient evidence of the efficacy of LCPUFA is not yet conclusive to mandate a LCPUFA content of infant formula. However, these fatty acids are a usual component of human milk and therefore are permitted to the levels in breast milk. Similarly nucleotides, carnitine, taurine, choline and inositol are found in human milk and there is evidence that these substances may be beneficial to infants. The maximum permission for the inclusion of these substances in infant formula is also based upon the level found in human milk.

To address concerns that 'novel' ingredients or ingredients sourced from novel sources may be used in infant formulas without suitable safety assessment, it is recommended that a requirement for assessment of safety be included in the standard for such ingredients, and that the Authority be the agency responsible for that assessment. Therefore it is recommended that a prohibition on the use of novel foods not listed in the table of the proposed Standard A19 be included in the standard for infant formula.

[Editorial Note: P168 - Novel Foods is currently with the ANZFSANZ and is expected to be implemented prior to the gazettal in the revised infant formula standard.]

The safety of soy-based formula for infants was assessed at preliminary inquiry. It is recommended that these formulas only be consumed by infants for whom human milk or a modified cow's milk formula is contraindicated. The Authority is considering strategies to reduce the incidence of inappropriate soy-based formula consumption in Australia and New Zealand to the level necessary on medical grounds in a separate project. A general advisory statement will be required on an infant formula product label which is intended to direct carers to medical or health advice to ensure the most suitable formula is selected for each infant. Specific labelling statements are not proposed at this time for soy-based formula but policy guidance may be appropriate for reference groups such as doctors and community based-nurses about the general suitability of soy-based formulas.

There are a number of concerns about formulas in general which health workers may need to receive specific information to enable best advice to carers of infants. For example, health workers may need more information in relation to the impact of

fluoride content in made up formulas on potential dental fluorosis or that there may be higher levels of aluminium in soy-based formulas. Therefore, the Authority may need to provide information specifically targeted to health professionals to enable these people to assess the suitability of a specific formula for a particular infant.

The risk to health of potential level of contaminants in infant formulas was assessed. It is concluded that limits for lead and aluminium contents are required to protect infants. Other potential contaminants will not pose a risk to infants or are to be regulated by other mechanisms, such as water quality guidelines. An advisory labelling statement to alert carers to seek specific health advice is proposed for formulas with unnecessarily high fluoride contents.

The provisions proposed are aligned internationally or prescriptive only where necessary to protect the health of infants in Australia and New Zealand. It is considered the risk to infants in Australia and New Zealand from potential gluten content of infant formulas is such that a prohibition on gluten inclusion in formulas is required, although not specifically prohibited in the Codex standard.

Microbiological criteria and the use of specific food additives are recommended to ensure safety of infant formulas.

Specific labelling is recommended to ensure advice is sought to determine whether formula is the most appropriate method of feeding and if so whether the specific formula is the most appropriate formula for the individual infant. Labelling is also required to ensure carers have advice as to 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 are also reflected within the Standard. These include a reference to breast milk as the optimum source of nourishment for infants so that potential purchasers of formula products can be informed of the full range of feeding options. Advertising and promotion of infant formulas to the general public are not advisable in the interests of public health. However, industry managed Codes of Practice are already in operation in both Australia and New Zealand which restrict the advertising and promotion of formulas to the public. It is not considered necessary to incorporate advertising restrictions into the FSC whilst Codes of Practice can achieve the necessary restrictions.

A food standard for infant formulas which protects of 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 which provides for a food which is intended to be the principal source of nourishment for a vulnerable group is necessarily more prescriptive than standards for other foods which form part of a varied diet.

WORLD TRADE ORGANIZATION (WTO) 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.

REPORT ON THE NUTRITIONAL COMPOSITION OF INFANT FORMULA
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REPORT: THE NUTRITIONAL COMPOSITION OF INFANT FORMULAS.

Submission was made that the draft revised infant formula standard was overly prescriptive, and that it lacked consistency with current regulatory practice and international standards. The following preliminary inquiry into the provisions for nutritional composition proposed at full assessment addresses these concerns. This assessment should be read in conjunction with the Full Assessment Report published in 1995. Further copies of that report are available from the Authority. The Food and Drug Administration of the USA has recently released a report '*An assessment of nutrient requirements for infant formulas*' prepared by the Life Science Research Office (LSRO) for food regulatory purposes (1). This report based upon comprehensive literature reviews and specialist expertise, recommends nutrient requirements for infant formulas which serve as the sole source of nutrition. The report by the LSRO has been used as a major resource by the Authority in its inquiry into nutrient provisions for the joint ANZ standard for infant formula products.

1. GENERAL PROVISION FOR COMPOSITION

The way in which infant formula is defined in the ANZ standard will be a key factor in determining the need for specific prescription for the compositional aspects of infant formula in the standard.

The definitions in the current Codex standard and the current Standard R7 are as follows. (It should be noted that the current Codex standard was adopted in the 1980's. However, the proposed new Codex standard which has been at step 3 of the Codex process since 1995 incorporates the definitions in the current Codex standard.

Current provisions

Codex and draft Codex

Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.

AFSC Standard R7 (2)(a)

Infant formula is ... a product suitable for infant feeding prepared from milk of cows or other animals or other edible constituents of animal or plant origin or a mixture of all of them, save that infant formula described as 'suitable from birth' shall not contain cereal proteins. ...

Issue

The provision included in the current Codex standard and the proposed Codex standard provides for a wide range of base ingredients without the need for specific prescription. This provision is included in the current Australian Standard R7 but was omitted from the draft standard proposed at full assessment.

Assessment

Inclusion of a provision similar to the Codex requirement in the ANZ standard for infant formula will reduce the need for specific prescription of some food ingredients and thus simplify the standard. The intent of this clause is to permit the addition of other foods to infant formula where they can be demonstrated to be safe but to prohibit the addition of isolated or synthesised ingredients to infant formulas and follow-on formulas unless specifically permitted. A recent instance has highlighted the need for this provision. The intent of this clause has recently been questioned by some members of the infant formula industry and needs clarification in the light of the Authority's objective to promote fair trade. Therefore it is recommended that an interpretation clause be included in the standard to clarify the intent of the clause.

The rider, 'which have been proved to be suitable for infant feeding' in the Codex standards serves to limit ingredients to those to which there is scientific consensus about suitability for infant feeding. In some cases this will be evident, for example it is expected that anti nutritional or toxic components such as anti vitamins, goitrogens, trypsin inhibitors and lectins must not be present or must be deactivated before use in the food.

All foods are required to be fit for human consumption, however, the level of assessment or scientific consensus for 'novel' ingredients or novel sources of ingredients or ingredients not usually found in human milk is ill defined by this rider. Inclusion of the term 'suitable for infant feeding' means specific prohibitions on the use of particular food sources is generally not necessary in

the standard and it establishes that manufacturers must be able to demonstrate the safety or suitability of any ingredient they put into infant formula.

Without such a provision in the definition, it could be construed that any ingredient could be added to infant formula unless it had been demonstrated to be unsafe. Therefore inclusion of the following modified rider affords an additional measure of protection for the health and safety of infants. It is recommended the a definition similar to the following be included in the joint ANZ standard for infant formula:

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

It is also recommended that a process be established to assess the safety and suitability of potential new ingredients proposed for use in infant formula products marketed for infants in Australia and New Zealand. Such a process may assess the safety and suitability of novel ingredients, novel sources of ingredients or ingredients not usually found in human milk. Therefore it is recommended that the potential use of novel foods be regulated by the Proposed new standard for novel foods Standard A19- Novel foods and a prohibition on unsuitable novel foods be included in the standard.

Prohibition on gluten or cereal proteins

At full assessment justification was provided that infant formula should be 'gluten free' as there is evidence that dietary exposure to gluten early in life increases the risk of developing coeliac disease. Therefore it is recommended that to protect the health of infants in Australia and New Zealand, infant formula marketed as a principal source of nourishment to infants should be 'gluten free'. The Codex definition does not include a prohibition on gluten in infant formula . However, a prohibition on gluten content is consistent with the European Commission (EC) Directives for follow up formula and infant formula, where the carbohydrates included in infant formula must be free of gluten. Canada also requires infant formula to be 'gluten free'.

The prohibition on the use of cereal proteins in the current standard R7 was probably included to ensure that all formulas were gluten free. However, this broad prohibition is unnecessarily restrictive as the risk to infants of coeliac disease is minimised by the requirement for infant formula to be 'gluten free'. The term 'gluten free' is currently regulated by prohibitions in food law and also in fair trading law on false, misleading or deceptive representations about food and therefore needs no further regulation.

Submission was made for a method of analysis for gluten to be defined in the standard. However, the review of Australian and New Zealand food standards for gluten free foods is proposing that gluten free foods should have 'no

detectable gluten', regardless of which method of analysis is used. This requirement offers the highest level of protection for infants as it ensures the most advanced method of analysis should be used in determining the potential gluten content of infant formula. Therefore it is proposed not to include a method of analysis for gluten but to require infant formula not to contain 'any detectable gluten'.

RECOMMENDATION:

The following description based upon the Codex and draft Codex standards is recommended for inclusion in the joint ANZ standard for infant formula intended to be the principle source of nutrition for infants:

'Infant formula is a product based on milk or other edible constituents naturally derived from animal or plant origin, which have been demonstrated to be suitable for infant feeding and which is intended to be the principal source of nourishment for infants'.

It is also recommended a prohibition on gluten be included in the joint ANZ standard for infant formula .

2. SPECIAL PURPOSE FORMULAS

The removal of current Standard R7 clause 2(b) from the draft proposed at full assessment has caused concern with industry and health professionals. Clause 2(b) states that:

'infant formula may be specifically formulated to satisfy particular well recognised dietary requirements that are a result of a specific physical or physiological condition, disease or disorder, but in all other respects shall comply with this Standard. All deviations from the requirements of this Standard necessary to suit the condition, disease or disorder shall be declared on or attached to a package containing the food'.

There are some infants for whom breast feeding or standard milk- based formulas are unsuitable. Codex does not specifically provide for formula specialised for infants with special medical needs. In particular, Codex does not provide for specialised formulas which may be based solely upon amino acid mixtures. However, there are some infants who need such specialised formula. These 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.

It is recommended that a modified version of this current provision be included in the joint ANZ standard for infant formula to cover infants with highly specialised needs. It is therefore proposed to include the necessary permissions in the new standard, at least on an interim basis even though this will make the provisions of the standard more liberal than most international standards.

Use of the term, physiological

It is not considered appropriate to include the term 'physiological' within this provision. Loose interpretation of the current Standard R7 provisions has led to thickened formulas being marketed as anti-reflux formulas for general use.

Regurgitation after a feed is common in infants, including by those who are breastfed and is usually not serious. The recent general marketing of thickened formulas marketed as anti-reflux formulas is of concern as carers may be influenced to cease breastfeeding to use these formulas. Special purpose formulas, including thickened formulas are only recommended for infants for whom breastfeeding or milk-based formulas are not suitable. Usually special purpose formulas will be significantly more costly than 'standard' infant formula products which will 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. These formulas should not be fed to infants without prior medical advice and the current marketing situation is considered problematic by the Advisory Panel on the Marketing in Australia of Infant Formula.

The lack of clarity of Standard R7 in respect to reasons for which formulas may be modified has led to the marketing of thickened formulas. Therefore it is proposed not to provide specific permission for such modifications until evidence is presented to show that such formulas are not detrimental to breastfeeding rates in Australia and New Zealand. Therefore it is recommended that permissions for modifications to infant formulas be limited to those formulas prepared for infants with metabolic or immunological disorders.

Inclusion of the following provision similar to the previous Standard R7- clause 2(b) will provide temporary regulatory status and control for these special purpose infant formulas:

'Infant formula may be specifically formulated to satisfy particular metabolic or immunological conditions, but in all other respects shall comply with this Standard.'

The inclusion of this clause is intended to provide for formula for infants who are not able to tolerate human milk or the infant formula manufactured for healthy infants. All deviations from the requirements of this Standard necessary to suit the

condition, disease or disorder will be required to be declared in the label on or attached to a package containing the food.

Labelling requirements for these specialised formulas have been redrafted to reduce prescription and to increase the amount of information provided to carers about the specific use of the product and the products nutritional composition.

However, such formulas may be unsafe for infants who do not need the special modifications in the formula and it is not desirable that these special formula be freely available. Therefore an advisory statement alerting carers to use the formula only under medical supervision is recommended. Also a statement targeted to the carers of infants for whom the special modifications are inappropriate to advise that the product is not for general use.

3. PROTEIN CONTENT OF INFANT FORMULAS

2a) CALCULATION OF PROTEIN CONTENT

Issue

The calculation factors for protein determination which were proposed at full assessment did not cover all potential mammalian milks, and did not provide sufficiently for partial protein hydrolysates or specialised formula which may be based solely upon amino acid mixtures. Therefore the following factors which are consistent with the Codex factors are now recommended:

The protein content of an infant formula, must be calculated as follows:

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

Protein content = nitrogen content x 6.38

- (b) For all other cases

Protein content = amino acid nitrogen x 6.25.

The proportion of nitrogen from milk proteins and from other sources in mixtures of milk and other proteins must be determined in calculating the protein content.

Assessment

The current Codex standard, proposed Codex standard and most other international standards permit isolated amino acids to be added to infant formula for healthy infants, but only if they improve the nutritional value of the formula for infants. The permission to manufacture specialised formula for infants with special needs which may be based solely upon amino acid

mixtures is not provided for in the current or proposed Codex international standards or in most standards. However, there are some infants who need such specialised formula and therefore a calculation factor for these special purpose formulas is necessary..

The calculation of protein content from amino acid mixtures is dependent upon the quantity and profile of amino acids used in the special formula but can be estimated by $6.25 \times \text{amino acid nitrogen}$.

2b) PROTEIN QUALITY

Current Codex provisions and provisions proposed at Full assessment

Regulation	Provision relating to protein quality
Codex standards for Infant formula and Follow up Formula	The Codex standard requires the minimum quality of protein to be 85% that of casein and notes that the minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.
Proposed Codex standard for infant formula	For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together. [The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.]
Proposed at full assessment	The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein (breast milk, as defined in Annex 1). Must have an amino acid score of: at least 1.0 when the protein in the food is modified cows' milk protein or 0.8 in all other cases. (infant formula; and follow-on formula;) 0.8 - 1.2 (Proximate modified formula)

Issue

Submissions in response to the full assessment were generally supportive for the introduction of a measure of protein quality for infant formula. However submissions questioned the dual level approach in the draft standard.

Assessment

The interrelationship between protein content and protein quality is significant for infant health and safety. The lower the protein content of a formula the more important the quality of that protein becomes for infant health. If we took

an amino acid score of 1.0 (using breast milk as the reference protein) as is presupposed by Codex, most infant formula manufacturers would need to fortify their products with selected amino acids to achieve this amino acid score. However, if we set a slightly lower score but one that is achievable from the industry context and recommend slightly higher protein content, it will be better than the current R7 and the objective will be achievable by industry.

The LSRO has also recommended the assessment of protein quality be on the basis of an amino acid score with human milk as the reference protein and proposed minimum and maximum levels for each of the amino acids considered indispensable for humans.

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

Recommendation:

The clauses 21(b), 30(1)(b) and 39(1) in the draft standard should be amended to: 'must have a amino acid score of at least 0.8' .

Reference amino acid composition of human milk

A number of submissions questioned the valine level (5.5 mg/100g protein) which would be required by the provision in Schedule 1 of the standard for infant formula proposed at full assessment. The proposed Codex standard for infant formula was amended in September 1998 to include levels which are in agreement with that proposed at full assessment for infant formula, including that proposed for valine. However, the levels for amino acids in the Codex draft standard are expressed per 100 kJ (or per 100 kcal) rather than g/100g protein as in the draft standard. This proposed Codex methodology creates inconsistencies and inaccuracies since variations in the fat and carbohydrate content of the formula would affect the energy value and consequently the calculation for protein quality. Therefore it is proposed to retain the references to the amino acid composition of milk at g/100g protein in the joint ANZ standard for infant formula at Appendix 1 to the standard proposed at full assessment .

2c) PROTEIN CONTENTS

Current provisions and proposed provisions

	infant formula g/100 kJ	follow-on formula g/100 kJ	pre-term formula g/100 kJ	proximate modified formula g/100 kJ
current R7	0.45 - 0.7	as for infant formula	not applicable	not applicable
Codex	0.45 - 0.7	0.7-1.3	not applicable	not applicable
proposed Codex	0.45 - 0.7	not applicable	not applicable	not applicable
proposed at full assessment	0.45 - 0.7	0.7 - 1.0	<u>for < 1kg weight</u> 0.72 - 0.76 <u>for > or = 1kg weight</u> 0.6 - 0.72	0.45 -1.4
LSRO recommendations	0.4 'true protein' - 0.8 'total protein'	as for infant formula	not applicable	not applicable
proposed at preliminary inquiry	0.45 -0.7	0.45- 1.3	0.6-0.76	0.45-1.4 may be in the form of protein equivalents

There was general support in submissions for the protein concentrations proposed at full assessment for infant formula. However, some issues were raised about the levels proposed for follow-on formula, pre-term formula and proximate modified formula.

Issues

Follow-on formula

The maximum protein content proposed at full assessment for follow-on formula is more restrictive than the Codex standard for maximum protein content.

Pre-term formula

Submissions asserted that the range for the protein content proposed for pre-term formula was too narrow and difficult for compliance, particularly for formula for infants under 1kg weight.

Proximate modified formula

There is no Codex standard for these formulae. Submissions noted these formulae could fit within the general standards for infant formula and no major issues were raised concerning the broader range for protein content.

Assessment

Protein content and protein quality are interrelated in determining the biological use of a food protein source. The protein content of an infant formula contributes to the load on the infants kidneys.

The LSRO noted reports of the protein content of human milk declining over the course of six months of lactation from approximately 1.4 to 0.83 g/100 mL and considered concerns that the minimum protein requirements for infant formulas are too high when considered against the levels breast fed infants receive. The LSRO also provided for the contribution from non-protein nitrogen included in a protein to the biological value of a protein defined and minimum protein requirements in terms of 'true protein'.

Where 'true protein' (g) is $[\text{alpha amino acid nitrogen (g)} \times 6.25]$. The LSRO recommended infant formulas contain a minimum 'true protein' content of 0.4g/100 kJ signalling the importance of considering only those protein sources that are the main sources of nitrogen for tissue deposition and growth as the inclusion of non protein nitrogen sources in the specifications for minimum protein content could result in formulas with inadequate protein for growth. It is recommended that the minimum protein level proposed at full assessment be included in the joint ANZ Standard for infant formula as it is consistent with international regulations and is higher than the minimum level recommended by the LSRO. The maximum protein content recommended for infant formulas by the LSRO is 0.8 g/100 kJ of crude or total protein. True protein was not specified for the maximum requirement as protein from all forms affects the Renal Solute Load (RSL).

Follow-on formula

The maximum level for protein proposed at full assessment for follow-on formula is consistent with that in the EC Directive for follow-on formula but lower than and more restrictive than in the Codex standard for follow-on formula.

As the protein content of an infant formula contributes to the load on the infants kidneys. Any consideration to increase the maximum protein content to that set in the Codex standard should be conditional upon inclusion of a prescribed Potential RSL (PRSL) value to protect infants from high renal solutes loads which may place the infants at risk of kidney damage.

Pre-term formula

There is no Codex standard for preterm infants.

The sole difference between the regulation for pre-term formula for the two weight categories is the variation in proposed protein contents. Preterm infants would be under the care of specialist medical officers who would regularly evaluate the appropriateness of the food by monitoring the infant's weight change and other parameters. Therefore, preterm infants would not be likely to be placed at risk by rationalising the two levels of protein as medical attendants would be monitoring the infants growth rate.

Proximate modified formula

The protein content of these formula is occasionally higher than that proposed for infant formula for healthy infants. Infants who consume these formulas are expected to be under medical supervision and potential risks for the higher protein intake can be monitored and symptoms treated. Therefore it is recommended that the levels proposed at full assessment be included in the joint standard for infant formula.

Recommendation

The protein levels proposed at full assessment be included in the joint ANZ standards for infant formula however, the maximum permitted protein content for follow-on formula should be increased to 1.3 g/100 kJ provided the PRSL of the formula is regulated to protect infants from the risk of kidney damage and the protein content of pre-term formula be set at 0.60 - 0.76 g/ 100 kJ.

2d) SOURCE OF PROTEIN

Current provisions and proposed provisions

	protein must be one or more of:
Codex infant formula and follow-on formula	regulated in a general way by the essential definition clause
Current R7	regulated in a general way by an essential definition clause
proposed at full assessment for Infant formula and follow-on formula	unmodified cows' milk protein; modified cows' milk protein; unmodified goats' milk protein; soy protein isolate.
proposed at full assessment for pre-term formula (for < 1kg weight and for > or = 1kg weight)	unmodified cows' milk protein; modified cows' milk protein; unmodified goats' milk protein; and must have an amino acid score of at least 1.0 when the protein in the food is modified cows' milk protein; or 0.8 in all other cases.
proposed at full assessment for proximate modified formula	unmodified cows' milk protein, or modified cows' milk protein; or must be a protein substitute; and must have an amino acid score between 0.8 and 1.2.
proposed at preliminary inquiry	regulated in a general way by an essential definition clause

Issues

At full assessment specific protein sources were nominated for the different infant formula types. As shown in the table above the proposed sources were not consistent for the infant formula varieties. The specification of protein source for the infant formula varieties proposed at full assessment is more restrictive than Codex and the draft Codex standard and would constitute a technical barrier to trade unless it was necessary to protect public health and safety.

Draft Codex

Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

Draft R7

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

Assessment

It is proposed to regulate the protein content and the protein quality of infant formula to protect Australian and New Zealand infants, therefore specification of protein source may be unnecessarily restrictive. Lack of regulation of protein source may however create confusion for carers unless there is an indication on the label of the food as to the protein source. Codex standards for infant formula and follow up formula require a declaration of the source of protein or proteins on the food label. Therefore it is recommended that a statement of the source of protein be included on the label of the food. This requirement is consistent with that required by Codex. However, the Codex standard for follow up formula specifies the location of this declaration as 'in close proximity to name of the food'. The ANZFA external team was of the opinion that this declaration should be immediately adjacent to the name of the food to clarify the true nature of the food. Therefore, it is recommended the statement of the source of protein be included on the label of the formula 'in immediately adjacent to the name of the food'.

3. FAT CONTENT OF INFANT FORMULAS

Many submissions commented on the proposed provisions for the fat content of infant formula.

3a) LACK OF HARMONISATION

Issue

Submissions noted variations between the levels proposed at full assessment and levels recommended by other international agencies.

At full assessment minimum and maximum levels were proposed for most of the fatty acids present in infant formulae. These are generally opposed by industry as being 'too tight'. In addition industry warns of the consequences to the physical state of the product of changes in the proportion of saturated fat to polyunsaturated fat. However, one industry submission agrees with the concept Panel but argues that different figures should be used to harmonise with the EC.

Assessment

The provisions proposed at full assessment for the fat content of infant formula are more prescriptive and restrictive than the Codex standard. It was proposed to regulate total fat content, limit total saturated fat and specifically lauric, myristic and $> C=18$ fatty acids, require a monounsaturated, linoleic and alpha - linolenic acid content (ALA) and permit omega 3 and omega 6 series fatty acids. The current Codex standards for infant formula and follow up formula only regulate total fat and require a linoleic acid content.

There is international recognition that the current Codex standard is not completely in line with current scientific knowledge about the nutritional needs of infants. This is reflected in the draft standard currently being considered by Codex which considers the introduction of an ALA fatty acid content, the linoleic acid / ALA ratio, and limits on erucic and *trans*- fatty acid contents. However, as mentioned earlier, this draft standard has remained at step 3 of the Codex process for several years as agreement on its content has not been able to be reached. The individual fats proposed for regulation at full assessment are reassessed in the context of current review policy and international provisions and regulations considered necessary to protect the health and safety of infants are recommended for inclusion in the joint ANZ standard.

3b) TOTAL FAT CONTENT

Current provisions and proposed provisions

	Infant formula g/100 kJ	Follow-on formula g/100 kJ
current R7	0.8-1.5	as per infant formula
proposed at Full Assessment	1.1-1.4 (pre-term formula: 1.1-1.4) (proximate modified formula: 0.93-1.4)	0.9-1.4
Codex	0.8-1.5	0.7-1.4
proposed Codex standard	1.05-1.5	Not applicable
LSRO recommendations	1.05-1.52	as per infant formula

proposed at Preliminary Inquiry	1.05-1.5 (pre-term formula: 1.05-1.5) (proximate modified formula: 0.93-1.5)	1.05 -1.5
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Issues

The level of fat proposed for infant formula at full assessment is not consistent with levels in international regulations.

Assessment

A fat intake 30-55% of total energy is noted in the LSRO report to produce appropriate growth rates in infants. The LSRO stated that higher or lower levels of fat are generally regarded as physiologically inappropriate for infants. Therefore the LSRO recommended that the fat content of infant formula should be within the range 1.05-1.52 g/100 kJ or 40-57% of total energy. The minimum at 40% of energy in infant formula provides for the overall reduction in percentage energy from fat in the infant diet due to the energy contribution of weaning foods (fruits, vegetables and cereals) which are generally not high in fat. This recommendation aligns with the levels in the EC directive, the levels being considered for the revised Codex standard and is similar to that recommended by the Expert Panel. There is no known health or safety contraindication to widening the range for fat to 1.05 g/100 kJ to 1.5 g/100 kJ to harmonise with the international standards and government recommendations for infant health.

Follow-on formula is intended to be suitable as the principal source of nutrition for older infants. The New Zealand government recommends the fat content of the diet of older infants should not fall below 35% of the energy as fat ² and the NHMRC in Australia recommends older infants consume approximately 40% of the energy as fat ³. The Codex follow up formula standard was prepared more than 10 years ago and specifies a minimum fat content for follow up formula of 0.7 gm/100kJ which is approximately 26% of the energy content. This Codex minimum level is not consistent with the recommendations for fat intakes of Australian and New Zealand infants. Weaning foods may not contribute sufficient fat content for the older infants needs. Therefore it is recommended that the minimum fat content of follow-on formula be aligned with the minimum level for infant formula.

Formulated infant formula for metabolic and immunological conditions

The fat content of these formula is occasionally lower than that proposed for infant formula for healthy infants. Infants who consume these formulas are expected to be under medical supervision and any adverse symptoms can be monitored and treated. Therefore it is recommended that the levels proposed at full assessment be included in the joint standard for infant formula.

Recommendation:

The minimum level of fat required for all infant formula except for special purpose formulas should be lowered to 1.05 g/100 kJ and the maximum level of fat permitted for all infant formula be increased to 1.5 mg/100 kJ. The minimum fat content proposed at full assessment for special purpose formulas is recommended to be included in the joint ANZ standard

3c) ESSENTIAL FATTY ACID CONTENT

Ratio of linoleic to linolenic acid

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	not specified	as per infant formula
proposed at Full Assessment	4:1-10:1	as per infant formula
Codex	not specified	not specified
proposed Codex standard; UK and EC	5:1-15:1	Not applicable
LSRO recommendations	6:1-16:1	as per infant formula
proposed at Preliminary Inquiry	5:1-15:1	as per infant formula

Issue

Industry argued against the tightening of the tolerance for the ratio of linoleic to ALA and in favour of the ratio used in the EC which is 5:1-15:1.

Assessment

The LSRO noted that the metabolic pathways for linoleic and ALA appear to use some enzymes in common and that therefore the ratio between the two sets of fatty acids is important in determining the metabolic outcomes of these fatty acids. Studies were reported which showed formula with ratios in excess of 16:1 resulted in lower docosahexanoic acid (DHA) and higher 22:5 omega-6 fatty acid concentrations in tissues, and that formula with very high ratios resulted in reduction in red blood cell membrane levels of DHA. However, the LSRO concluded that at this stage a clear understanding of all potential interactions of the omega-3 and omega-6 fatty acid precursors and end products is not possible. The LSRO stipulated the ratio of linoleic acid to ALA be 6:1-16:1 to ensure there is no interference with production of either of the longer chain fats of the omega-3 and omega-6 fatty acid series.

It was proposed at full assessment that the linoleic acid to ALA range of 4:1 to 10:1. The Expert Panel has considered this ratio in response to submissions and recommended that this be changed to 4:1 to 15:1. However to harmonise with the ratio in the EC directives, that recommended by the European Society of Paediatric Gastroenterology and Nutrition, Committee on Nutrition (ESPGAN) and that being considered by Codex for the revised infant formula standard it is recommended that the ratio 5:1-15:1 be included in the joint ANZ infant formula standard. There are no known health or safety implications of adopting this range.

Linoleic acid (as glycerides)

Current provisions and proposed provisions

	Infant formula	Follow-on formula
current R7	>or = 70 mg/100 kJ	as per infant formula
proposed at Full Assessment	8-20 % total fatty acids	as per infant formula
Codex	>or = 70 mg/100 kJ	>or = 70 mg/100 kJ
proposed Codex standard	70 - 285 mg/100 kJ	Not applicable
LSRO recommendations	8-35 % total fatty acids	as per infant formula
proposed at Preliminary Inquiry	9-26% total fatty acids	as per infant formula

Assessment

Human milk typically provides 8-17% total fatty acids as linoleic acid. Linoleic acid is essential as mammalian cells cannot synthesis this fat and the level of linoleic acid together with ALA is a key determinant of arachadonic acid synthesis.

The LSRO recommended a minimum linoleic acid content of 8% of total fatty acids (approx 85 mg/100 kJ) as although human milk contents of linoleic acid vary widely, values are rarely below this level. The LSRO notes formulas based upon corn oil have historically contained linoleic acid levels well in excess of 35% fatty acids without adverse effects to infants. However, the LSRO recommended that the maximum linoleic acid content not exceed 35% of total fatty acids (approx 535 mg/100 kJ) as this is within the limits reported for human milk.

Codex currently only specifies a minimum linoleic acid content but is considering including a maximum level based upon the level in human milk for the proposed revised infant formula standard. The proposed Codex maximum aligns with the maximum linoleic acid content (285 mg/100 kJ or approx 19% of total fat) included in EC and UK regulations and also that proposed for the infant formula standard at full assessment. The Expert Panel considered there should be no change to the level of linoleic acid proposed for inclusion in the joint ANZ standard. The Codex minimum linoleic acid content is 70 mg/100 kJ which aligns with the Code of Federal Regulations (CFR) and the EC however, Canada and ESPGAN recommend a minimum of 500 mg/100 kcal (119 mg/100 kJ). The LSRO claimed currently marketed infant formula rarely have levels below 8% or 85 mg/100 kJ. It is recommended that the minimum linoleic acid content of infant formula be 9% total fatty acids and the maximum linoleic acid content be 26% total fatty acids to accommodate the increased minimum and maximum for the linoleic: ALA ratio of 5:1 - 15:1.

These levels align internationally for the minimum and are more liberal for the maximum and meet the current market levels according to the assessment by the LSRO.

Alpha- Linolenic acid (ALA)

Current provisions and proposed provisions

	Infant formula	Follow-on formula
current R7	not specified	as per infant formula
proposed at Full Assessment	2 - 4 % total fatty acids	as per infant formula
Codex	not specified	not specified
proposed Codex standard	>or = 12 mg/100 kJ	Not applicable
LSRO recommendations	1.75 - 4.0 % total fatty acids	as per infant formula
proposed at Preliminary Inquiry	1.75 - 4.0 % total fatty acids	as per infant formula

Issue

The levels of ALA proposed at full assessment are not consistent with the revised ratio of linoleic to ALA.

Assessment

The LSRO noted human milk typically provides 0.5-1.0 % total fatty acids as ALA with varying contents of other PUFA. Studies reviewed by the LSRO showed an intake of ALA less than 0.5% of the total energy resulted in infants becoming deficient in long chain polyunsaturated fatty acids (LCPUFA) of the omega 3 series, particularly docosahexanoic acid (DHA) despite adequate intakes of linoleic acid. ALA is a precursor for the omega 3 LCPUFA, particularly DHA. This report also noted studies suggested formula with ALA contents less than 0.7% of energy may be associated with delayed development of visual function and possibly lower levels of DHA in the brain. The LSRO noted the essentiality of ALA and recommended an ALA content of 1.75% total fatty acids (18 mg /100 kJ) to 4% (61 mg /100 kJ) and further stipulated the ratio of linoleic acid to ALA be 6:1-16:1.

The minimum ALA content of 2% of fatty acids proposed at full assessment has an additional margin of safety over that recommended by the LSRO. However, the minimum ALA currently being proposed for the revised Codex standard is much lower at 12 mg/100 kJ; aligning with the EC directive level.

It was proposed at full assessment that ALA be 2-4% of the total fatty acids which is a higher content than the EC although close to that recommended by the LSRO. The LSRO claimed that studies suggest that formula providing ALA below 1.75% (18 mg/100 kJ) may be associated with delayed development of visual function and possibly lower levels of DHA in the brain, therefore a level below this is not justified and is not in the interests of the health of infants who rely on the formula. It is recommended that the minimum ALA content be that recommended by the LSRO as this recommendation is more recent than the Expert Panel recommendation. Therefore it is recommended that the minimum ALA content of infant formula be 1.7% of total fatty acids. The maximum ALA proposed at full assessment is the level proposed by the LSRO and is recommended to be included in the joint ANZ standard for infant

formula.

3d) LONG CHAIN POLYUNSATURATED FATTY ACIDS (LCPUFA)

Issues

It was proposed at full assessment to permit the addition of LCPUFAs of both series 6 and series 3 types to infant formulas. Additionally it was proposed to regulate the maximum content of the series 3 and series 6 fatty acids and the maximum content of three specific individual LCPUFAs in infant formulas ie arachidonic acid, DHA and EPA. The EC and UK standards are the only known international standards which currently permit the use of LCPUFA's in infant formulas. These directives regulate the maximum level of two of three series of LCPUFAs and arachidonic acid and also specify that the EPA content should not be more than the DHA content. They do not give specific permissions for specific sources of LCPUFAs.

Assessment

LCPUFA's (20-22 carbon atoms) are fats metabolised from the essential fatty acids (linoleic and ALA) and include DHA, eicosapentanoic acid (EPA) and arachidonic acid (refer diagram below).

Metabolic pathways for LCPUFA

omega 6 series PUFA:

LINOLEIC ACID --> gamma linolenic acid --> **arachidonic acid** --> --> --> --> omega 6 C22:5

omega 3 series PUFA:

ALA --> --> **EPA** --> --> --> --> **DHA**

Conclusions of recent major assessments of the use of LCPUFAs in infant formulas

In 1991 the ESPGAN committee on nutrition suggested LCPUFAs may be useful in infant formulas.

The LSRO reviewed studies of infant growth and neurodevelopment and was unable to conclude that the addition of LCPUFA to infant formula with adequate linoleic and ALA was beneficial. The LSRO did not recommend the addition of either arachadonic acid or docosahexanoic acid (DHA) to infant formula due to concerns that the metabolic and nutritional effects have not yet been adequately addressed.

Health Canada, in its assessment of the potential benefits of LCPUFA inclusion in infant formulas for preterm infants, concluded current evidence does not support a nutritional requirement for these fatty acids and in particular that oils containing EPA are not suitable for inclusion in infant formulas.

Forsyth 1998 has also reviewed infant formula lipid, in particular LCPUFA issues. He notes the EC directives have permitted the addition of LCPUFAs to infant formulas "despite the current paucity of information on clinical benefit. Moreover there are currently no accepted specifications on quality and quantity of an optimum LCPUFA supplement. The safety of LCPUFA supplementation has not been properly evaluated". Forsyth notes there are published studies which have reported potentially hazardous complications from LCPUFA supplementation.

Subsequent to the publication of the full assessment report, the Authority's Expert Panel reconsidered the maximum level of arachidonic acid and decided this should be raised from 0.5% to 1% and a maximum level of 3:1 should be introduced for DHA/EPA. The Expert Panel also considered that the maximum for long chain omega - 3 series fatty acids should be lowered from 2% to 1% total fatty acids.

Other major regulations:

Codex, the CFR and Canada do not make specific provision for LCPUFAs in the standards for infant formula and there is currently no consideration of their inclusion in the revised Codex infant formula standard. However, the EC and the UK make provision for these fatty acids as optional ingredients but limit the maximum content to 1%, 2% and 1% of total fat for omega -3 fatty acids, omega-6 fatty acids and arachidonic acid respectively. These standards also stipulate that EPA content should not exceed the DHA content.

Reconsideration

Both arachidonic acid and DHA are found in human milk at levels much higher than EPA which is consistently very low (Jensen). Arachidonic acid and DHA are known to be essential for normal growth and development. There is evidence that EPA interferes with arachidonic acid metabolism (Innes in Tsang). Forsyth reports the series 6 to series 3 LCPUFA ratio in human milk is relatively constant at 2.

The general compositional permissions for infant formulas permit the use of other foods. The Authority believes the LCPUFA content of infant formulas (likely to be preterm) currently marketed in Australia and New Zealand with LCPUFAs is sourced from edible oils (egg lipid, blackcurrant seed oil, fish oil) rather than from purified fatty acids.

Options

Option 1

Do not provide express permission

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

express permission would leave the LCPUFAs content regulated by the general permissions for the addition of other foods, the safety assessment of novel foods or ingredients from novel foods and the due care of manufacturers.

Levels could be included in the guideline proposed to be provide with the 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 in infants. However, there is also evidence to suggest that different LCPUFAs of the 3-, 6-, and 9- series may interfere with each others metabolisms to varying extents. Therefore it is proposed as at full assessment to given a broad permission for a LCPUFA content similar to that found in human milk, sourced from food ingredients (subject to the novel food standard requirements) rather than individual fatty acids and control the maximum levels as per the EC and UK since these are currently in force.

Option 3

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.

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.

The provisions proposed at Full Assessment were more liberal than the Codex standards in permitting specific LCPUFA's as optional ingredients. However, they constituted a barrier to trade to formula manufactured to EC standards. The provisions now proposed are still more liberal that Codex and do not constitute a barrier to trade unless non approved novel foods or ingredients from novel sources are used.

Although, there is no consensus of the public health benefit for these provisions, it is agreed that the permissions for arachidonic acid and LCPUFAs in the joint ANZ food standard align with those currently in use in the EC except that the ratio of series 6 to series 3 LCPUFAs should be equivalent to that in human milk.

3e) SATURATED FATTY ACIDS AND *CIS*-MONOUNSATURATED FATTY ACIDS

Total saturated fat content and *cis*- monounsaturated fat content

Issues

It was proposed at full assessment to limit total saturated fatty acids to a maximum of 50% total fatty acids. No other agency expressly regulates the total saturated fatty acid content of infant formula.

It was also proposed at full assessment to require a *cis*-monounsaturated fatty acid content of 30 to 60% total fatty acids. The requirement to include a *cis*-monounsaturated fatty acid content is currently not proposed in the draft Codex standard and could be regarded as a restraint of trade because it includes a minimum level which must be present.

Assessment

There are no international regulations which expressly control the total saturated fatty acid or *cis*-monounsaturated fatty acid content of infant formula. Therefore the limitation on saturated fatty acids and the requirement for *cis*-monounsaturated fatty acids as proposed in the draft are more restrictive than Codex and constitute a barrier to trade. The health and safety of infants is protected by the regulation of total fat content and the requirement for the essential fatty acid content. Therefore it is not proposed to retain these restrictions in the joint ANZ infant formula standard.

Lauric acid and Myristic acid

Issue

The lauric acid and myristic acid content of infant formula was proposed to be restricted at full assessment but Codex does not propose to restrict these fats in infant formula.

Assessment

The LSRO noted myristic acid is present to levels of approximately 8% of the total fatty acids of human milk. However there is no known nutritional role for myristic acid. The LSRO did not make any recommendations for lauric acid. The EC limits the maximum lauric and myristic acid content to 15% of the total fatty acids but Codex has recently removed the proposed restriction on lauric and myristic acid contents from its proposed infant formula standard.

The LSRO in noting the lack of known role for myristic acid recommended this not be added to infant formula. Myristic acid content of infant formula will be that which results from the ingredients used to manufacture the formula. The regulation for lauric and myristic acid does not appear warranted if no express permission is granted for addition of these two substances to infant formula.

Therefore, it is recommended no regulation be included in the joint ANZ standard for infant formula.

Erucic acid

Issue

The EC limits the erucic acid content of infant formula to not more than 1% of the total fat content and Codex is considering limiting the erucic acid content of infant formula to not more than 1% of the total fat content in the revised standard. No limit on erucic acid was included in the proposed revised infant formula standard.

Assessment

Erucic acid is unsafe causing fatty infiltration of the heart muscle. Erucic acid in some seed varieties can be the major fat type in the seed oil. With the potential liberalising of permissions for use of other foods in infant formula, it may be prudent to include a regulation on the erucic acid content and align with the EC provision.

It is recommended that the maximum erucic acid content be limited to not more than 1% of the total fat content.

3f) *Trans- Fatty Acids*

Current provisions and proposed provisions

	Infant formula % total fatty acids	Follow-on formula % total fatty acids
current R7	not specified	as per infant formula
proposed at Full Assessment	8 (including 6 for <i>trans</i> -monounsaturated fatty acids)	as per infant formula
Codex	not specified	not specified
proposed Codex standard	4	Not applicable
LSRO recommendations	level not specified but recommended that hydrogenated oils representing the major source of <i>trans</i> - fatty acids not be used in the manufacture of infant formula	as per infant formula
proposed at Preliminary Inquiry	4	as per infant formula

Issues

Submission was received to increase the proposed maximum level of *trans*-fatty acids to 12-15%. Submission was also received that *trans*- fatty acids should be counted as saturates.

Assessment

Trans- fatty acids originate primarily from hydrogenation of unsaturated vegetable oils during processing but small amounts are present in animal fats. *Trans*-fatty acids may inhibit the metabolism of PUFA and cholesterol in infants. The LSRO reports *trans*- fatty acids found in infant formula are derived from the use of partially hydrogenated vegetable oils in the formula or are formed during the formula manufacturing process. The LSRO reports *trans*-fatty acids in human milk are sourced from the maternal diet and levels of 4.4% of the fatty acids are reported in USA human milk samples and 4.8% of the fatty acids in German human milk samples. The contribution to the total fatty acid content of *trans*- fatty acids is approx 1% in milk from women consuming non-Western diets (Jensen et al).

The LSRO reviewed reports of analyses of *trans*- fatty acid content of formula prepared in Europe and reported these ranged from 0.2% to 4.6% of the total fat content.

The LSRO noted there was no known nutritional function and many adverse actions attributed to *trans*- fatty acids. The EC restricts *trans*- fatty acids to 4% of the total fatty acids in infant formula and Codex has included this restriction in the new draft infant formula standard currently under consideration. The current Codex standards for infant formula and follow up formula do not refer to *trans*- fatty acids. The LSRO recommended that due to the potential long term and short term harmful effects of *trans*- fatty acids and the absence of any nutritional benefit from them that hydrogenated oils not be used in infant formula as these oils are the major source of *trans*- fatty acids.

It was proposed at full assessment to limit *trans*- fats to a maximum of 8% total fatty acids, of which 6% were permitted to be *trans*- monounsaturated fatty acids. The proposed permission is higher than levels reported for human milk and higher than that in the EC directives for infant formula and follow up formula (maximum 4%). It does not appear to be in the interests of infants to increase the maximum permission for *trans*- fatty acids and it would appear prudent to align with the EC and limit the maximum permission to 4% of the total fatty acids.

3g) MEDIUM CHAIN TRIGLYCERIDES (MCT'S)

Issues

The proposed definition of 'fat modified' as meaning that the food contains medium chain triglycerides (MCT's) has been challenged by industry. Many say that the definition should be deleted. Similarly industry required clarification in relation to the definition of MCT's.

Submission was received that coconut oil should be prohibited from being used as an ingredient in infant formula.

At Full Assessment it was proposed to prohibit MCTs in formulas for healthy infants and for preterm 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 provision would disadvantage preterm infants and manufacturers.

Assessment

MCTs are defined as by Francis as 'triglycerides containing fatty acids with 8-10 carbon atoms'. Health Canada defines MCTs as 'semi-synthetic triglycerides which contain predominantly the saturated fatty acids 8:0 and 10:0'. Coconut oil which is used to prepare MCT oil contains fatty acids from C6:0 - C12:0.

The LSRO reported from Jensen (1996) that 8-10% of the fatty acids in human milk are medium chain fatty acids. However, the MCT content of human milk is much lower, reported at less than 2%.

The LSRO noted the main metabolic pathway for MCTs in infants is catabolism to acetyl CoA. Therefore there is a potential concern for high intakes of MCTs as the concentration of serum ketones and the excretion of carboxylic acids increases linearly. The LSRO also notes whilst impaired function has not been shown in infants, there are reports of alterations of tissue prostaglandin synthesis in adults who consumed MCT oils.

The LSRO found no justification for the addition of MCTs to formula for term infants but excepted certain special dietary formulae from this decision. The LSRO did not make a recommendation about the MCT content of pre-term formulas. No other agencies have regulated the minimum or maximum MCT contents of infant formula. At full assessment it was proposed to prohibit MCT content. The Expert Panel reconsidered the prohibition on MCTs and recommended permission given for them to be present to a maximum of 10% of total fatty acids in infant formula including those prepared for preterm infants.

The EP considered medium chain triglycerides should be defined in the standard as 'fatty acids with less than 12 carbon atoms'. However, dairy fats with chain length of less than 12 carbon atoms would also be defined as MCTs under this definition. Therefore, it is recommended that no provision be made for MCT oil use as an ingredient in the manufacture of infant formula for healthy infants, but that a permission be provided for the MCT carry over from milk based ingredients.

Special purpose infant formula prepared for infants suffering malabsorption or liver disorders may require a higher than usual MCT content. Therefore express permission is required for MCT's to be added to some formulas manufactured for infants with special dietary needs. It is recommended permission be granted for the use of added MCT oils in formulated infant

formula for metabolic, immunological and other conditions. The levels of added MCT will be constrained by the need to provide sufficient essential fatty acids for the needs of the infants.

Pre-term formulas

At FA it was proposed to prohibit MCTs in formulas for healthy infants and for preterm infants.

The rationale stated in the FA Report for this decision was:

- *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 provision would disadvantage preterm infants.

Consideration

Historically, MCT's have been added to pre-term formula to improve the digestion and absorption of formulas for these very small infants with immature physiological mechanisms, particularly fat absorption. The LSRO noted some pre-term formula supply 50% of the total fat as fatty acids containing no more than 12 carbons (MCTs) but did not make a recommendation on the level of MCT in pre-term formulas.

Health Canada noted clinical studies have not confirmed a benefit for MCTs. Health Canada concluded that 'the inclusion of high amounts of MCT in formulas does not seem desirable since there appears to be no benefit to energy balance or growth and there is clear evidence on abnormal fatty acid metabolism'. However, Health Canada also noted there was no convincing data to contradict MCT inclusion in formulas'.

It is believed that many manufacturers are reducing the MCT content of pre-term formulas although still believing there are reasons for a significant MCT content. A prohibition on a MCT content of these products may disadvantage preterm infants as some of these formulas may become unavailable in the short term. The Authority requires assistance in resolving the requirements for MCT content of pre-term formulas.

Therefore, submission is sought from industry, in particular about:

- (i) the current MCT content in formulas, particularly pre-term formulas; and
- (ii) evidence to show MCT 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 preterm infants.

3h) SOURCE OF FATTY ACIDS

Prohibitions on specific sources of fat

Prohibitions on sesame, cottonseed, peanut and coconut oil

Issue

The prohibition on sesame and cottonseed oil in the draft R7 is not consistent with Codex and draft Codex and may constitute a barrier to trade. No submissions addressed this provision. However, submission was received that coconut and peanut oils should be prohibited from being used as an ingredient in infant formula. Coconut because of its saturated fatty acid content and peanut because of its high allergenicity.

Fungal and algal sources of fatty acids

Issue

The Expert Panel considered the DHA and AA must originate from normal sources such as edible oils not fungal or algal oils or the like.

Assessment

There is no Codex provision which expressly prohibits the use of a particular source of fatty acid in the manufacture of infant formula. It may be possible to source DHA from algal sources if purity can be assured. It is recommended that novel foods or novel sources of food ingredients be assessed as safe before being used in infant formulas available for infants in Australia or New Zealand. Ingredients which are not safe for infants are to be excluded by virtue of the proposed rider to the general provision for essential composition clause 'suitable for infant feeding'. Therefore specific prohibitions are not currently proposed for the standard. The review of specific labelling statements has considered substances which are likely to be responsible for adverse reactions and determined these substances should always be declared on the label of a food if present in the food. Sesame and peanut are both proposed to be required to be declared on the label of a food. Label information of sesame or peanut content will enable carers or their advisers to determine whether it is advisable for an infant at risk to consume a formula which contains either of these ingredients. Many proteins including milk proteins are considered highly

allergenic but no prohibition is proposed for these proteins for infant formula for healthy infants. Therefore it is not consistent to prohibit sesame or peanut oils on this basis.

The prohibition on the use of coconut oil is also not warranted as the issue of excessive saturated fatty acids are countermanded by the requirements for essential fatty acids and limitations on MCT and *trans*- fatty acids. Introduction of a prohibition on coconut oil would constitute a trade barrier and be counter to the WTO obligations of Australia and New Zealand.

The LSRO examined the toxicology of micro algal and fungal sources of LCPUFAs in its review. The LSRO reported that safety concerns have been raised in regard to the production of toxins from the micro algae, *Cryptosporidium parvum*. However, the *in vitro* and animal toxicology studies of micro algal sources did not reveal toxic effects and after 3 month subchronic studies a NOAEL was established at 1.25 g/kg/d by the commercial laboratory.

The safety studies of fungal sources of LCPUFAs using *in vitro* and animal studies did not reveal toxic effects and after 3 month subchronic studies a NOAEL was established at 2.5g/kg/d by the commercial laboratory. The LSRO notes micro algal and fungal sources of DHA and AA have been approved for use in infant formula in some European Communities. However, 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.

CONCLUSION

As regulations for infant formula have evolved there has been an increase in the level of regulation of the types and amounts of fatty acids in the total fat content. Some aspects of this control seem to have gone further in the provisions proposed at full assessment than in comparable sets of regulations. It is therefore, recommended that to protect the health of infants who consume infant formula, the fat content of infant formula be regulated as follows:

- total fat content of infant formula be 1.05-1.5 g/100 kJ;
- essential fatty acids be required with the linoleic acid content to be 9-26% of the total fatty acids and the ALA content to be 1.75- 4 % of the total fatty acids;
- the linoleic to ALA ratio to be 5:1-15:1;
- the *trans*-fatty acid content be limited to 4% of the total fatty acids;
- MCT oil not be used for infant formula for health infants;

- the erucic acid content be limited to 1% of the total fatty acids;
- LCPUFAs be permitted but limited to 2%, 1%, and 1% of total fatty acids content for omega 6 series, omega 3 series and arachidonic acid respectively and if LCPUFAs are added to formulas the ratio of total omega 6 series to total omega 3 series should be 2 as in human milk and the EPA content should not exceed the DHA content; and
- novel sources of fatty acids for formulas be assessed as safe and suitable for infants before use in formulas in Australia or New Zealand.

4. CARBOHYDRATE CONTENT OF INFANT FORMULAS

The draft proposed at full assessment is more prescriptive and restrictive than the Codex standards for the types of carbohydrates permitted in infant formula. At full assessment it was proposed that the carbohydrate content of infant formula be at least 80% lactose. This requirement excluded formula based upon soya bean. Additionally the permitted sources of carbohydrate were not consistent from one formula type to another in the proposed standard.

4a) LEVEL OF CARBOHYDRATE

The Codex Standards for infant formula 72-1981 and follow up formula 156-1987 (amend 1989) do not prescribe a specific carbohydrate level for infant formula although the standard for follow up formula specifies that the carbohydrate should be nutritionally available and permits the carbohydrate content to be determined by the requirement to meet the energy requirement for the formula. The EC directive regulations include a carbohydrate range of 1.7-3.4 mg/100 kJ and this level is proposed by Codex for the revised infant formula standard. The range of carbohydrate proposed at full assessment is 1.7 - 3.4g/100 kJ which is consistent with that of the proposed revised Codex Standard and the EC directive. The LSRO recommended infant formulas have a minimum carbohydrate level of 2.1g/100 kJ. This level was estimated from glucose requirements for central nervous system oxidation and was set sufficiently high to accommodate the needs of infants up to 12 months of age. The maximum level recommended by the LSRO of 3.1 g/100 kJ was derived after determining the contribution of energy from protein and fat.

Then standard regulates the protein, fat and energy contents. Therefore the carbohydrate content is regulated by default as it is assumed that carbohydrate would be the third nutrient to contribute to energy content. It is proposed to include a provision to clarify that it is carbohydrate and not organic acids which are expected to make the remaining contribution to the energy content of infant formula.

Recommendation:

The carbohydrate content of infant formula, follow-on formula and pre term infant formula not be prescribed other than to clarify that it is carbohydrate and not organic acids which are expected to make the remaining contribution to the energy content of infant formula.

4b) TYPE OF CARBOHYDRATE

The type of carbohydrate permitted in infant formula is not specified in the Codex standard nor in the proposed draft Codex standard. Prescription of carbohydrate types in the joint ANZ standard for infant formula may create a trade barrier. The EC prescribes carbohydrate types for use in infant formula, requires a minimum lactose content and specifies that starches used must be naturally free of gluten.

Formula based upon mammalian milk will inherently contain lactose as the main carbohydrate unless specifically manufactured to lower the lactose content. Therefore prescription of the carbohydrate types may not be required as the generic requirement for ingredients to be suitable for infant feeding limits the use of unsafe constituents. This provision would preclude the use of fructose as a carbohydrate in infant formula for healthy infants without the need for specific prohibition as fructose is recognised as a cause of malabsorptive diarrhoea in some people including infants. Formula based upon soy protein usually contains sucrose or glucose as the main carbohydrate source. The LSRO found that sucrose is safe for addition to infant formula and the upper limit is controlled by the limit to the carbohydrate content of the formula. It also considered that whilst the addition of glucose to infant formula offers no advantage over other carbohydrates it may unnecessarily increase the osmolality of the formula. However, it is proposed to regulate the osmolality of infant formula in the joint ANZ standard.

Therefore it is recommended the clauses proposed at full assessment which prescribe carbohydrate types not be included in the joint ANZ standard.

4c) LACTOSE FREE AND LOW LACTOSE INFANT FORMULAS

Issues

The proposed at full assessment specified that lactose free human milk substitutes must not contain any detectable lactose and low lactose human milk substitute must not contain more than 2.4 g/L of lactose if based on cows' milk protein or modified cows' milk protein; or 1.9 g/L of lactose if based on goats' milk protein.

Submissions questioned the different maximum level of lactose for goat and cow milk. The Dairy Goat Co-operative noted that cow and goat milk have the same level of lactose and therefore the levels should be the same and suggested 2.4 g/L.

Submissions also requested prescription of a method of analysis for lactose.

Assessment

Codex has no specific standard for infant formula prepared for the lactose maldigesting infant. However, lactose maldigestion occurs secondary to gastroenteritis in infants and can be life threatening. Therefore provision is for lactose free and low lactose infant formula is necessary to protect infants sick with a gastrointestinal disease.

The Authority has recently developed a 'lactose free' food category within Standard R1 (Clause (5)). This provision which requires a 'lactose free' food to be free of detectable lactose was developed in accordance with the Authority's statutory process and a method of analysis was not prescribed.

Lactose maldigesting infants are more susceptible to lactose content than others who are lactose maldigesters. The requirement for a lactose free food to contain 'no detectable lactose' regardless of method of analysis used affords infants the highest level of protection as it requires the most advanced method of analysis be used at all times. Therefore no further assessment of these issues is necessary. Therefore it is recommended that lactose free infant formula and lactose free follow-on formula should contain no detectable lactose.

It is proposed to revise the provisions for low lactose formulas such that low lactose formula regardless of base ingredient should not contain more than 2.4 g/L. This maximum level may be revised when Standard R1(5) is reviewed in the review of food standards to ensure consistency.

Low lactose formula should list the lactose content in the label to allow carers of infants who are intolerant to lactose to easily determine the lactose content of a formula. This will facilitate formula changes which may be necessary to protect the susceptible infant from adverse symptoms due to lactose intake.

4d) GALACTOSE

Declaration of galactose content on formula which claim a lower lactose content than usual

Galactosemia is treated by the exclusion of galactose from the diet. However the major dietary source of galactose is dietary lactose. Therefore the usual dietary treatment is a galactose /lactose free diet. Lactose is broken down to the monosaccharides, glucose and galactose in the preparation of low lactose,

reduced lactose and lactose free foods based upon milk for lactose maldigesters. Therefore information suggesting a reduction in lactose content may be misconstrued to infer a reduction in galactose content. Low lactose, reduced lactose and lactose free foods based upon milk are therefore currently required to provide information about the galactose content of the food (Standard R1(5)). Infant formula prepared for lactose maldigesting infants is required to provide information about the galactose content by virtue of the provisions in Standard R1(5). This information enables carers of children or infants with galactosemia to determine how much of the food, if any, is suitable for galactosemics. It is recommended that this provision be retained and information about the galactose content of the food be included in the nutrition information of an infant formula prepared to lower the lactose from the standard formula level.

Warning statement for infants with galactosemia.

The proposed at full assessment proposed that lactose free human milk substitutes in which the protein is milk protein include the following statement:

'NOT SUITABLE FOR INFANTS WITH GALACTOSEMIA'

The current AFSC, NZFR and Codex do not make any provision for such a warning statement about unsuitability for galactosemics.

Issues

Submission was made that the warning statement be tied to a maximum level of galactose. One submission suggested this be 5 mg/100 mL until such time as there is verification of a 'safe' level of galactose ingestion for infants with galactosemia and that this statement be on milk-based human milk substitutes, all 'lactose-free' and 'low lactose' formulae and all soy-based formulae containing more than 5 mg/100 mL of galactose. The rationale for this request was that some galactose is present in virtually all formulae, including 'lactose free', 'low lactose', 'hydrolysed lactose' and 'proximate modified' human milk substitutes, where the galactose is present in complex carbohydrates such as raffinose, stachyose and galactosides etc.

Assessment

The value of this warning statement was questioned on the basis that galactosemia is often not diagnosed until later in infancy. The incidence of galactosemia is low (1 in 50,000 in the USA⁸, 1 in 88 000 in Scotland⁹) and all infants with this disorder would be expected to be under specialist medical supervision. Therefore carers of infants with galactosemia would be provided with expert advice about which formula to purchase and therefore would not benefit from a warning statement as it is considered unlikely that they would be relying solely on label information when choosing formula. Additionally, there is lack of consensus of the contribution of galactose content to the blood galactose level from dietary sources of soya.

It is concluded that it is neither desirable nor necessary to require a warning statement, because the majority of infants using 'lactose-free' formula do not suffer from galactosemia, and the carers of such infants would purchase the formula on the basis of their doctor's advice.

5. ENERGY CONTENT OF INFANT FORMULAS

5a) ENERGY CONTENT

i) Energy value for carbohydrate

The draft ANZ infant formula standard provides for the calculation of energy using the following values:

1 g fat yields	37 kJ
1 g protein yields	17 kJ
1 g carbohydrate yields	16 kJ.

Issue

Industry submissions all argued against the energy value of carbohydrate being 16 kJ as it is in the proposed at full assessment.

Assessment

Codex and the EC both quote 17 kJ as the energy value of carbohydrate.

Although an energy conversion factor for carbohydrate of 16 kJ/g is considered more accurate for formula where the predominant form of carbohydrate is disaccharide, it is accepted that the Codex general factor of 17 kJ/g, which is most appropriately applied to foods with mixed carbohydrate sources within a mixed diet, should be adopted on the basis of international consistency. Industry submissions argued against the use of 16 kJ/g by pointing out that confectionery as a sugars-based food was also prescribed the general factor of 17 kJ/g within the Food Standards Code. However, confectionery, unlike infant formula, is not a sole source of nutrition and therefore the error in overestimating its energy content is not as significant in the context of a total diet.

Midrange nutrient gram amount/100 kJ	Factor	Contribution to energy
Codex		
protein, 0.575	17	9.775
fat, 1.275	37	47.175
carbohydrate, 2.55	17	43.35
total		100.300
Proposed at full assessment		
protein, 0.575	17	9.775
fat, 1.25	37	46.25
carbohydrate, 2.55	16	40.8
total		96.825

There is no need to adjust the other energy dependent macronutrient limits, given the decision also to harmonise macronutrient limits with the Codex Standard.

The Authority has energy factors for foods under review in P177 - Energy Factors, which is currently at Inquiry. It is proposed that the joint ANZ Code will include a table of energy factors for food components in section 8 of the general labelling standard. It is proposed in P177 to assign an energy factor of 17kJ/g for carbohydrate (excepting for unavailable carbohydrate) and a factor of 8kJ/g for unavailable carbohydrate. These energy values are recommended for calculating the energy value of infant formulas.

Recommendation:

In the interest of harmonization, the Authority agrees that 17 kJ should be used as the energy value for carbohydrate even though this may lead to underestimating the energy value of infant formula. However, the prescribed energy values assigned to food components in the joint ANZ FSC are recommended for use in calculating the energy values of infant formulas.

5b) ENERGY VALUE RANGE

Current provisions and proposed provisions

	Infant formula kJ/litre	Follow-on formula kJ/litre
current R7	2700 - 3000	as per infant formula
proposed at Full Assessment for infant formulas for healthy infants	2700 - 3000	2700 - 3000
proposed at Full Assessment for pre term infant formulas	2720 - 3556	Not applicable
proposed at Full Assessment for proximate modified infant formulas	2700 - 3000	Not applicable
Codex	2500 - 3150	2500 - 3550
proposed Codex standard; EC	2500 - 3150	Not applicable
LSRO recommendations	2645- 2980	as per infant formula
proposed at Preliminary Inquiry	2500-3000 <u>For pre term formula:</u> 2720 - 3556 <u>For Formula based upon protein substitutes:</u> as per Infant formula and follow-on formula)	2500-3550

Issues

Infant formula

The energy range required by the draft Codex standard for infant formula is 250 kJ/100 mL to 315 kJ/100 mL and two industry submissions request harmonization with the EU range, 250 kJ/100 mL to 315 kJ/100 mL.

Follow-on formula

The energy range required by the Codex standard for follow-on formula 250 kJ/100 mL to 355 kJ/100 mL is much wider than proposed at full assessment and submissions request harmonization with the international standard.

Pre term infant formula, Proximate modified infant formula

There were submissions which suggested that the maximum value for proximate modified infant formula should be raised to 3010 or 3150 kJ/100L and the those which suggested that the energy range for pre-term formula was at variance to that for other infant formula.

Assessment

The LSRO has recommended a narrower range of energy for infant formulas than most current regulations. The LSRO noted that energy intakes of formula fed infants were different from breast fed infants after the first few months of life and energy deposition and weight gain are greater in formula fed infants than breast fed infants. The LSRO reported new proposals for defining total energy expenditures have been submitted to WHO/FAO/UNU and that these and subsequent investigations will impact on the recommended energy densities for infant formulas. The LSRO recommended 63-71 kcal/100 mL (approx 2645- 2980 kJ/L) as history of use of formulas with energy contents outside this range is limited.

Infant formula

The proposed Codex standard provides for a broader range of energy than the draft ANZ Standard which quotes 2700 kJ/L to 3000 kJ/L. The standard proposed at full assessment is more restrictive than the draft Codex standard. There is no public health contradiction to widening the energy value range for infant formula to be consistent with the draft Codex requirement. Therefore in the interest of harmonization with Codex, it is recommended that the range for energy value be adjusted to 2500 kJ/L to 3150 kJ/L.

Follow-on formula

The Codex standard for follow-on formula provides for a broader range of energy than proposed at full assessment. The provisions proposed at full assessment are more restrictive than the draft Codex standard. There is no public health contradiction to widening the energy value range for infant formula to be consistent with the draft Codex requirement. Therefore in the interest of harmonization with Codex, it is recommended that the range for energy value be adjusted to 2500 kJ/L to 3550 kJ/L.

6. VITAMIN AND MINERAL CONTENT OF INFANT FORMULAS

6a) PRE-TERM FORMULA LEVELS

The needs of preterm infants for vitamins and minerals are very different from those of term infants due to altered nutrient reserves and differing rates of metabolism. Preterm infants who are under 2 kg bodyweight are usually under medical care in specialist hospital units. Many of these infants are initially fed intravenously with solutions controlled for every nutrient, particularly if unable to breastfeed. Oral formula fed to these 'at risk' infants should closely mimic breastmilk or intravenous solutions and therefore should have tight control over maximum nutrient levels. Particular infants who require supplementation with specific nutrients would need to be provided with specially monitored doses of these nutrients. These needs are more appropriately met by medicinal supplements in addition to the pre term formula supply of nutrients.

Minimum and maximum levels were justified for all vitamins and minerals in pre-term formula at full assessment. Therefore, it is recommended that except for minor 'rounding off' of values, the nutrient permissions for pre-term formula proposed at full assessment be included in the joint ANZ infant formula standard.

6b) VITAMIN AND MINERAL PERMISSIONS FOR INFANT FORMULA PRODUCTS (NOT PRE TERM FORMULAS)

It was proposed at full assessment to prescribe maximum levels for all vitamins and minerals in the standard. There is strong industry opposition to the mandatory maximum limits for vitamins and minerals other than for safety concerns.

Concerns were expressed in relation to:

criteria for setting nutrient levels

Submissions commented on the criteria used for setting nutrient levels. It was submitted that the main criteria should have been harmonization with New

Zealand and consideration of the Recommended Dietary Intake (RDI) levels for infants set by NHMRC.

lack of harmonisation

Industry note:

- neither Codex, the EC, or the FDA has set maximum values for water soluble vitamins in infant formulas, due to the low toxicity of these vitamins;
- the FDA includes only upper limits for protein, fat, sodium, potassium, chloride, iron, iodine, and Vitamins A and D in infant formula;
- Codex has only upper limits for protein, fat, sodium, potassium, chloride and vitamins A and D in infant formula;

It is claimed that if no maximum levels for nutrients are set, general provisions for the manufacture of safe food would apply, and oblige manufacturers to ensure that the levels that are considered appropriate would not be harmful to health.

overages

It was claimed that maximum levels for some nutrients are not practical or feasible as vitamins are routinely added at levels greater than shown on the label. This 'overage' allows for some decrease in potency over the shelf life of the powder. Additionally, formulas are frequently made from a premix of fixed composition containing the micronutrients for which there is a prescribed minimum and with overages of certain vitamins under the current draft Standard one single premix would no longer be an option.

compliance difficulties

It is claimed that maximum levels for some nutrients are not practical or feasible because there is natural variation, sometimes seasonal, in vitamin and mineral content in the base foods. The base food may contain certain nutrients at levels exceeding the maximum permitted levels proposed at full assessment, eg sodium, potassium, calcium and phosphorus in cow's milk and magnesium, phosphorus and potassium in soya beans.

The setting of maximum values for all micronutrients makes the Standard much more difficult to comply with as control of the level of micronutrients within a narrow range, particularly at the mg level, is difficult, especially when using dry mixes where the variation throughout is +/- 15%.

Industry submissions also claimed there was no need for maximum levels for nutrients which are coincidental components of other ingredients and have a wide margin of safety (eg vitamin K in soy oil, riboflavin in cows milk, tocopherols in vegetable oils); and only nutrients deliberately added to infant formula should have upper limits (eg iron as ferrous salts, vitamin B6 as pyridoxine);

special requirements for special formula

Submissions note that for some metabolic and malabsorptive conditions, higher levels of some vitamins and minerals are required to overcome losses due to malabsorption. Therefore some special purpose formulas will therefore have levels above the maximum, and these will not be permitted under the new Standard. For example, some MCT predominant proximate-modified formulas need higher than normal levels of fat-soluble vitamins to meet the needs of infants with eg. liver disease and cystic fibrosis.

Assessment

Codex currently does not set maximum levels, other than for vitamin A, D, sodium, potassium, chloride for IF and vitamin A, D, sodium, and iron for Follow up Formula. However, Codex proposes maximum for phosphorus magnesium, iron, copper, selenium in the revised Codex standard for infant formula.

The Authority has reviewed the policy underpinning the vitamins and minerals content of infant formula with the assistance of the Authority's Panel of Experts (EP).

The following points are made in support of having maximum levels for all vitamins and minerals:

- infant formula is the sole source of nutrition, and vitamins and minerals used in excess can be toxic; where toxicity is a concern, there need to be maximum limits, for public health and safety reasons;
- although not all vitamins and minerals are toxic in large quantities, an excess of one nutrient can 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;
- Codex has introduced maximum levels for more vitamins and minerals in its proposed revised Standard for Infant Formula, and the UK is moving towards setting maximum levels for recommended intakes of nutrients, even in the absence of specific health and safety issues;

- this is a quality control issue and the manufacturer should ensure the best quality and least contamination of the product, otherwise they should be liable; there is need for quality control to cover the situation where accidental additions are made; and
- there is no guarantee of quality control on imported products.

The following points are made against having maximum levels for all vitamins and minerals:

- manufacturers add extra vitamins and minerals in the production of infant formula to ensure that after processing and sitting on a shelf for a period of time there are still adequate amounts of the vitamins and minerals left in the product as indicated on the label. This is called overage. If a maximum is set, industry is concerned that they may not be able to meet their overage needs and hence products may not contain the adequate amount of vitamins and minerals throughout their shelf life;
- industry would be unlikely to add excess amounts, because of cost considerations; and
- industry does not add excess amounts at the present time, although there are no maximum levels for most vitamins and minerals in the current Standard.

The LSRO:

- concluded the differences in needs of infants from birth through to 12 months could be accommodated in one set of recommendations.
- considered in making its recommendation about nutrient content essentiality, stability, historical use, safety and toxicity and in almost all cases the LSRO recommended both minimum and maximum levels. In the case of chromium and molybdenum the LSRO considered insufficient evidence was available to justify inclusion and therefore did not recommend a minimum content.
- considered potential nutrient interactions which would affect bioavailability and utilisations of other nutrients when setting minimum and maximum levels.
- recommendation were made for 'as fed' and for throughout the shelf-life of the product

In the interests of harmonisation, the Authority has reviewed internationally infant formula standards where possible but notes many of these standards are

being reviewed, which makes harmonisation difficult. Whilst harmonisation will be considered where possible, the Authority's first obligation is to public health and safety.

6c) THE REGULATION OF MAXIMUM LEVELS OF NUTRIENTS

Industry submission to the Authority state the medical, regulatory and economic implications of setting maximum levels for nutrients in infant formula which are not considered 'unsafe' for infants is high and not justified.

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 insignificant according to reports of toxicity or nutrient-nutrient interactions.

High or unlimited intakes of the following nutrients were considered to pose a significant risk to infants:

vitamin A, vitamin D, vitamin E, vitamin B₆, calcium, chloride, copper, iron, iodine, magnesium, manganese, potassium phosphorus, selenium, sodium, and zinc. It is recommended that maximum levels be set in the joint standard for infant formula for these nutrients. The LSRO notes reports that water soluble analogues of menadione can cause toxic reactions in infants. Therefore it is recommended this form of vitamin K not permitted for use in infant formula.

There are no known reports of toxicity or major interactions with other nutrients for the following nutrients and therefore risk characterisation is provisionally assessed as 'not significant'. Human milk does not contain unlimited levels of these nutrients. Therefore it is considered 'nature' or 'natural selection' has set intrinsic upper levels for these nutrients for human infants. The Authority believes it is in the best interests of infants not to be exposed to excessive or unsubstantiated levels of nutrients.

Whilst upper limits are recommended for nutrients provisionally assessed with a risk characterisation as 'not significant' these upper limits will not be mandatory upper limits. Rather the limits will serve as guidelines to be implemented by Good Manufacturing Practice. Infant formula could then be designed to comply with these guidelines in the best interests of infant consumers.

Therefore, it is recommended that a guideline accompany the joint ANZ standard for infant formula to provide manufacturers with advisory guides to the recommended maximum levels for some nutrients in infant formula.

Conclusion:

Infant formula is the sole source of nutrition for infants and vitamins and mineral used in excess can be harmful. Although not all vitamins and minerals are toxic in large quantities, an excess of one nutrient can interact adversely with others. Nutrient-nutrient interactions are not well understood and poorly documented. Human milk has a self limiting level for all vitamins and minerals and the setting of maximum levels mimic this natural protective factor. The Authority does not recommend unlimited nutrient contents for infant formulas represented as human milk substitutes. Therefore maximum levels should be established for all vitamins and minerals.

Where there are known health or safety concerns maximum levels are proposed to be mandatory. In the case of nutrients whose risk characterisation is provisionally assessed as 'not significant', maximum levels are recommended as advisory levels. Levels which are set on the basis of public health and safety should be the same for soy-based and milk-based formulas.

6d) VITAMINS

VITAMIN A

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
Current R7	18-37	as per infant formula
Proposed at Full Assessment	17 - 54	as per infant formula
Codex	18-37	18-54
Proposed Codex standard	14-43	Not applicable
LSRO recommendations	14-36	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	14-43	as per infant formula

Issues

An industry submission suggests the recommended maximum should be lowered to 37 mcg/100 kJ, as in the current Standard as there is no justification for raising it to 54 mcg/100 kJ.

It was also noted that the minimum level of vitamin A proposed at full assessment is 17 mcg/100 kJ, compared with 18 mcg/100 kJ in Codex.

Assessment

High intakes of vitamin A have been associated with toxic responses in infants. Therefore a significant risk exists for infants who consume high levels and the maximum level in infant formula should be regulated.

The EP considered there should be no change to the levels set for vitamin A because the increase in the maximum level was justified in the full assessment report

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 425 mcg vitamin A as RE. A formula at the maximum energy content which contains 16.7 mcg vitamin A/100 kJ would provide an infant consuming 850 mL of formula with the RDI.

Codex has recently altered the proposed range for vitamin A to 14-43 mcg/100 kJ. This level is consistent with that in the EC and UK regulations for both infant formula and follow-on formula for infants and will provide infants with their vitamin A requirements. Therefore it is recommended this level be included in the joint ANZ standard for infant formula.

Recommendation:

The levels proposed at full assessment be amended to the proposed Codex range for vitamin A of 14-43 mcg/100 kJ.

THIAMIN (VITAMIN B₁)

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	10 - not specified	as per infant formula
proposed at Full Assessment	10 - 22	as per infant formula
Codex	10-not specified	10 - not specified
proposed Codex standard	10-not specified	Not applicable
LSRO recommendations	7.1 - 47.6	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	10 mcg/100 kJ - not specified [Advisory guideline maximum of 48 mcg/100 kJ]	as per infant formula

Issues:

Industry submissions are opposed to a mandatory maximum level, however request the maximum level of thiamin be increased to 40 mcg/100 kJ to provide for losses during storage as thiamin is not very stable and to accommodate the natural range of variation in the raw material, particularly for goat milk based follow-on formula. It was claimed the increased maximum levels would pose no toxicity problems and urinary excretion rates of oral thiamine are high.

Assessment

No reports are known of toxicity concerns for high intakes of thiamin for infants or interaction with other nutrients. However, excess thiamin is required to be excreted by the infant. Risk from high intake is considered not to be of major concern for infants on the basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 0.25 mg thiamin. A formula at the maximum energy content which contains 9.8 mg/100 kJ of thiamin would provide an infant consuming 850 mL of formula with the RDI. Therefore it is recommended the minimum proposed at full assessment be retained in the standard. However, it is recommended manufacturers contain the maximum thiamin content of infant formula to the level recommended by the LSRO which is 48 mg/100 kJ. This would provide infants with 5 x the RDI.

RIBOFLAVIN (VITAMIN B₂)

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	14- not specified	as per infant formula
proposed at Full Assessment	14 - 86	as per infant formula
Codex	14- not specified	14- not specified
proposed Codex standard	14- not specified	Not applicable
LSRO recommendations	19.0 - 71.4	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	14 mcg/100 kJ - not specified [Advisory guideline maximum of 86 mcg/100 kJ]	as per infant formula

Issues

Industry submissions are opposed to a mandatory maximum level, however request the maximum levels be increased to allow for inherently high levels in milk ingredients. One submission requests the maximum levels be 100 mcg /100 kJ whilst another requests 110-120 mcg /100 kJ. Submissions claim because of the relatively low solubility of riboflavin, it is rare for higher intakes to result in toxic levels in the blood (US RDA 1989).

Assessment

No reports are known of toxicity concerns for infants with high intakes of riboflavin or interaction with other nutrients. However, excess riboflavin is required to be excreted by the infant. Risk to the infant from high intake is considered not to be of major significance on basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 0.4 mg riboflavin. A formula at the maximum energy content which contains 15.7 mcg/100 kJ of riboflavin would provide an infant consuming 850 mL of formula with the RDI. Therefore it is recommended the minimum proposed at full assessment be retained in the standard. However, it is recommended manufacturers contain the maximum thiamin content of infant formula to the level proposed at full assessment. This would provide infants with 5 x the RDI.

NIACIN (NE)

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	60-not specified	as per infant formula
proposed at Full Assessment	60-71	as per infant formula
Codex	60-not specified	60-not specified
proposed Codex standard	200-not specified	Not applicable
LSRO recommendations	130-480	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	130 mcg/100 kJ - not specified [Advisory guideline maximum of 480 mcg/100 kJ]	as per infant formula

Issues

Industry are opposed to the specification of a maximum level for niacin in the infant formula standard and the minimum recommended in the proposed Codex standard is significantly higher than proposed at full assessment.

Assessment

There have been reports of toxic effects from excess nicotinic acid but these adverse reactions are not produced with nicotinamide or niacinomide. Therefore nicotinic acid is not recommended as a permitted form of niacin for infants.

The risk to infants of high intake of nicotinamide or niacinomide is considered not to be of major significance on basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula.

The infant formula niacin values proposed for the Codex standard and recommended by the LSRO exclude the expected niacin contribution from tryptophan.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 4 mg niacin equivalents. A formula at the maximum energy content which contains 156 mcg/100 kJ of niacin equivalents would provide an infant consuming 850 mL of formula with the RDI. Therefore it is recommended the minimum requirement for preformed niacin in the standard be increased to that recommended by the LSRO.

It is recommended manufacturers contain the maximum niacin content of infant formula to the maximum level proposed by the LSRO which is 480 mcg/100 kJ and approximately 3X RDI.

FOLATE

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	1-not specified	as per infant formula
proposed at Full Assessment	1.7-7.9	as per infant formula
Codex	1-not specified	1-not specified
proposed Codex standard	1-not specified	Not applicable
LSRO recommendations	2.62-9.52	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	2.0 mcg/100 kJ - not specified [Advisory guideline maximum of 8.0 mcg/100 kJ]	as per infant formula

Issues

Industry are opposed to the specification of a maximum level for folate in the infant formula standard and the minimum recommended in the proposed Codex standard is significantly lower than proposed at full assessment.

Assessment

The minimum folate content specified in the Codex standard and the 1996 EC Directive may not provide sufficient folate to meet intakes recommended by the NHMRC for bottle fed infants. The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 50 mcg folate. A formula at the maximum energy content which contains 1.96 mcg/100 kJ of folate would provide an infant consuming 850 mL of formula with the RDI. Therefore it is recommended infant formulas contain a minimum of 2.0 mcg/100 kJ of folate.

No reports are known of toxicity concerns from high intakes of folate for infants or interaction with other nutrients. Excess folate is required to be excreted by the infant. Risk of high intake of folate is considered not to be of major significance on basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula. It is recommended manufacturers contain the maximum folate content of infant formula to 8.0 mcg/100 kJ. This would provide approximately 4X RDI.

VITAMIN B₁₂ (CYANOCOBALAMIN)

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	0.04 -not specified	as per infant formula
proposed at Full Assessment	0.04-0.13	as per infant formula
Codex	0.04-not specified	0.04-not specified
proposed Codex standard	0.025-not specified	Not applicable
LSRO recommendations	0.02- 0.17	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.025 mcg/100 kJ - not specified [Advisory guideline maximum of 0.17 mcg/100 kJ]	as per infant formula

Issues

Industry submissions are opposed to a mandatory maximum level, however request the maximum for vitamin B₁₂ in infant formula be increased from 0.13 mcg /100 kJ to 0.2 mcg /100 kJ to accommodate inherently high levels in the base foods, the fact that vitamin B₁₂ is a microbiological assay with a standard deviation of 40% and to enable some currently available products to maintain fortification rates at existing levels. Submissions note vitamin B₁₂ is not considered toxic as no toxic effects have been found in man and excess vitamin B₁₂ (not bound by serum and tissue protein) is excreted in the urine.

Assessment

No reports are known of toxicity concerns for high intakes of vitamin B₁₂ by infants or interaction with other nutrients. However, excess vitamin B₁₂ is required to be excreted by the infant. Risk of high intake of vitamin B₁₂ is considered insignificant on basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 0.34 mcg vitamin B₁₂. A formula at the maximum energy content which contains 0.013 mcg vitamin B₁₂/100 kJ would provide an infant consuming 850 mL of formula with the RDI. Therefore it is recommended the minimum level proposed at full assessment be lowered to that proposed for the revised Codex standard (0.025 mcg/100 kJ) for inclusion in the joint ANZ standard.

It is recommended manufacturers contain the maximum vitamin B₁₂ content of infant formula to 0.17 mcg/100 kJ as recommended by the LSRO. This is 13 x RDI for infants.

VITAMIN C (ASCORBIC ACID)

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	1.9-not specified	as per infant formula
proposed at Full Assessment	1.7-5.4	as per infant formula
Codex	1.9-not specified	1.9-not specified
proposed Codex standard	1.9-not specified	Not applicable
LSRO recommendations	1.43-3.57	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	1.7 mg/100 kJ - not specified [Advisory guideline maximum of 5.4 mg/100 kJ]	as per infant formula

Issues

Industry submissions are opposed to a mandatory maximum level, however request the proposed maximum (5.4 mg/100 kJ) be increased to 7.5 mg/100 kJ to accommodate overage added to allow for decay from oxidation and heat processing (dehydroascorbic acid is less stable in heat) and for the natural level of vitamin C in goat milk based follow-on formula.

Submissions also note the minimum level of vitamin C proposed at full assessment is 1.7 mg compared with 1.9 mg in the proposed Codex.

Assessment

The LSRO reports a case of toxicity from intakes of beverages fortified with vitamin C in children when large intakes (3-4000 mg) were ingested over a short time. Reports of excessive vitamin C intake causing raised uric acid levels, iron overload, impaired vitamin B12 status or mutagenicity were discounted by Rivers for healthy individuals as reported in the LSRO.

Vitamin C does interact with other nutrients and excess vitamin C is required to be excreted by the infant. The risk to infants from high intake is considered not to be of major significance on basis of current knowledge, however manufacturers are recommended to contain the vitamin C content of infant formula.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 25 mg vitamin C. A formula at the maximum energy content which contains 0.98 mg vitamin C/100 kJ would provide an infant consuming 850 mL of formula with the RDI. Therefore whilst the LSRO recommends a lower minimum than that proposed at full assessment, it is recommended the minimum level proposed as full assessment be included in the joint ANZ standard.

It is recommended manufacturers contain the maximum vitamin C content of infant formula to the level proposed at full assessment although this is higher than the maximum recommended by the LSRO. This will provide approximately 5.5 x the RDI for infants.

VITAMIN D

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	0.25-0.48	as per infant formula
proposed at Full Assessment	0.25-0.61	as per infant formula
Codex	10-25 IU	0.25-0.75
proposed Codex standard	0.25-0.63	Not applicable
LSRO recommendations	0.24-0.60	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.25-0.63	as per infant formula

Assessment

High intakes of vitamin D are associated with toxic responses in infants and the potential of significant interaction with other nutrients exists. Therefore a significant risk exists for infants from high consumption of vitamin D and the maximum level in infant formula should be regulated.

The NHMRC has not recommended an intake level for vitamin D as it considered the needs of Australian infants would be met by exposure to sunlight. However, the FNB (1989) has recommended a vitamin D intake of 7.5 mcg per day for infants to 6 months and 10 mcg for infants 7-12 months. A formula at the maximum energy content which contains 0.3 mcg vitamin D /100 kJ would provide an infant consuming 850 mL of formula or 0.23 mcg/100 kJ for an older infant consuming 1.3 L of follow-on formula, with this RDI. Therefore, it is recommended the minimum vitamin D content of infant formula be that proposed at full assessment.

The levels proposed for the revised Codex standard are recommended to be in the joint ANZ standard for infant formula. The maximum level in the standard will be approximately 2.7x RDI for infants.

VITAMIN K

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	1-not specified	as per infant formula
proposed at Full Assessment	1.0-3.6	as per infant formula
Codex	1-not specified	1-not specified
proposed Codex standard	1-not specified	Not applicable
LSRO recommendations	0.24-5.95	as per infant formula

PROPOSED AT PRELIMINARY INQUIRY	1.0 mcg/100 kJ - not specified [Advisory guideline maximum of 5.0 mcg/100 kJ]	as per infant formula
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Issue

Industry submissions are opposed to a mandatory maximum level, however submit that the maximum (3.6 mcg/100 kJ) should be increased to 5.0 mcg/100 kJ, to allow for levels in goats' milk of up to 5.0 mcg/100 kJ noting vitamin K toxicity is rare, probably because the vitamin is so poorly stored.

Assessment

The LSRO reports that the mena-dione form of vitamin K can cause severe toxic effects in infants. The form of vitamin K, 'phyloquinone' is unlikely to cause toxicity. There may be a potential link to vitamin E metabolism but there does not appear to be confirmed interaction with other nutrients. The risk to infants of high intake of vitamin K is considered insignificant on basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula.

The FNB (1989) has recommended a phyloquinone or menaquinone intake of 5 mcg per day for infants to 6 months and 10 mcg for infants 7-12 months (ESADI). A formula at the maximum energy content which contains 0.2- 0.39 mcg vitamin K /100 kJ would provide an infant consuming 850 mL of formula with this ESADI. Therefore, it is recommended the prescribed minimum vitamin K content of infant formula be that proposed at full assessment.

The LSRO recommended maximum level is based on the 90th centile of formulas analysed by the FDA and therefore it is recommended manufacturers of formula for infants in Australia and New Zealand contain the maximum vitamin K content of infant formula to a comparable level of 5.0 mcg/100 kJ which is 12 x ESADI.

PANTOTHENIC ACID

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	70- not specified	as per infant formula
proposed at Full Assessment	71 - 360	as per infant formula
Codex	70- not specified	70 - not specified
proposed Codex standard	70- not specified	Not applicable
LSRO recommendations	71-286	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	70 mcg/100 kJ - not specified [Advisory guideline maximum of 360 mcg/100 kJ]	as per infant formula

Issue

Industry submissions are opposed to a mandatory maximum level. Industry have reported that the repeatability error in the analysis of pantothenic acid is 10%.

Assessment

No reports are known of toxicity concerns for infants with pantothenic acid or interaction with other nutrients. Risk to infants of high intake of pantothenic acid is considered not significant on basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula.

The FNB (1989) has recommended an intake of 2-3 mg pantothenic acid per day for formula fed infants based upon usual intakes of breastfed infants (ESADI). A formula at the maximum energy content which contains 0.08-0.12 mg pantothenic acid /100 kJ would provide an infant consuming 850 mL of formula with this ESADI.

Therefore, it is recommended the minimum pantothenic acid content of infant formula be that proposed at full assessment and manufacturers be advised to contain the maximum pantothenic acid content of infant formula to proposed at full assessment. This maximum is approximately 3x av ESADI - 300 mcg/100 kJ.

BIOTIN

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	0.4- not specified	as per infant formula
proposed at Full Assessment	0.36-2.7	as per infant formula
Codex	0.4- not specified	0.4- not specified
proposed Codex standard	0.4- not specified	Not applicable
LSRO recommendations	0.24-3.57	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.36 mcg/100 kJ - not specified [Advisory guideline maximum of 2.7 mcg/100 kJ]	as per infant formula

Issues

Industry submissions are opposed to a mandatory maximum level.

Assessment

No reports are known of toxicity concerns for infants from biotin or interaction with other nutrients. The risk to infants of high intake is considered not significant on basis of current knowledge, however it is recommended manufacturers contain the maximum level in infant formula.

The FNB (1989) has recommended an intake of 10-15 mcg per day for formula fed infants based upon usual intakes of breastfed infants (ESADI). A formula at the maximum energy content which contains 0.39-0.59 mcg biotin/100 kJ would provide an infant consuming 850 mL of formula with this ESADI.

Therefore, it is recommended the minimum biotin content of infant formula be that proposed at full assessment and manufacturers be advised to contain the maximum biotin content of infant formula to that proposed at full assessment. This maximum level would provide approximately 5.5X average ESADI.

PYRIDOXINE (VITAMIN B6)

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	9- not specified (> 15 mcg/g protein for form with 0.6 mg/100 kJ)	as per infant formula
proposed at Full Assessment	8.9-36	as per infant formula
Codex	9-not specified	11- not specified
proposed Codex standard	15- not specified mcg/g protein but not less than 9-not specified)	Not applicable
LSRO recommendations	7.14-30.95	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	9-36 mcg/100 kJ	as per infant formula

Assessment

High intakes of pyridoxine have been associated with toxic responses in adults, there is potential of significant interaction with other nutrients reported, and excess pyridoxine required to be excreted by infant. Therefore a significant risk exists for infants who consume high levels of pyridoxine and the maximum level in infant formula should be regulated.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 0.25 mg vitamin B6. A formula at the maximum energy content which contains 9 mcg vitamin B6/100 kJ would provide an infant consuming 850 mL of formula with the RDI.

Some regulations link vitamin B6 requirements with protein content because Vitamin B6 is involved in protein metabolism. The LSRO reports formula which provides 5.56 mcg pyridoxine /g protein will prevent convulsions which occur as a result of pyridoxine deficiency in most infants. The maximum protein levels recommended to be included in the joint ANZ standard for infant

formula, follow-on formula and proximate modified formula are 0.7, 1.0 and 1.4 g/100 kJ respectively. Therefore the minimum content to cover this protein content is 3.9, 5.56, and 7.8 mcg pyridoxine. The minimum pyridoxine content recommended at full assessment provides for the maximum protein content of all formulas. However, it is proposed to align this level with that in the Codex standard and recommend a minimum content of 9 mcg pyridoxine/ 100 kJ and to retain the maximum level proposed at full assessment. This maximum level is unlikely to create trade restrictions as it is higher than the LSRO recommendation of 31 mcg vitamin B₆/100 kJ is the 90th centile of formula sold in the USA.

VITAMIN E

Current provisions and proposed provisions

	Infant formula /100 kJ	Follow-on formula /100 kJ
current R7	150- not specified	as per infant formula
proposed at Full Assessment	0.9 mg/g linoleic acid 0.11 - 1.1 mg	as per infant formula
Codex	0.7 IU/g linoleic acid but in no case < 0.15 IU /100 kJ	0.15 IU /100 kJ
proposed Codex standard	0.5 mg/g linoleic acid but in no case < 0.11 - 1.1 mg	Not applicable
LSRO recommendations	0.12- 1.19	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.5 mg/g linoleic acid (0.11-1.1 mg)	as per infant formula

Issues

Industry submissions note an inconsistency in the ratio of alpha tocopherol equivalents to PUFA in the draft standard as clauses 24(3) and 33(3) specify a minimum of 0.9 mg of d-alpha-tocopherol equivalents whilst clause 42(3) and Schedule 3 specify a minimum of 0.5 mg. Submission was made that the level of 0.5 mg/g for this ratio should apply across the Standard (in line with the EU and Codex).

Assessment

High intakes of vitamin E are associated with toxic responses in infants and potential of significant interaction with other nutrients reported. Therefore a significant risk exists for infants and the maximum level in infant formula should be regulated.

The EP agreed that the correct value for normal formula was 0.5 mg/g, and that the 0.9 mg/g in the previous subclause 24 (3) should be amended to 0.5 mg/g.

The 0.5 mg/g value aligns with the 1996 Proposed revised Codex Standard and the EC Directive.

The NHMRC recommends bottle fed infants up to 12 months of age have a daily intake of 4 mg vitamin E (alpha tocopherol equivalents). A formula at the maximum energy content which contains 0.16 mg vitamin E/100 kJ would provide an infant consuming formula as the principal source of nourishment with the RDI. Therefore it is recommended the level of vitamin E proposed for infant formula at full assessment be included in the joint ANZ standard as it is consistent with Codex and provides for the needs of infants. The relationship between vitamin E level and linoleic acid level should also be regulated for the protection of infants. The LSRO recommend a max of 5 mg alpha tocopherol/g PUFA as being below the intake levels which would result in toxicity based upon animal studies, and reports of adverse effects in preterms.

Therefore as proposed at full assessment 0.5 mg vitamin E should be provide per g linoleic acid in the formula. This requirement is consistent with most international regulations.

6B MINERALS

CALCIUM

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	12- not specified	as per infant formula
proposed at Full Assessment	12- not specified	as per infant formula
Codex	12- not specified	22- not specified
proposed Codex standard	12- not specified	Not applicable
LSRO recommendations	12-33	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	12 mg- not specified [Advisory guideline maximum of 33 mg/100 kJ]	as per infant formula

Issues

Industry did not comment on Calcium levels.

Codex follow-on formula contains a minimum of 22 mg / 100 kJ but no maximum is specified therefore it is greater than the level proposed for follow-on formula at full assessment.

Assessment

High intakes of calcium are not known to be associated with toxic responses in adults, however calcium is known to have significant interaction with many

other nutrients affecting bioavailability and utilisation of other nutrients. Therefore high intakes are considered to pose a significant risk for infants and the maximum level should be regulated in the joint ANZ standard by a limit on the ratio of calcium: phosphorus in the formula.

Human milk is reported to contain up to approx 11 mg calcium /100 kJ but the LSRO report the absorption of calcium from formula is approx 38% of intake compared to 58% for breastfed infants. The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 500 mg calcium and those infants 7-12 months of age have a daily intake of 550 mg calcium. A formula at the maximum energy content which contains 19.6 mg calcium/100 kJ would provide an infant consuming 850 mL of formula or an older infant consuming 1.3 L of follow-on formula which contains 12.6 mg calcium/100 kJ with the RDI. The minimum proposed at full assessment provides for the needs of all infants who may consume an infant formula as the sole or principle source of nourishment. It is recommended the minimum of 12 mg per 100 kJ be prescribed in the standard. Whilst the maximum is regulated by the calcium:phosphorus ratio, it may be useful for some manufacturers to have access to an advisory guideline level for the maximum calcium content of infant formula, therefore it is proposed to include 33 mg/100 kJ as a guide. This level is consistent with the LSRO recommendation for maximum calcium content of infant formula.

Additionally infants consuming follow-on formula are expected to be consuming other foods which will contribute to calcium intake. Therefore there is no health need to require a higher maximum level for follow-on formula. It is recommended the minimum levels proposed at full assessment be included in the joint standard.

Recommendation

The following permissions for calcium be provided in the joint ANZ Standard:

Infant formula and Follow-on formula 12 mg / 100 kJ– not specified

PHOSPHORUS

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	6-25	as per infant formula
proposed at Full Assessment	6-22	as per infant formula
Codex	6- not specified	14- not specified
proposed Codex standard	6-22	Not applicable
LSRO recommendations	4.8-16.7	as per infant formula

PROPOSED AT PRELIMINARY INQUIRY	6-25 [Advisory guideline maximum of 22 mg/100 kJ]	as per infant formula
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Issues

Industry submission requests the maximum level be raised to 25 mg / 100 kJ to provide for seasonal variations in the base ingredients.

Assessment

Significant interactions which affect bioavailability and utilisation of other nutrients have been reported for phosphorus. Phosphorus makes a significant contribution to RSL as excess intake is required to be excreted by the kidneys. Therefore it is considered high intakes of phosphorus pose a significant risk for infants and the maximum level of phosphorus should be regulated in the standard.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 150 mg phosphorus and infants 7-12 months of age have a daily intake of 300 mg phosphorus. A formula at the maximum energy content which contains 5.9 mg phosphorus/100 kJ would provide an infant consuming 850 mL of formula or a formula which contains 6.9 mg phosphorus/100 kJ would provide an older infant consuming 1.3 L of follow-on formula with the RDI.

The minimum proposed at full assessment provides for the needs of infants and is consistent with the Codex requirement. The maximum aligns with that in the EC, the UK regulations and currently proposed for use in the revised Codex standard.

The maximum Ca:P ratio of 2:1 is currently prescribed in Standard R7, Codex, the EC, the Canadian and UK regulations and is recommended for inclusion in the joint ANZ infant formula standard.

Modelling of potential nutrient ranges which comply with the ratio of 1.2-2.0 :1 indicates if a maximum phosphorus content of:

- 25 mg/100 kJ was provided in a formula then the maximum calcium level would need to be 30- 50 mg/100 kJ; and
- 22 mg/100 kJ was provided in a formula then the maximum calcium level would need to be 26.4 - 44 mg/100 kJ.

The LSRO has recommended the maximum calcium content of formulas not exceed 33 mg/100 kJ which is achievable at a phosphorus content of 25 or 22 mg/100 kJ. It is recommended the maximum level proposed at full assessment for phosphorus be increased to 25 mg/100 kJ to provide for seasonal variation of ingredients. However industry should be encouraged to reduce the

maximum phosphorus content of infant formula to 22 mg/100 kJ the level consistent with the Codex level of 22 mg/100 kJ. Therefore it is recommended whilst the maximum is regulated at 25 mg/100 kJ, industry should attain a guideline level of 22 mg/100 kJ in most cases.

Recommendation

The following permissions for phosphorus be provided in the joint ANZ Standard:

Infant Formula and Follow-on formula - 6 mg to 25 mg / 100 kJ

RATIO OF CALCIUM TO PHOSPHORUS

Issue

Industry submission request the minimum ratio of calcium to phosphorus (1.2:1) in Standard R7 be retained to accommodate natural variation in the raw materials used to manufacture infant formulas.

Assessment

The LSRO reports the ratio of calcium : phosphorus found in human milk is generally found at 2:1. This ratio sets a safety factor to minimise the incidence of neonatal hypocalcaemia which has been reported due to the consumption of high phosphorus containing formulas or undiluted cow's milk. The current and proposed Codex standards require the minimum value for the calcium to phosphorus ratio to be not less than 1.2. Therefore, it is proposed to retain the current requirement of a minimum of 1.2 which aligns with the Codex requirements.

Recommendation:

The following permissions for the calcium to phosphorus ratio be provided in the joint ANZ Standard:

Infant formula and Follow-on formula - 1.2 to 2.0

CHLORIDE

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	14-35	as per infant formula
proposed at Full Assessment	14-35	as per infant formula
Codex	14-35	14- not specified
proposed Codex standard	12-29	Not applicable
LSRO recommendations	11.9-33	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	12-35	as per infant formula

Assessment

High intakes of chlorine have been associated with adverse effects in adults. Chlorine makes a significant contribution to RSL, is known to have significant interaction with sodium and excess chlorine is required to be excreted by kidneys. Therefore high intakes of chlorine pose a significant risk to infants and maximum levels in infant formula should be regulated as proposed at full assessment. The minimum level should be lowered to the level in the proposed Codex standard 12 mg/100 kJ. This level is consistent with the level recommended by the LSRO.

Recommendation

The following permissions for chloride be provided in the joint ANZ Standard:
Infant Formula and Follow-on formula- 12 mg – 35 mg / 100 kJ

COPPER

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	14- not specified	as per infant formula
proposed at Full Assessment	14-36 (non soy based formula) 21-43 (soy based formula)	as per infant formula
Codex	14- not specified	not specified
proposed Codex standard	4.8-19	Not applicable
LSRO recommendations	14.3-38.1	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	14-43 EP recommendation	as per infant formula

Issues

Since there are separate ranges for iron and zinc for soy-based and non-soy formulas in the proposed revised Codex Standard, it is suggested that the same rationale be applied to copper levels. The ranges used for copper for both types of formula in the draft revised Australian Standard.

The EP has recommended that the soy and non-soy ranges be telescoped to one range 14 to 43, including for follow-on formula.

Presumably there is a safety factor in the different range for pre-term formula.

Assessment

High intakes of copper have been associated with toxic responses in infants. There are significant interactions between copper and other nutrients which

affect bioavailability and utilisation of other nutrients. Therefore high intakes of copper are considered a significant risk for infants and the maximum level in infant formula should be regulated. In setting a maximum level the potential levels of zinc and iron need to be considered.

The FNB has established a ESADI 0.4-0.6 mg copper /day for infants to 6 months and 0.6-0.7 mg copper /day for infants 7-12 months. In 1985 , the American Academy of Pediatrics recommended infant formulas provide 14.3 mcg copper/100 kJ. A formula at the maximum energy content which contains 0.02 mg copper/100 kJ would provide an infant consuming 850 mL of formula or an older infant consuming 1.3 L of follow-on formula with the ESADI.

See following discussion on zinc: copper ratio.

It is proposed not to set different nutrient levels for milk-based and non-milk based formula. The significantly lowered minimum copper level proposed for the Codex standard does not appear to be consistent with providing infants with the ESADI of copper and is not recommended for inclusion in the joint ANZ standard for infant formula. The minimum proposed at full assessment will provide for the needs of infants, therefore it is proposed to retain this minimum level in the standard plus the maximum proposed at full assessment for soy-based formula.

Recommendation

The following permissions for copper be provided in the joint ANZ Standard:
 Infant Formula and Follow-on formula - 14g to 43g

ZINC

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	0.12- not specified	as per infant formula
proposed at Full Assessment	0.12-0.36 (non soy based) 0.18-0.43 (soy based)	0.18-0.43
Codex	0.12- not specified	0.12- not specified
proposed Codex standard	0.12- not specified (0.18-0.6 soy based form)	Not applicable
LSRO recommendations	0.09-0.24	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.12 - 0.43	as per infant formula

Issues

Industry did not comment on the level of zinc except in relation to the zinc to copper ratio.

Assessment

High intakes of zinc have been associated with toxic responses in infants and significant interactions which affect bioavailability and utilisation of other nutrients are reported for zinc. Therefore high intakes of zinc pose a significant risk for infants and it is recommended the maximum zinc content of infant formula be regulated. In setting a maximum level the permissions for copper and iron must be considered.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 3-6 mg zinc and infants 7-12 months of age have a daily intake of 4.5 mg zinc. A formula at the maximum energy content which contains 0.02 mg zinc/100 kJ would provide an infant consuming 850 mL of formula or 0.01 mg zinc/100 kJ for an older infant consuming 1.3 L of follow-on formula with the RDI. However, the LSRO reports the absorption of zinc from formulas may be 1/3 less than that from breast milk and from soy-based formulas even less due to phytate content. The LSRO determined that a minimum zinc content of 0.9 mg zinc /100 kJ would assure adequate zinc absorption from all formulas.

Therefore it is recommended the minimum level proposed at full assessment be included in the joint ANZ standard for infant formula as this is consistent with Codex and will provide adequate zinc for the needs of infants. The maximum level proposed for follow-on formula and soy based infant formula is proposed to be included in the standard.

Recommendation

The following permissions for zinc be provided in the joint ANZ Standard.

Infant Formula and Follow-on formula - 0.12 mg to 0.43 mg

RATIO OF ZINC TO COPPER

Issues

It was proposed at full assessment that the ratio of zinc to copper must not be more than 10:1.

Submissions were made that Codex did not specify a zinc to copper ratio. However industry as a whole finds that a ratio is acceptable provided that it is high enough to meet the problems of formulation. Most submissions suggest 12 : 1 as an appropriate ratio.

Assessment

The LSRO noting the copper: zinc ratio of human milk is 1:10 reviewed studies of the interaction between copper and zinc. The LSRO concluded high copper: zinc ratio are hazardous for infants and noted suggestions that the copper: zinc ratio should not exceed 1:20 based upon adult toxicology studies. The needs of industry are likely to be met by a ratio of Copper: Zinc ratio of 1:12. Therefore it is advised this ratio be used in the manufacture of infant formula.

Modelling of a Zinc: copper ratio of 12:1 indicates sufficient copper in the formula if the maximum zinc levels are included in a formula.

In spite of no specification for the zinc to copper ratio existing in Codex, the ratio provides a safety measure to protect infants from the symptoms of copper deficiency.

Recommendation

The following permissions for the zinc to copper ratio be provided in the joint ANZ Standard:

Infant Formula, Follow-on formula - Zn : Cu not greater than 12 : 1

CHROMIUM

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	not specified	as per infant formula
proposed at Full Assessment	not specified (for proximate Modified Formula 3.5 mcg to 15 mcg)	as per infant formula
Codex	not specified	not specified
proposed Codex standard	not specified	Not applicable
LSRO recommendations	did not recommend Min or max levels	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	[Advisory guideline maximum of 15 mcg/100 kJ] for proximate modified formulas: 0.35- 15.0 mcg/100 kJ	as per infant formula

Issue

The decision to allow for chromium to be added to proximate modified formula is supported by industry. There appears to be a decimal point error in the levels proposed at full assessment.

Assessment

Chromium is believed to be linked to important metabolic actions and human milk has self limiting levels of chromium at 0.007-0.014 mcg/100 kJ independent of maternal intake according to the LSRO. No evidence of toxicity to chromium is known at present. Chromium may be involved in fat and carbohydrate metabolism and excess is required to be excreted in urine. High intakes are considered to pose an insignificant risk to infants at this stage. Therefore no maximum chromium content for infant formula is recommended for inclusion in the standard at this time.

The FDA has estimated a chromium intake of 10-40 mcg per day for infants to 6 months and 20-60 mcg per day for infants 6-12 months as safe and adequate dietary intakes. A formula at the maximum energy content which contains 1.57 mcg chromium /100 kJ would provide an infant consuming 850 mL of formula or an older infant consuming 1.3 L of follow-on formula which contains 1.38 mcg/100 kJ with the ESADI. The LSRO notes chromium is ubiquitous in the diet and it is unlikely a standard infant formula would be prepared with insufficient chromium. However, the joint ANZ standard also provides for some special purpose formulas which will not have an innate chromium content. Therefore a chromium content is required to be specified for those formulas.

The EP reconsidered the chromium content of formulas with protein in the form of extensively hydrolysed protein or solely in the form of amino acids and recommended the chromium content of proximate modified formula to 0.35 mcg to 2.0 mcg/100 kJ in the interests of infant health.

Recommendation:

0.35 mcg to 2.0 mcg chromium be a mandatory requirement for formulas with protein in the form of extensively hydrolysed protein or solely in the form of amino acids and included as advisory guideline levels for infant formula products.

MOLYBDENUM

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	not specified	as per infant formula
proposed at Full Assessment	not specified (for proximate Modified Formula 0.36 mcg to 0.71 mcg*)	as per infant formula
Codex	not specified	not specified
proposed Codex standard	not specified	Not applicable
LSRO recommendations	did not recommend a Min or max	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	[Advisory guideline maximum of 3.0 mcg/100 kJ] for proximate modified formulas: 0.36 - 3.0 mcg/100 kJ	as per infant formula

Issues

Industry supports the addition of molybdenum to proximate modified infant formula noting that molybdenum is an essential nutrient. Industry has requested a maximum of 3 mcg / 100 kJ if a maximum is necessary.

*Industry has pointed out an error in the units used which has been corrected in the preliminary inquiry drafting. The units should have been 'mcg' not 'mg'.

Assessment

No evidence of toxicity from high intakes of molybdenum is known at present. Therefore high intakes of molybdenum are considered to pose insignificant risk to infants and a maximum is not proposed to be included in the joint ANZ standard for infant formula. The LSRO noted that as molybdenum was ubiquitous in the diet, a regular infant formula was unlikely to be produced with a molybdenum content lower than human milk. However, the joint ANZ standard also provides for some special purpose formulas which will not have an innate molybdenum content. Therefore a minimum and maximum molybdenum content is recommended as a guide for manufacturers of these formulas.

Jensen (1995) reports the molybdenum content of human milk to be 1 ng/mL (10-20 ng/mL for colostrum). The FDA has estimated a molybdenum intake of 15-30 mcg per day for infants to 6 months and 20-40 mcg per day for infants 6-12 months as safe and adequate dietary intakes. A formula at the maximum energy content which contains 1.18 mcg molybdenum /100 kJ would provide an infant consuming 850 mL of formula or an older infant consuming 1.3 L of follow-on formula which contains 0.92 mcg/100 kJ with the ESADI.

Recommendation

The range 0.36 - 3.0 mcg molybdenum /100 kJ be provided as a requirement for formulas with protein in the form of extensively hydrolysed protein or solely amino acids formulas. This maximum level will provide 3X ESADI.

IODINE

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	1.2 -10	as per infant formula
proposed at Full Assessment	1.2 - 18	as per infant formula
Codex	1.2- not specified	1.2- not specified
proposed Codex standard	1.2-not specified	Not applicable
LSRO recommendations	1.9-8.3	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	1.2 - 10	as per infant formula

Issues

Submissions did not address the iodine content of infant formula. The USFDA limits the iodine content of infant formula at 17.8 mcg / 100 kJ.

Assessment

There are reports of potential toxicity in infants from high intakes of iodine, including premature infants and any excess iodine must be excreted by the kidneys. Therefore high intakes of iodine are considered to pose a significant risk for infants and the maximum iodine content of infant formula should be regulated. The LSRO considered the current level in the CFR of 17.8 mcg/ 100 kJ to be too high for infants and recommended the US government seek means to reduce the iodine content of infant formula sold in the USA. The LSRO noted there were no studies which reported on the efficacy of the minimum CFR requirement of 1.2 mcg / 100 kJ for infant formula.

The iodine content of human milk is reported to range from 4.81-9.21 or 3.89-9.52 mcg / 100 kJ but is significantly influenced maternal intake.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 50 mcg iodine and infants 7-12 months of age have a daily intake of 60 mcg iodine. A formula at the maximum energy content which contains 2.0 mcg iodine/100 kJ would provide an infant consuming 850 mL of formula or which contains 1.4 mcg iodine/100 kJ would provide an older infant consuming 1.3 L of follow-on formula with the RDI.

The LSRO reported that based on US data (Fisher, 1989), a milk-based formula without added whey proteins will provide about 7 mcg/100 kJ of iodine, from the iodine in cows' milk.

It is recommended the level currently included in Standard R7 be retained in the joint ANZ standard as the minimum level is consistent with Codex and the maximum level is more consistent with that recommended by the LSRO.

Recommendation

The following permissions for iodine be provided in the joint ANZ Standard:

Infant Formula and Follow-on formula - 1.2 - 10 mcg / 100 kJ

IRON

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	0.1-0.48	as per infant formula
proposed at Full Assessment	0.2-0.5	as per infant formula
Codex	0.25 - not specified 0.4 - not specified (soy based)	0.25-0.50
proposed Codex standard	0.12-0.36 0.25-0.5 (soy based)	Not applicable
LSRO recommendations	0.05-0.39	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.2-0.5 Min is proposed codex and max is soy Codex	as per infant formula

Issues

Some industry submissions questioned the increase to the maximum level and noted that intermediate levels have been adequate.

Assessment

High intakes of iron have been associated with toxic responses in infants and iron has significant interactions which affect bioavailability and utilisation of other nutrients. Therefore high intakes of iron pose a significant risk for infants and the maximum iron content of infant formula should be regulated. In setting a maximum level for iron the permissions for zinc and copper must be considered.

The LSRO considered the current maximum level of 0.7 mg/100 kJ which is set in the CFR to be unjustified and recommended the lower level of 0.39 mg/100 kJ. This maximum iron level when provided with a minimum copper content gives a iron : copper ratio which is considered to impose no risk of copper insufficiency.

Codex provides for formula with added iron and requires a formula with not less than 0.25 mg iron/100 kJ to be labelled 'infant formula with iron'. The proposed revised Codex standard has not agreed on the approach to iron fortified formula.

It was proposed at full assessment to raise the minimum level of iron from 0.1 to 0.2 mg / 100 kJ, essentially requiring all formulas to be iron fortified for the following reasons:

- the use of iron fortified formula is credited with a declining prevalence of anaemia in US infants;
- there is a lack of side effects (at this level) from constipation and inhibition of zinc and copper absorption;
- even mild iron deficiency may result in impaired cognitive and behavioural development, and the deleterious effects may be permanent;
- the amount of iron absorbed from commercial iron-fortified cereal is low and the amount of iron-fortified cereal consumed by infants is small.

The LSRO recommended a minimum iron of 0.05 mg/100 kJ based upon the intake a breastfed infant would receive, although recognising this level would place older infants at risk if no supplemental foods were consumed by the infants. In recommending the lower minimum level, the LSRO noted that some authorities in paediatric nutrition are of the opinion that a low iron content may be preferable during the first 4 months.

The EP was of the opinion that a separate category for iron supplemented formula was not appropriate as all formulas are expected to contain sufficient levels of all nutrients and agreed that the range in normal formula (0.2 - 0.5 mg/100 kJ) should remain as proposed at full assessment.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 3 mg iron and infants 7-12 months of age have a daily intake of 9 mg iron. A formula at the maximum energy content which contains 0.12 mg iron/100 kJ would provide an infant consuming 850 mL of formula or 0.21 mg iron/100 kJ for an older infant consuming 1.3 L of follow-on formula with the RDI.

Therefore it is recommended that the levels proposed at full assessment be included in the joint ANZ standard for infant formula as these levels can accommodate the needs of infants to 12 months.

Recommendation

The following permissions for iron be provided in the joint ANZ Standard:

Infant Formula and Follow-on formula 0.2 mg to 0.5 mg / 100 kJ

MAGNESIUM

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	1.2 -not specified	as per infant formula
proposed at Full Assessment	1.4-3.6	as per infant formula
Codex	1.4 - not specified	as per infant formula
proposed Codex standard	1.2-3.6	Not applicable
LSRO recommendations	0.9-4.05	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	1.2-4.0	as per infant formula

Issues

Industry requests a maximum of 4.5 mg to allow for the level of magnesium in goats' milk.

Assessment

High intakes of magnesium have been associated with toxic responses in adults, and significant interaction with other nutrients is reported for magnesium. Therefore high intakes of magnesium are considered a significant risk for infants and it is recommended the maximum level of magnesium in infant formula be regulated in the joint ANZ standard for infant formula. The EP agreed that a maximum of 4.5 mg is suitable for infant formula.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 40 mg magnesium and infants 7-12 months of age have a daily intake of 60 mg magnesium. A formula at the maximum energy content which contains 1.6 mg magnesium/100 kJ would provide an infant consuming 850 mL

of formula or which contains 1.4 mg magnesium/100 kJ would provide an older infant consuming 1.3 L of follow-on formula with the RDI.

The minimum magnesium content proposed for the revised Codex Standard is 1.2 mg/100 kJ which is consistent with that required by the EC and the UK. Therefore it is recommended the minimum requirement for magnesium in the joint ANZ infant formula standard be lowered to 1.2 mg/100 kJ. To accommodate the needs of industry, the maximum proposed at full assessment could be safely increased to 4.0 mg /100 kJ as recommended by the LSRO. This will provide 2.5x the RDA for infants.

Recommendation

The following permissions for magnesium be provided in the joint ANZ Standard:

Infant Formula	1.4 mg to 4.0 mg
Follow-on formula	1.4 mg to 4.0 mg

MANGANESE

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	1.2-not specified	as per infant formula
proposed at Full Assessment	1.2-13 (1.2- 7.2 for proximate modified formula)	as per infant formula
Codex	1.2-not specified	not specified
proposed Codex standard	1.2-not specified	Not applicable
LSRO recommendations	0.24-23.8	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.24-24.0 (Advisory guideline maximum 7.2 mcg/100 kJ for formulas for infants with liver disease)	as per infant formula

Issues

The main issue to arise is the maximum manganese level for different formulas. Submissions request the maximum level of manganese for proximate modified formulas be increased to the level of regular infant formulas as hydrolysed protein and soy formula have levels higher than the 7.2 mcg /100 kJ. The current Codex Standard has not specified a maximum and no maximum is currently proposed for the revised Codex Standard. The minimum level is agreed at 1.2 mcg /100 kJ.

Assessment

Significant interaction of manganese with other nutrients which affect bioavailability and utilisation of other nutrients has been reported. High intakes of manganese are considered to pose a significant risk for infants and it is recommended that the maximum manganese of infant formula be regulated.

The FNB has estimated a manganese intake of 0.3-0.6 mcg per day for infants to 6 months and 0.6-1.0 mcg per day for infants 6-12 months as safe and adequate dietary intakes. A formula at the maximum energy content which contains 0.02 mcg manganese /100 kJ would provide an infant consuming formula as the principal source of nourishment with the ESADI. However, the LSRO notes reports which suggest the level of manganese estimated as a safe and adequate dietary intake for infants and levels found in infant formula may be too high. On the basis of extensive review, the LSRO has recommended the minimum level of manganese in infant formula be much lower than proposed at full assessment or included in the Codex standard, therefore is recommended this lower minimum be included in the joint ANZ standard for infant formula. The maximum level recommended by the LSRO is also recommended to be included in the joint ANZ standard.

The concern that some infants with liver disease may not be able to excrete usual levels of manganese suggests manufacturers should be advised to prepare formula for such infants with a much lower manganese content. Therefore is proposed to include 7.2 mcg manganese /100 kJ as a guideline level for such formulas.

Recommendation

The following permissions for manganese be provided in the joint ANZ Standard:

Infant formula and Follow-on formula - 0.24-24.0 mcg / 100 kJ
Proximate modified formula - Advisory guideline maximum level of 7.2 mcg / 100 kJ

POTASSIUM

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	20-50	as per infant formula
proposed at Full Assessment	20-50	as per infant formula
Codex	20-50	20-not specified
proposed Codex standard	20-35	Not applicable
LSRO recommendations	14.8-38.1	as per infant formula

PROPOSED AT PRELIMINARY INQUIRY	20-50	as per infant formula
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Issues

Industry requested an upper limit of 65 mg / 100 kJ to accommodate goat milk.

Assessment

High intakes of potassium have been associated with adverse effects in infants, and potassium makes a significant contribution to RSL as excess potassium is required to be excreted by the kidneys. Therefore high intakes of potassium are considered to pose a significant risk to infants and the maximum level of potassium is recommended to be regulated.

The US safe and adequate level for the 7-12 month age group is 700 mg/day (35.6 mg/100 kJ). The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 390-580 mg potassium and infants 7-12 months of age have a daily intake of 470-1370 mg potassium. A formula at the maximum energy content which contains 22.7 mg potassium (19.0 mg potassium (midrange value)) /100 kJ would provide an infant consuming 850 mL of formula or which contains 31.5 mg potassium (21.0 mg potassium (midrange value))/100 kJ would provide an older infant consuming 1.3 L of follow-on formula with the RDI. Therefore the minimum level provides for the needs of infants.

The EP reconsidered the maximum level for potassium content in response to industry's request but recommended that the maximum level should not be raised to 65 mg for infant formula. It is noted lower levels are proposed for the Codex revised infant formula standard and that the LSRO recommended a maximum of 38 mg/100 kJ.

Recommendation

The permissions for potassium proposed at full assessment be retained in the joint ANZ Standard as these are consistent with the Codex requirements:

Infant formula and Follow-on formula - 20 mg – 50 mg / 100 kJ

SODIUM

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	5- not specified	as per infant formula
proposed at Full Assessment	5-14	as per infant formula
Codex	5-15	5-21
proposed Codex standard	5-15	Not applicable
LSRO recommendations	5.9-11.9	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	5-15	as per infant formula

Issues

There were no industry submissions about the sodium range.

Assessment

High intakes of sodium have been associated with adverse effects in adults and infants. Sodium makes a significant contribution to RSL, as excess is required to be excreted by the kidneys. High sodium has also been reported to have a negative impact on calcium balance. Therefore it is considered high intakes of sodium pose a significant risk to infants and the maximum level of sodium in infant formula should be regulated.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 140-280 mg sodium and infants 7-12 months of age have a daily intake of 320-580 mg sodium. A formula at the maximum energy content which contains 11.0 mg sodium (8.2 mg sodium (midrange value)) /100 kJ would provide an infant consuming 850 mL of formula or which contains 13.3 mg sodium (10.3 mg sodium (midrange value))/100 kJ would provide an older infant consuming 1.3 L of follow-on formula with the RDI. Therefore the minimum level provides for the needs of infants.

It is noted that the Codex maximum figures are just above the range proposed for the ANZ joint Standard, except for follow-on formula which is significantly above the Australian recommendation. It is proposed to align the sodium range in the joint ANZ standard for infant formula with the range in the Codex standard.

Recommendation

The following permissions for sodium be provided in the joint ANZ Standard

Infant Formula and Follow-on formula - 5 mg to 15 g/100 kJ

SELENIUM

Current provisions and proposed provisions

	Infant formula mcg/100 kJ	Follow-on formula mcg/100 kJ
current R7	not specified	as per infant formula
proposed at Full Assessment	0.42-0.89	0.79-0.89
Codex	not specified	not specified
proposed Codex standard	not specified - 0.7	Not applicable
LSRO recommendations	0.36-1.19	as per infant formula
PROPOSED AT PRELIMINARY INQUIRY	0.36- 0.9	as per infant formula

Issues

Submissions regarded the minimum levels as too high.

Assessment

High intakes of selenium have been associated with toxic responses in adults, and potential interactions which affect bioavailability and utilisation of other nutrients are known for selenium. Therefore high intakes of selenium are considered to pose a significant risk to infants and the maximum selenium content of infant formula level should be regulated as proposed at full assessment.

The NHMRC recommends bottle fed infants up to 6 months of age have a daily intake of 10 mcg selenium and infants 7-12 months of age have a daily intake of 15 mcg selenium. A formula at the maximum energy content which contains 0.39 mg selenium /100 kJ would provide an infant consuming 850 mL of formula or which contains 0.34 mcg selenium /100 kJ would provide an older infant consuming 1.3 L of follow-on formula with the RDI. Therefore it is recommended the minimum level be decreased to 0.36 mcg/100 kJ which is consistent with the LSRO recommendations and will provide for the needs of infants. The maximum proposed at full assessment provides approximately 2.5 x RDA and is more liberal than currently being proposed for Codex.

Additional selenium would also be contributed from other foods consumed by the infant . The minimum for proximate modified formula should be lowered to 0.36/100 kJ, for consistency with normal and follow on infant formula.

Recommendation

The following permissions for selenium be provided in the joint ANZ Standard.

Infant Formula, Follow-on formula, Proximate Modified Formula -
0.39 mcg to 0.9 mcg/100 kJ

OPTIONAL NUTRITIONAL SUBSTANCE CONTENT OF INFANT FORMULAS

Submissions were received about the nucleotide, carnitine, choline, inositol and taurine content and the following assessment of these nutrients should be read in conjunction with the Full Assessment Report published in 1995. The policy previously established for claims about infant formula content of optional nutrients is reaffirmed. Therefore, a minimum level which will be specified in the standard must be present in the formula for declaration of content. This minimum level will be based upon the levels in human milk.

Nutritional substances other than the macronutrients (protein, fat carbohydrate), vitamins and minerals require clearer definition in the joint ANZ Food Standards Code as these may be added to foods but are not currently considered 'food additives' and are not 'foods'. Such review and assessment is broader than the requirements for infant formula, therefore the definition of 'nutritional substance' (or alternative term) will be considered by the P166 - review of vitamins and minerals for the purposes of the development of a joint ANZ Food Standards Code. For the purposes of the development of a joint infant formula standard, the term 'nutritional substances' will be used for substances which are not: foods, food additives, macronutrients, vitamins or minerals (including electrolytes).

NUCLEOTIDES

The permission to add nucleotides is not specifically granted in the current infant formula standard. Some infant formulae sold in the USA, ECC, Japan and Australia already contain nucleotides. It was proposed at full assessment to give permission for the addition of five specific nucleotides to infant formula and to regulate the maximum total nucleotide content and the maximum content for each of the five individual nucleotides permitted to be added to infant formulas. It was also proposed to require a minimum specified content for a claim about nucleotide content.

In general, the inclusion of nucleotides as optional nutritional substances is supported. However, opinion was expressed that scientific evidence seems to be premature as to the forms of nucleotides that may be added, limitations on levels added, safety and stability etc.

One submitter noted that some nucleotides bind strongly to milk proteins and may be difficult to measure. Therefore care must be used since current chemical analysis may not detect particular added nucleotides.

INOSINE MONOPHOSPHATE (IMP)

Issues

The Authority requested submission on the permission to add IMP to infant formula as a recent publication had raised doubts as to whether IMP was present in human milk.

Submission was made that:

- although recent literature suggests that the level of IMP in human milk is lower than previously reported, IMP is the known precursor in the biosynthesis of adenosine mono phosphate (AMP) and guanosine monophosphate (GMP) and it would be expected that IMP present in formulas would be converted to GMP and AMP once absorbed into cells;
- since the status of IMP in human milk has not been proven, permission to include in infant formula should not be granted; and
- there is only one paper suggesting that IMP may be a sample preparation artefact and therefore IMP should be permitted only if there is further evidence to substantiate this claim.

Assessment

There is some uncertainty as to the derivation of the IMP detected in human milk sample analyses. The UK and EC infant formula food standards give permission for the addition of IMP. The Life Science Research Organisation's assessment of nutrient requirements for infant formulas (LSRO) has not considered individual nucleotide contents but it does not prohibit IMP. Therefore in the absence of evidence of specific harm to infants from IMP, permission for use in formulas is recommended.

PERMITTED LEVELS OF NUCLEOTIDES

Issues

There was support for the levels included in the draft standard although one industry submission requested an increase to the maximum level to achieve the average total potentially available nucleotides in breast milk.

Submission noted that the total limit on nucleotides of less than 1.2 mg/100 kJ in the draft revised standard is lower than the sum of maximum permitted

levels of individual nucleotides specified in the table to the draft revised standard.

Assessment

Codex does not give specific permission for the addition of nucleotides but gives permission through a general permission for 'nutrients other than vitamins and minerals' to be added provided these are normally found in human milk, have been shown to be useful and the levels should be based upon those normally found in human milk. There are significant variations reported for the nucleotide content of human milk due to lack of standardised analytical methodology. Consequently standardising to human milk levels is currently difficult.

The maximum levels proposed for the inclusion of the nucleotides CMP, UMP, AMP, GMP, IMP in infant formula are consistent with the maximum levels stated in the EC directive. In 1996 the Scientific Committee for Food in assessing an application to increase the levels threefold, did not agree to increase the levels of nucleotides from these levels as there was no evidence of health benefit for infants from the higher levels.

The LSRO did not find reason to require the addition of nucleotides to infant formula, although noted there is some evidence of their potential benefit to infants. The LSRO recommended a maximum content of 16 mg/100 kcal (3.8 mg/100 kJ) 'nucleotides and nucleotide precursors' in infant formula; a value claimed to be similar to the upper limit reported for human milk.

It is proposed to permit the use of the five nucleotides currently being added to infant formula and to regulate the total nucleotide content at a level consistent with the upper limit reported for human milk. The specific levels proposed at full assessment for five specific nucleotides were justified in the full assessment report. The sum of the maximum permitted levels for individual nucleotides proposed is more than the total permitted nucleotide content allowing manufacturers more flexibility in formulation. This permission is consistent with the EC provisions, will facilitate trade in these infant formulas and has the potential to offer advantage to some infants who consume formula. Therefore it is recommended that the permissions proposed at full assessment be included in the joint ANZ standard for infant formula.

PURITY OF NUCLEOTIDES

Issue

The New Zealand Ministry of Health sought assurance that appropriate purity standards would be achieved for the nucleotides permitted to be added to infant formula.

Assessment

Manufacturers need to be sure of the safety and purity of the different forms of nucleotides added to infant formula. Until further evidence of safety and efficacy, only 5 of the 13 nucleotides which have been isolated from human milk are recommended to be permitted to be added to infant formula standardised in the joint ANZ infant formula standard. These proposed permitted forms are consistent with those permitted by the EC.

Specifications for purity have been supplied by industry as follows:

A) Description/ Physical Constraints

Inosine - 5' monophosphate disodium salt (IMP)

1. Chemical nomenclature: $C_{10}H_{11}N_4Na_2O_8P \cdot 7.5H_2O$
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 grams is soluble in 100g of water at 20°C; is stable in acid liquids under the identical conditions

Uridine - 5' monophosphate disodium salt (UMP)

1. Chemical nomenclature: $C_9H_{11}N_2O_9PNa_2$
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: $C_{10}H_{14}N_5O_7P$

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 disodium monophosphate 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 grams is soluble in 100g of water at 20°C; becomes gelatinous in acid liquids under the identical conditions

B) 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:

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

3. Assay (HPLC):
Optimum - not less than 96% (corrected for moisture content).

4. IMP and GMP have a pH of a 1 in 20 solution: between 7.0 and 8.5

5. Clarity and colour of solution:

500mg/10 mL H₂O for IMP : is colourless and shows only a trace of turbidity

100 mg/10 mL H₂O for GMP : is colourless and shows only a trace of turbidity

6. Moisture

Inosine - 5' monophosphate disodium salt	Not more than 28.5%: Karl Fischer
Uridine - 5' monophosphate disodium salt	Not more than 26.0%: Karl Fischer
Guanosine - 5' monophosphate disodium salt	Loss in drying - not more than 25% (4 hrs @ 120°C)
Cytidine - 5' monophosphate	Not more than 6.0%: Loss in drying (4 hrs @ 120°C)
Adenosine- 5' monophosphate	Not more than 6.0%: Loss in drying (4 hrs @ 120°C)

7. Impurities - all nucleotides

Impurity	Nucleotide
amino acids: negative	IMP, GMP
ammonium salts: negative	IMP, GMP
arsenic: not more than 2ppm	IMP, UMP, AMP, CMP, GMP
heavy metals: not more than 10ppm	IMP, UMP, AMP, CMP, GMP

8. Related foreign substances:

For IMP: only 5' - inosinic acid is detected by thin layer chromatography.

For GMP: only 5' - guanylic acid is detected by thin layer chromatography.

9. Bacteriological profile

- a) SPC: not more than 1000/g, test per current FDA/BAM procedures
- b) Coliforms: Negative by test; test per current FDA/BAM procedures
- c) Yeast and mould: not more than 300/g, test per current FDA/BAM procedures
- d) Salmonella: negative, test per current FDA/BAM procedures

Recommendation

The provisions for nucleotide inclusion in infant formula proposed at full assessment are recommended for inclusion in the joint ANZ standard for infant formula. These are that five specific nucleotides should be permitted as optional ingredients in infant formula provided the total maximum nucleotide level is not more than 1.2 mg/100 kJ. Claims for nucleotide content should only be made if a minimum specific amount of nucleotide is present in the formula to ensure carers are not misled by information about these unfamiliar constituents of formula. Comment is sought on the specifications for nucleotides provided by industry.

CHOLINE

Current and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	not specified	as per infant formula
proposed at Full Assessment	0 - 5.4 (1.7 for claim)	as per infant formula
Codex	1.7 - maximum not specified	1.7 - maximum not specified
proposed Codex standard	1.7 - maximum not specified	Not applicable
LSRO recommendations	1.7 - 7.1	as per infant formula

proposed at Preliminary Inquiry	0 - 7.1 (1.7 for claim)	as per infant formula
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Issues raised

Submissions from two food industry groups claim the existing maximum level may not be technically feasible because of naturally high and seasonal variability in levels of free choline in whey proteins. Anchor (NZ Dairy Group) claim the seasonal variation of choline in milk solids is 55 - 95 mg/100 g (measured in whole milk powder) and in addition to the choline in milk, a maximum of 5 g/L of lecithin must be accounted for in setting the choline maximum.

Maximum levels of 7-10 mg/100 kJ are requested.

Assessment

The Codex standard requires a minimum choline content but does not specify a maximum level for choline. No maximum level has been agreed for the proposed revised Codex standard.

The maximum level of choline in infant formula was reviewed by the previous Expert Panel who noted:

- i) the range for choline should remain as specified at full assessment, namely 1.7 - 5.4 g/L, because the maximum covers technological need (i.e. the maximum corresponds to the maximum permitted level of lecithin, 5 g/L);
- ii) choline **or choline equivalents** should be permitted within the specified range, where choline equivalents are defined as "lecithin (phosphatidyl choline) and phosphatidic acids calculated as choline"; and
- iii) the permission relates to **total** choline, as is the case with all other nutrients, because chemical analysis does not distinguish between different sources of a nutrient.

As a dietary requirement has been demonstrated for animals although not yet for humans, the LSRO recommended infant formula contain 1.7 mg choline /100 kJ based upon the lower level of the range found in human milk. It was also suggested that infants may have a higher need for choline than older humans. It is not proposed to mandate a choline content in infant formula as although Codex requires a choline content, the dietary use for choline is still inconclusive and it has not been declared an essential nutrient.

The LSRO was unaware of studies designed to assess the toxicological or nutritional aspects of choline in infant formula and recommended that the

maximum level of choline in infant formula be 7mg/100 kJ. This recommendation was based upon extrapolation from adult data on the safe level of intake with allowances for age-related metabolic differences. The maximum level recommended by the LSRO is based upon more recent information than the Expert Panel decision and therefore is recommended for inclusion in the joint standard for infant formula. As proposed at full assessment, formula should contain at least a minimum choline content of 1.7 mg/100 kJ if any claim is made for choline content.

Recommendation

Choline should be permitted as an optional nutritional substance for use in infant formula. Infant formula should not contain more than 7mg choline or choline equivalents/100 kJ and must contain at least 1.7 mg choline or choline equivalents/100 kJ if a claim for choline content is made.

CARNITINE

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	0.27 - maximum not specified	as per infant formula
proposed at Full Assessment	minimum not specified- 0.42 (Minimum for claim: 0.21)	as per infant formula
Codex	not specified	not specified
proposed Codex standard	not specified	Not applicable
LSRO recommendations	0.28 - 0.48	as per infant formula
proposed at Preliminary Inquiry	minimum not specified- 0.8 (Minimum for claim: 0.21)	as per infant formula

Issues raised

Industry submissions note the specified maximum may not be technically feasible in milk-based formulations, because level of carnitine in milk is so naturally high and that the maximum level proposed at full assessment, 0.42 mg/100 kJ, is less than the natural level of carnitine typically in formulae, 0.6-0.8 mg/100 kJ. Submission was also made that carnitine is usually added to soy-based formulas at levels of 0.48 - 0.72 mg/100 kJ which would exceed proposed maximum levels.

It was also submitted that the proposed provision does not clarify whether more than the specified maximum is permitted if it is from a natural contribution and there is no mention made of carnitine under 'Other permitted additions' to provide for the addition of carnitine.

Assessment

The Codex standards and proposed Codex standard do not include a specific provision for the addition of carnitine. However, there are increased health benefits for some infants by the inclusion of this provision as the full assessment report noted:

'Requirements for carnitine are met by endogenous synthesis and by diet. Newborn infants appear to have reduced stores of carnitine as well as a low capacity for synthesising it; in the absence of an endogenous supply, their carnitine stores could be depleted by two and a half months. When normal infants are fed carnitine-free diets, plasma carnitine decreases to low levels, there is an increase in the concentration of free fatty acids in plasma and there is increased urinary excretion of medium-chain dicarboxylic acids. However, it is not known whether having a low plasma carnitine has demonstrable functional consequences.

In contrast to human milk and formulae based on cow's milk protein, soy based formulae have no intrinsic L-carnitine. Although there is no unequivocal evidence that infants fed soy based products are at serious

risk of developing carnitine deficiency, the ESPGAN Committee on Nutrition support the view that soy-based formulae should be supplemented to a level approximating that in human breast milk'.

At full assessment provision was made for addition of carnitine to infant formula as an optional ingredient on the basis that carnitine is normally present in human milk; there is no safety concern; there are some data suggesting that its addition to infant formulae (especially soy formulas) could be of nutritional benefit to infants; Standard R7 requires L carnitine to a level of 0.27 mg/100 kJ; and the EC Directive requires a minimum carnitine level of 0.29 mg /100 kJ in formula containing soy protein isolates, and it is permitted (level unspecified) by Codex, the US and New Zealand.

The LSRO noted that while evidence that carnitine is essential for term infants is not convincing, there are anecdotal reports of abnormal clinical manifestations in infants fed diets low in carnitine. Therefore the LSRO recommended a minimum of 0.28 mg carnitine /100 kJ in infant formula. However, the LSRO was unaware of any toxicological studies for infant exposure to carnitine and in the absence of data concluded the maximum should be set at 0.48 mg/100 kJ which is the level in human milk.

As proposed at full assessment, formula should contain at least the minimum carnitine content of human milk (0.21 mg/100 kJ) if any claim is made for carnitine content.

The maximum levels specified was based on human milk values, i.e 0.21 - 0.42 mg/100 kJ. The maximum level of carnitine in infant formula was subsequently reviewed by the previous expert panel who agreed that :

- i) the maximum level proposed at full assessment could be raised from 0.42 mg/100 kJ proposed at full assessment to 0.8 mg/100 kJ, as requested, to accommodate the natural level of carnitine typically found in cows' milk-based formulae (0.6 - 0.8 mg/100 kJ) due to the high level of carnitine in cows' milk; and
- ii) it should be clarified that permission relates to **total** carnitine .

Recommendation

It is recommended the maximum permitted level in the joint ANZ standard for carnitine in infant formula be 0.8 mg/100 kJ.

The permission is given to afford infants who consume soy based formula similar health advantages as those who consume milk based formula.

INOSITOL

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	not specified	as per infant formula
proposed at Full Assessment	minimum not specified- 5.4 (minimum for claim 1.0)	as per infant formula
Codex	not specified	not specified
proposed Codex standard	not specified	Not applicable
LSRO recommendations	0.95 - 9.5	as per infant formula
proposed at Preliminary Inquiry	minimum not specified- 9.5 (minimum for claim 1.0)	as per infant formula

Issues raised

An industry submission has requested an increase in the maximum permitted level for inositol from 5.4 mg/100 kJ to 7 mg/100 kJ claiming the current maximum does not allow for any overage.

Assessment

Of the major international regulations for infant formula only the CFR specifies a minimum inositol content. The minimum inositol content required is 0.95 mg/100 kJ but no maximum is specified in the CFR.

The LSRO reviewed several studies of human milk inositol levels which reported levels which ranged from 5 - 12 mg/100 kJ, although levels decreased over lactation. Inositol content in plants exists as phytate and therefore is likely to impact on the bioavailability of several essential nutrients. The LSRO has recommended that although the essentiality of dietary inositol is still unresolved, infant formula should contain a minimum of 4 mg/100 kCal (0.95 mg/100 kJ) and a maximum of 40 mg/100 kcal (9.5 mg/100 kJ) myo-inositol which is based upon the level in human milk.

Inositol has not been declared an essential nutrient for infants. Therefore the addition of inositol to soy formulae, as requested, should not be mandated, because there is no evidence that it is necessary. Imposition of a mandatory minimum content in the joint ANZ standard would be more prescriptive than Codex and may constitute a technical barrier to trade.

It is recommended that inositol be permitted as an optional ingredient, and that a maximum content based upon the levels found in human milk be specified. The maximum in the joint standard could be raised from 5.4 mg/100 kJ to 9.5 mg/100 kJ which is consistent with levels found in human milk .

As proposed at full assessment, formula should contain at least a minimum inositol content of 1 mg/100 kJ if any claim is made for inositol content.

Recommendation

Inositol be permitted as an optional nutritional substance and the maximum level be set at 9.5 mg/100 kJ which is consistent with levels found in human milk and recommended by the LSRO. Formula should contain at least 1 mg/100 kJ of inositol if any claim is made for inositol content.

TAURINE

Current provisions and proposed provisions

	Infant formula mg/100 kJ	Follow-on formula mg/100 kJ
current R7	1.5 mg/kJ	as per infant formula
proposed at Full Assessment	minimum not specified -3 (minimum for claim 0.8)	as per infant formula
Codex	not specified	not specified
proposed Codex standard	not specified	Not applicable
LSRO recommendations	0 - 3.0	as per infant formula
proposed at Preliminary Inquiry	minimum not specified -3 (minimum for claim 0.8)	as per infant formula

There is evidence that taurine may be involved in infant development although no agencies have declared taurine to be an essential nutrient for infants.

The LSRO did not find any reason to require a taurine content in infant formula but recommended a maximum of 12 mg/100 kcal (3 mg/100 kJ) taurine for infant formula based upon the upper limit in human milk.

Taurine has not been declared an essential nutrient for infants. Therefore it is recommended that taurine be permitted as an optional ingredient, and that the maximum content proposed at full assessment be specified in the standard as it is based upon the levels found in human milk. As proposed at full assessment, formula should contain at least a minimum taurine content of 0.8 mg/100 kJ if any claim is made for taurine content.

Recommendation

Taurine be permitted as an optional nutritional substance and the maximum level be set at 3 mg/100 kJ which is consistent with levels found in human milk. Formula should contain at least 3 mg/100 kJ of taurine if any claim is made for taurine content.

CLAIMS ABOUT OPTIONAL NUTRITIONAL SUBSTANCES

Industry submitted that the position proposed at full assessment was not clear for the circumstance of when an optional ingredient is added at less than the minimum level specified for a claim. Industry also questioned the position about claims for information leaflets for medical detailing.

Assessment

A minimum claimable level is set for optional ingredients to ensure carers of infants are provided with meaningful information and are not misled as to the significance of an ingredient for their infant. It is intended that an optional ingredient added at less than the claimable amount would be listed in the statement of ingredients, but not in the NIT. For a claim to be made, the minimum amount must be present allowing a listing in the NIT and thereby a claim.

Publications

The provisions in the Food Standard Code cover all types information about foods, including infant formula. Therefore information on leaflets for medical detailing would need to comply with the same regulations as for food labels and therefore no claims for optional nutritional substance content should be made unless the minimum amount is present.

THE OSMOLALITY OF INFANT FORMULA

Current provisions

The existing Standard R7, Infant Formula, has a requirement for infant formula to have an osmolality of not more than 325 mOsm/kg. The Codex standards do not specify an osmolality value

An osmolality level of 325 mOsm/kg was proposed for infant formula, follow-on formula and pre-term formula, and 360 mOsm/kg was proposed for proximate modified formula at full assessment.

Issues

Submission was received suggesting the osmolality levels of all infant formulas should be 360 mOsm/kg.

Assessment

Osmolality refers to the number of osmoles of the particles (solutes) in a kg of solvent. It is generally expressed as milliosmoles (mOsm) a measure of osmotically active particles per kilogram of water. Electrolytes, amino acids and simple sugars all contribute significantly to the osmolality of a solution or liquid feeding. However, Fomon ⁽¹²⁾ reports the solute concentration of a feed does not indicate the renal solute load (RSL) of the feed.

The RSL is the amount of metabolic waste products that must be excreted by the kidney. Protein, sodium, potassium, phosphorus and chloride are the main dietary contributors to RSL. It is an important consideration in infant feeding, primarily during the first six months of life, when the kidney's urine

concentrating ability is limited. Adequate fluid must be available to excrete wastes, maintain water balance and prevent dehydration.

The LSRO reports the potential renal solute load (PRSL) of human milk to be 3.33 mOsmol/ 100 kJ, cow's milk to be 10.95 mOsmol/ 100 kJ and soy based formula to be 6.2 mOsmol/ 100 kJ. The LSRO reports that the PRSL of whole cow's milk is considered too high for the food to be used safely as sole food for infants.

The LSRO reported Ziegler and Fomon (1989) after reviewing epidemiological data noted infants consuming formulas providing a PRSL of 9.3 mOsmol/ 100 kJ or more were at a substantially higher risk of developing hypertonic dehydration during illnesses than infants fed human milk (PRSL is approx 3.33 mOsmol/ 100 kJ). Intervention to reduce the PRSL as a result of public health policy in the UK lead to a decrease in the incidence of hypernatremic dehydration.

Fomon (12) suggests the following formula as suitable for estimating the PRSL of a formula with the assumption that all dietary nitrogen is converted to urea.

<p style="text-align: center;">Potential Renal Solute Load (PRSL) in mOsmol/100 kJ</p> $= [\text{Na (mg)} / 23^*] + [\text{Cl (mg)} / 35^*] + [\text{K (mg)} / 39^*] + [\text{P (mg)} / 31^*] + [\text{protein (mg)} / 175^{**}]$
--

* conversion factor for nutrient from mg to mmol

** PRSL from protein is protein (mg)/175 where PRSL from nitrogen content of the diet is 14 (atomic weight of N) * 2 as urea contains 2 atoms of N = N / 28. However, there are 6.25 mg protein / 100 mg nitrogen .

Fomon (12) notes that the actual RSL is the PRSL minus the PRSL lost through non renal pathways and that used for growth and may be estimated as PRSL - (0.9 * weight gain (g/day)).

Using the above equation, modelling of the PRSL provided by infant formulas for healthy infants manufactured to the:

- minimum electrolyte and protein levels currently proposed indicates a PRSL range of 3.83 (regular infant formula) to 7.74 mOsmol/100 kJ for follow-on formula; or
- maximum electrolyte and protein levels currently proposed indicates a PRSL range of 7.74 if phosphorus is 25 mg/100 kJ as currently proposed for the standard (regular infant formula) to 11.17 mOsmol/100 kJ for follow-on formula.

For special purpose formulas similar modelling of the PRSL indicates a maximum PRSL of 11.74.

The safety of formula for infants is influenced by the PRSL of the formula. Dehydration is life threatening and the risk of dehydration can be minimised by avoiding highly concentrated feeds with high renal solute loads and limited water and also by delaying the introduction of solids until 4-6 months. Evidence indicates a PRSL of 3 times the level in human milk contributes significantly to the incidence of infant hypernatremic dehydration. Modelling indicates the protein and electrolyte permissions granted to follow-on formula and infant formula based upon protein substitutes for specific dietary use could create unacceptably high PRSLs which may increase the risk of dehydration for infants. Whilst the kidneys of older infants are more capable of handling high PRSLs, the introduction of solid foods which have a very high PRSL and low water content necessitates a limitation on PRSL for formulas prepared for older infants. Therefore it is recommended the regulation for the osmolality of the formula be replaced by a regulation for PRSL as this is more critical to the health of infants. The PRSL of infant formula is controlled to safe levels by the permitted protein and electrolyte levels and it is not necessary to prescribe a PRSL for infant formula. However, there is a need to regulate the maximum PRSL of follow-on formula and infant formula based upon protein substitutes for specific dietary use to protect the health of infants. The LSRO has limited the potential PRSL of formulas to 7.86 mOsmol/100 kJ due to the recommended limits for electrolytes and protein. It is recommended that to reduce the risk of dehydration in infants the maximum PRSL of formulas be restricted to 2.5 X PRSL of human milk or 8 mOsmol/100 kJ.

On these grounds, it is recommended that the maximum PRSL of follow-on formula and infant formula based upon protein substitutes for specific dietary use be regulated to 8 mOsmol/100 kJ. There is no such regulation in the Codex standard but it is recommended that it be included in the joint ANZ standard for infant formula even though it is an extra regulation which Codex does not require.

Recommendation:

It is recommended to reduce the risk of dehydration in infants the maximum PRSL of follow-on formula and infant formula based upon protein substitutes for specific dietary use be restricted to 8 mOsmol/100 kJ.

CONCLUSION TO INQUIRY INTO NUTRITIONAL COMPOSITION OF INFANT FORMULA.

In order to satisfy the health and safety requirements for infants, the standard should stipulate the nutritional composition of infant formulas to provide fully for the nutritional needs of infants at all stages of growth and development.

Unlimited nutrient contents for infant formulas represented as human milk substitutes are not recommended in the best interests of infants. For nutrients considered as essential, a range of contents within minimum and maximum levels is recommended to ensure that the amounts of nutrients available from formula products are both safe and adequate to support health.

A less prescriptive and less restrictive standard for infant formula can be achieved by the provision of a statement of essential composition such as 'Infant formula is a product based on milk or other edible constituents of animal or plant origin, suitable for infant feeding and intended to be the principal source of nourishment for infants. Such as statement increases the scope of permitted ingredients for infant formula manufacture and eliminates the need for specific prohibitions on unsafe ingredients benefiting both infants who consume formula and industry. Infant formula should be required to be 'gluten free' as this affords an additional measure of protection by reducing the risk of coeliac disease to infants in Australia and New Zealand. It is recommended that novel ingredients or novel sources of ingredients be assessed as safe and suitable for infant feeding before being used in formulas marketed for infants in Australia and New Zealand.

The protein content and the protein quality of infant formulas should be regulated as recommended to protect Australian and New Zealand infant consumers. Specification of protein source is unnecessary if protein content and quality are regulated. However, information about the source of protein should be required to be included on the label of the formula 'in close proximity to name of the food' to enable carers to make appropriate food choices for their infant.

The total energy, total fat and essential fatty acids content is recommended to be regulated to ensure infants who are formulas fed receive sufficient but not excessive energy and fatty acid intakes. Fatty acids which are considered harmful to infants are recommended to be restricted where necessary to protect infants from adverse health consequences. Therefore, limits are recommended for *trans*-fatty acids and erucic acid which are considered unsafe for infants. Limits are also recommended for specific LCPUFAs, such as arachidonic acid, DHA and EPA where although known to be present in human milk, evidence about the usefulness and efficacy for these fatty acids is not yet available. All ingredients used in the manufacture of infant formula are required to be suitable for use in infant feeding. This requirement plus the generic requirement that food for sale must be fit for human consumption prohibits the use of unsafe ingredients without the need for specific prohibitions on sources of fats in the standard.

The carbohydrate content of infant formula is controlled by the general composition permissions and the energy, protein and fat requirements. Therefore specific provisions for carbohydrate source are not necessary and

would be unnecessarily restrictive. However, a general reference to the total carbohydrate content is included in the regulation to clarify the requirement for carbohydrate to be the third main contributor to energy.

Maximum levels are recommended all vitamins and minerals. Although not all vitamins and minerals are toxic in large quantities, an excess of one nutrient can 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. To eliminate unnecessary cost for industry, it is recommended mandatory maximum levels be set 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'. It is recommended that a guideline accompany the joint ANZ standard for infant formula to provide manufacturers with guidance as to these recommended maximum levels and that these guidelines be implemented by Good Manufacturing Practice.

High or unlimited intakes of vitamin A, vitamin D, vitamin E, vitamin B₆, 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 recommended for the joint ANZ standard for infant formula for these nutrients.

Where there is sufficient evidence of a sustainable health benefit from consumption of infant formulas containing other nutritional factors found in human milk, these factors are considered as optional additions to formula products and are permitted to be added up to a specified maximum level, to provide more scope for innovation. For example, LCPUFA are currently considered to assist in infant neurodevelopment. Sufficient evidence of the efficacy of LCPUFA is not yet conclusive to mandate a LCPUFA content of infant formula. However, these fatty acids are a usual component of human milk and therefore are permitted to the levels in breast milk. Similarly nucleotides, carnitine, taurine, choline and inositol are found in human milk and there is evidence that these substances may be beneficial to infants. However, the maximum levels of these optional nutritional substances are regulated to protect infants from excessive intakes and the nutritional substances must be present to the level in human milk for a declaration of content. The maximum permission for the inclusion of these substances in infant formula is also based upon the level found in human milk. The purity of some optional ingredients has been raised as a concern. Therefore it is recommended that novel ingredients ie those currently not in use in infant formulas be assessed as safe and suitable before being used in infant formulas marketed to infants in Australia and New Zealand.

Therefore, to protect the health and safety of Australian and New Zealand infants who consume infant formulas, nutritional composition provisions are stipulated for infant formulas which provide fully for the nutritional needs of infants at all stages of growth and development but which restrict excessive and unnecessary nutrient contents. Provisions are also be made for infants with special needs who are unable to consume 'regular' infant formulas.

References

1. Report '*An assessment of nutrient requirements for infant formulas*' (1998) prepared by the Life Science Research Office for the Centre for Food Safety and Applied Nutrition, Food and Drug Administration Department of Health and Human Services WASHINGTON DC. Published in The Journal of nutrition, NOV 01 1998 v 128 n 11 supp
2. Ministry of Health (1997), *Food and Nutrition Guidelines for healthy infants and toddlers* , New Zealand.
3. NHMRC (1995), *Dietary guidelines for children and adolescents* Commonwealth of Australia, AGPS, Canberra.
4. 'Guidelines for the Composition and Clinical Testing of Formulas for Preterm Infants' (1995) - Report of an Ad Hoc Expert consultation to the Health Protectorate Branch, Health Canada, Minister of Supply and Services Canada 1995.
5. Forsyth JS (1998) Lipids in Infant Formulas Nutr Res Revs 11, 255-278.
6. Jensen (1995) *Handbook of milk composition*, Academic Press, Inc California USA.
7. Tsang RC et al (1993) Nutritional needs of the preterm infant, Williams and Wilkins, Pawling NY
8. Francis D E M (1987) *Diets for sick children* 4th Ed, Blackwell Scientific Publications, London.
9. Davidson and Passmore *Human Nutrition and Dietetics* 8th ed, Churchill Livingstone p 348.
10. NHMRC *Recommended dietary intakes for use in Australia* (1991), Commonwealth of Australia, AGPS, Canberra.
11. Food and Nutrition Board (1989) *Recommended Dietary Allowances 10th Ed* National Academy Press, Washington DC.
12. Fomon SJ (1993) *Nutrition of normal infants* Mosby Year book, Inc. Maple-Vail USA.

FOOD TECHNOLOGY REPORT

The number of food additives permitted to be used in foods for infants should be restricted to the minimum necessary to achieve required technological functions. There should be strong evidence of need as well as safety before additives can be regarded as acceptable for use in foods for infants. Permissions for food additives that perform a technological function in infant formula in Australian, New Zealand and Codex food regulations are detailed below.

Australian Food Standards Code (AFSC)

Standard R7 - Infant Formula, currently contains permissions for the following food additives;

- (a) 5 g/L of lecithin;
- (b) 4 g/L in total of mono- and di-glycerides of fat-forming fatty acids;
- (c) 1 g/L in total of guar gum and locust bean gum;
- (d) 10 mg/L of tocopherols;
- (e) 0.3 g/L of carrageenan for liquid milk and soy-based infant formula;
- (f) 1 g/L of carrageenan for hydrolysed protein and liquid amino acid-based infant formula;
- (g) 25g/L of acetylated distarch phosphate, distarch phosphate and phosphated starch phosphate for hydrolysed protein and liquid amino acid-based infant formula; and
- (h) 5 g/L of acetylated distarch phosphate, distarch phosphate and phosphated starch phosphate for soy-based infant formula.

New Zealand Food Regulations (NZFR)

In NZFR, infant formula may contain any of the following:

- (a) The following thickening agents:
 - Carrageenan;
 - Casein and its sodium, calcium, and potassium compounds;
 - Distarch phosphate;
 - Acetylated distarch phosphate;
 - Phosphated distarch phosphate;
 - Guar gum;
 - Hydroxypropyl starch; and
 - Locust bean gum;
- (b) The following emulsifiers:

Lecithin;
Monoglycerides; and
Diglycerides:

- (c) The following acidity regulators:

Sodium hydroxide;
Sodium bicarbonate;
Sodium carbonate;
Potassium bicarbonate;
Sodium citrate;
Potassium citrate;
Lactic acid;
Lactic acid producing cultures;
Potassium hydroxide;
Potassium carbonate;
Calcium hydroxide; and
Citric acid:

- (d) The following antioxidants:

Mixed tocopherols; and
L-ascorbyl palmitate, -

neither of which shall be present in a proportion exceeding 10 ppm, calculated, in the case of an infant formula that requires dilution or preparation before consumption, after such dilution or preparation:

No food additives except those specified are permitted to be present in an infant formula as a result of carry over from raw materials or other ingredients.

Codex

The Codex Standard for infant formula contains the following food additive permissions:

Thickening Agents

Maximum level in 100 mL of the ready to drink product	
Guar gum	0.1 g in all types of infant formula
Locust bean gum	0.1 g in all types of infant formula
Distarch phosphate	0.5 g singly or in combination in soy-based infant formulae only
Acetylated distarch adipate	2.5 g singly or in combination in hydrolyzed protein and/or amino acid acid-based infant formulae only
Acetylated distarch phosphate Phosphated distarch phosphate Distarch phosphate	0.5 g singly or in combination in soy-based infant formulae only
Pectins	1 g in all types of infant formula
Carrageenan	0.03 g in regular, milk- and soy-based liquid infant formulae only 0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formulae only

Emulsifiers

Maximum level in 100 mL of the ready to drink product	
Lecithin	0.5 g in all types of infant formulae
Mono- and diglycerides	0.4 g in all types of infant formulae

pH-Adjusting Agents

Maximum level in 100 mL of the ready to drink product	
Sodium hydroxide	Limited by good manufacturing practice and within the limits for sodium in all types of infant formulae
Sodium hydrogen carbonate	Limited by good manufacturing practice and within the limits for sodium in all types of infant formulae
Sodium carbonate	Limited by good manufacturing practice and within the limits for sodium in all types of infant formulae
Potassium hydroxide	Limited by good manufacturing practice and within the limits for potassium in all types of infant formulae
Potassium hydrogen carbonate	Limited by good manufacturing practice and within the limits for potassium in all types of infant formulae
	Limited by good manufacturing practice and within the limits for potassium in all types of infant formulae
Calcium hydroxide	Limited by good manufacturing practice and within the limits for calcium in all types of infant formulae
Sodium citrate	Limited by good manufacturing practice and within the limits for sodium in all types of infant formulae
Potassium citrate	Limited by good manufacturing practice and within the limits for potassium in all types of infant formulae
L(+) Lactic acid	Limited by good manufacturing practice
L(+) Lactic acid producing cultures	Limited by good manufacturing practice
Citric acid	Limited by good manufacturing practice

Antioxidants

Maximum level in 100 mL of the ready to drink product	
Mixed tocopherols concentrate	3 mg in all types of infant formulae
alpha-tocopherol	3 mg in all types of infant formulae
L-Ascorbyl palmitate	5 mg in all types of infant formulae
L-Ascorbic acid and its sodium and calcium salts	5 mg (expressed as ascorbic acid) in all types of infant formulae

Carry-over of food additives applies to the Codex standard for infant formula.

SCIENTIFIC COMMITTEE FOR FOOD (SCF)

The SCF advises the European Commission on the justification for use of food additives. In 1997, the SCF released a paper titled - Opinion on Certain Additives for Use in Foods for Infants and Young Children in Good Health and in Foods for Special Medical Purposes for Infants and Young Children (see Attachment 1 to Appendix 3).

The recommendations of the SCF relate to three categories of foods: which are infant formula, weaning foods and foods for special medical purposes (FSMP). The full text of the opinion was adopted at the 106th Meeting of the SCF on the 21 March 97. The SCF noted FSMP for infants encompass a wide variety of formulas, including elemental and semi-elemental formulas.

The permission for the use of Diacetyl tartaric acid esters of mono- and di- glycerides of fatty acids (DATEM) in FSMP is temporary and will be reviewed in two years.

The SCF paper is the most recent review of food additive permissions for infant formula products, and the summary of the principles used and the conclusions reached is available for consideration. Those additive permissions proposed in the SCF paper that are relevant to infant formula, including the infant formulas for special dietary use are proposed to be included in the joint ANZ standard for infant formula. Technological justification, evidence of safety and efficacy is required for additional permissions.

RECOMMENDATION:

It is recommended the Codex provisions for food additive use in infant formula be adopted with adjustment for the SCF recommendations particularly for special purpose formulas. The following permissions for food additives are proposed with the restrictions stated below:

Food additive	Infant formulas (Division 1)	Additional permissions for special purpose infant formulas (Division 3-4)
	Maximum level in 100 mL of the ready to drink product	Maximum level in 100 mL of the ready to drink product
<u>Thickening agent</u>		
Guar gum	0.1 g in all types of infant formula	-
Locust bean gum	0.1 g in all types of infant formula	-
Distarch phosphate	0.5 g in soy-based infant formulae only	2.5 g/100mL in hydrolyzed protein and/or amino acid acid-based infant formulae only
Acetylated distarch phosphate	0.5 g singly or in combination in soy-based infant formulae only	2.5 g singly or in combination in hydrolyzed protein and/or amino acid acid-based infant formulae only
Phosphated distarch phosphate		
Hydroxypropyl starch		
Carrageenan	0.03 g in regular, milk- and soy-based liquid infant formulae only	0.1 g in hydrolyzed protein and /or amino acid-based liquid infant formulae only
<u>Emulsifiers</u>		
Lecithin	0.5 g in all types of infant formulae	-
Mono- and diglycerides	0.4 g in all types of infant formulae	0.5g in hydrolyzed protein and/or amino acid-based liquid infant formulae only
Diacetyl tartaric acid esters of mono- and diglycerides of fatty acids (DATEM).	Not permitted	0.4g in hydrolyzed protein and/or amino acid-based liquid infant formulae only
<u>pH-Adjusting Agents</u>		
Sodium hydroxide, Sodium hydrogen carbonate, Sodium carbonate	Limited by good manufacturing practice and within the limits for sodium set for all types of infant formulae	-

Potassium hydroxide, Potassium hydrogen carbonate, Potassium carbonate	Limited by good manufacturing practice and within the limits for potassium set for all types of infant formulae	-
Calcium hydroxide	Limited by good manufacturing practice and within the limits for calcium set for all types of infant formulae	-
Sodium citrate	Limited by good manufacturing practice and within the limits for sodium and calcium set for all types of infant formulae	-
Potassium citrate	Limited by good manufacturing practice and within the limits for potassium set for all types of infant formulae	-
L(+) Lactic acid	Limited by good manufacturing practice	-
Citric acid	Limited by good manufacturing practice	-
<u>Antioxidants</u>		
Mixed tocopherols concentrate	1 mg in all types of infant formulae	
L-Ascorbyl palmitate	1 mg in all types of infant formulae	-

Carry-over of Food Additives

No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

(a) of the food additives listed above within the limits of the maximum levels stipulated in this standard; and

(b) of the carrier substances mentioned in the permitted lists of vitamins and minerals within the limits of the maximum levels stipulated in that List.

CONTAMINANTS IN INFANT FORMULA

Regulation of contaminants in food

Food contaminants are generally considered to be those substances present in food at levels which serve no technological function and whose presence may lead to adverse health effects. In the majority of cases, contaminants also serve no nutritional function, although some, such as copper, selenium and zinc, are essential micronutrients which may have an adverse health effect at high levels of consumption.

Contamination of food with potentially hazardous substances can occur at all stages of food production. In many cases, the level of potential contamination with substances from environmental sources is self-limiting because of current manufacturing practices and adherence to agricultural or industrial best practices which identify potential points of contamination. A generally recognised benchmark for control of contaminants is that the levels in food should be as low as reasonably achievable. For some contaminants, there is a level in foods which can be considered as naturally-occurring, sometimes referred to as the "irreducible level". Levels lower than this level either cannot be achieved or can be achieved only using extraordinary methods. JECFA² defines this level as "that concentration of a substance that cannot be eliminated from a food without involving the discarding of that food altogether, severely compromising the ultimate availability of major food supplies".

Action to ensure that contamination of food is as low as reasonably achievable may be taken in a variety of ways, including the development of control measures at the source of contamination, the enforcement of both Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP) where applicable, and, if necessary, the establishment of food standards which define the maximum permitted concentrations of contaminants in particular commodities. The MPC for a contaminant is the maximum concentration of a substance permitted in a food commodity. MPCs are the legal limits enforced through Food Standards. Food standards are generally used only when other mechanisms of control are considered insufficient or inadequate to safeguard the health of consumers.

Food standards, including MPCs, however, must be consistent with the international trade obligations of Australia and New Zealand as signatories to the WTO SPS and TBT Agreements. Under these agreements, food standards must be able to be demonstrated to be a necessary means of achieving a legitimate objective, such as, *inter alia*, protecting human health and safety or

²Joint (FAO/WHO) Expert Committee on Food Additives

preventing deceptive practices. Food standards cannot be used to impede international trade where this is not able to be justified on the above grounds. MPCs in Australia and New Zealand, therefore, may not be set at levels lower than international norms unless there is an identified public health and safety concern or another legitimate reason. In this regard, MPCs are not always the most appropriate means of encouraging best practice in relation to achieving low levels of food contamination.

Rationale for controlling contaminants in foods in general

The underlying reason for having measures to control contamination of food is to protect public health and safety, however, because of the limitations of scientific knowledge, demonstrating that public health and safety is or is not at risk may not be possible in many cases. Because of this uncertainty, a cautious approach is generally accepted in relation to contaminants, namely, that since most contaminants serve no function in food, unnecessary exposure should be minimised and the level of contaminants in food should be as low as reasonably achievable. For those contaminants which are also nutrients, a minimum level is required for nutritional purposes.

When, on the basis of current scientific knowledge, a safe level of exposure to a particular contaminants can be established (known as the tolerable daily (or weekly) intake (TDI or TWI), it is still normal for this safe level to be considered "provisional" since new data could emerge suggest a different 'safe' level of exposure. The database upon which the TDI is based can change as further research on potential adverse effects is conducted. By minimising exposure as well as ensuring the exposure is below the TDI or TWI, a reasonable margin of safety can be maintained between the levels of actual exposure and levels known to cause adverse effects. Thus, while there can be reasonable confidence that intake of contaminants up to the established provisional tolerable daily or weekly intake (PTDI or PTWI) is safe, caution dictates that lower levels of intake should be encouraged where possible.

Rationale for controlling of contaminants in infant formula

In the case of infant formula, there are some compelling reasons for why a more cautious approach to the control of contaminants may be applicable, namely,

1. Infant formula is the sole source of nutrition for the infant in many cases;
2. The tolerable daily intake (TDI) for contaminants is not considered to be applicable to infants under 3 months of age;
3. The normal functions of the gastrointestinal tract and the metabolic processes of the liver are not fully developed in infants and, therefore, the fate of contaminants in the diet is unknown;

4. It is unlikely that data will become available to establish safe levels of exposure for many contaminants in infants.

Where there are significant concerns regarding the potential toxicity of contaminants in infants, it may be appropriate to establish MPCs at levels which will ensure a lower level of intake (on a weight for weight basis) than for other members of the population.

Use of MPCs to control contaminants in food

MPCs are the legal levels used by both industry and enforcement agencies to ensure food is safe for human consumption. In this regard, an MPC is generally established when there is potential for a contaminant in a food to cause a significant risk to public health and safety at the anticipated levels of dietary exposure.

The principles used to establish MPCs are shown in the box below.

Principles for establishing MPCs

The following principles for establishing an MPC were adopted by the ANZFA Board in June 1997 and endorsed by ANZFSC on 31 July 1997.

General principle

The MPC should reflect the principle that contaminant levels in food should be as low as reasonably achievable. This principle is based on the premise that contaminants have no intended function in food and their associated health risks may not yet be fully understood.

Specific principles

ANZFA also applies the additional principles which are secondary to the broader section 10 objectives of the *Australia New Zealand Food Authority Act 1991*.

1. An MPC will be established only where it serves an effective risk management function; and MPCs will be set for:
 - (a) all primary commodities (described using Codex food commodity groupings) which provide, or may potentially provide, a significant contribution to the total dietary contaminant intake, as indicated by dietary exposure assessments; and
 - (b) nominated processed foods where the setting of an MPC for the primary commodity is judged to be ineffective.
2. An MPC will be set at a level which is consistent with public health and safety as determined by an appropriate risk assessment procedure based on dietary modelling³ and which is reasonably achievable from sound primary production and natural resource management practices. Australian and New Zealand data will normally be used for this purpose.
3. In setting an MPC, consideration will be given to Australia's and New Zealand's international trade obligations under the WTO SPS and TBT Agreements⁴.
4. There are a number of measures, other than MPCs, that might be used to reduce contaminant levels in the food supply and consequent dietary intakes. Other measures include improving primary commodity production practices and developing appropriate education programs for population groups with potential for high exposure to particular contaminants.

³Dietary modelling is a technique which combines dietary intake data or model diets with concentration data for food chemicals to estimate dietary exposure to that food chemical.

⁴The principles for establishing MPCs were agreed by ANZFSC in July 1997. At this meeting the New Zealand Minister proposed alternate text for principle 3 to clearly state that MPCs should be consistent with Australia and New Zealand's international trade obligations under the WTO, SPS & TBT agreements. This proposal is scheduled for discussion at the next ANZFSC meeting in July 1998.

Consideration of specific contaminants

Cadmium

The most significant potential adverse health effects associated with excessive exposure to cadmium are related to renal and bone effects. These effects are the result of cumulative effects of cadmium exposure over many years. The effects on the kidney are considered to be the most sensitive and are characterised by tubular cell dysfunction, although glomerular dysfunction may also occur. A consequence of renal dysfunction in animals is disturbance of calcium and vitamin D metabolism, which according to some studies has led to osteomalacia and/or osteoporosis. A characteristic sign of tubular dysfunction is an increased excretion of low molecular weight proteins in urine. The current internationally accepted safe level of exposure to cadmium is 1 µg/kg bw/day based on a critical level of cadmium accumulation in the kidney (50 mg/kg in the renal cortex) obtained after continuous exposure for 50 years.

Given that the toxicity associated with cadmium is the result of long-term exposure, there is no immediate health concern for infants from exposure to low levels of cadmium via infant formula. Only low levels of cadmium are likely to occur in the raw materials used to prepare infant formula and, therefore, there is no reason to specifically restrict the level of cadmium in infant formula.

Fluoride

Expert Panel (EP) recommendations

The Authority's Expert Panel (EP) which included expertise in dentistry reconsidered the maximum permission for fluoride in infant formula in response to the submissions.

Considering the water supply is fluoridated in most areas of Australia and in NZ (55%; personal communication) the common practice of use of the standard concentration of fluoride in water supply for making up infant formula needs to be factored into the assessment of total fluoride intake by consumers of infant formula.

The EP recommendation was that a maximum level of fluoride for all formula be set at 0.5 mg/L because of the risk of dental fluorosis for infants.

Assessment

Estimated safe and adequate daily dietary intakes (ESADDI) of fluoride for infants have been set at between 0.1 to 1 mg/day. These estimated safe and adequate intakes of fluoride were primarily based upon intakes that were consistent with good dental health.

Sources of food and beverage products that may contribute to excess fluoride ingestion in infants are fluoridated water, infant formula (reconstituted with optimally fluoridated water) and infant foods (cereals). However, the fluoride content of infant formulas depend mainly on the fluoride concentration of the water used to reconstitute the products. Thus, daily intakes by individual infants from these products are highly variable and can range from as little as 0.1 to over 1 ppm/day of fluoride (equivalent to between 0.01-0.1 mg/kg bw/day in infants weighing up to 10 kg). Additionally, while it is recognised that an increase in fluorosis may be attributed to an increase intake of fluoride from infant formula(through processing with fluoridated water) others factors may contribute, such as the introduction of other sources of nutrition in the diet of infants and fluoride toothpastes at later ages.

A recent study has suggested that the threshold for dental fluorosis is 0.1 mg/kg bw (Silva and Reynolds, 1996). In this study the fluoride content of the infant formulae commonly used in Australia was determined. When milk-based formula was reconstituted with fluorine-free water the mean concentration of fluoride was 0.24 mg/L (range 0.031 to 0.532 mg/L). The results suggested that none of the formulae if reconstituted with water containing up to 0.1 ppm fluoride should provide a daily intake above the suggested threshold for fluorosis of 0.1 mg/kg bw. However, it was concluded that prolonged consumption (beyond 12 months) of infant formulae with water fluoridated at 1ppm could contribute to dental fluorosis.

Recent studies from New Zealand surveyed fluoride levels in infant formula(Vannoort et al, 1997). The mean fluoride content in all infant formula was 0.15 ppm (range 0.03-0.37 ppm); and, the mean fluoride content in weaning foods was 0.38 ppm (range <0.05-1.52 ppm). These levels in infant formula complied with the 1984 NZ regulations, and met the suggested upper limit of 0.4 ppm in infant formula (Ekstrand, 1989). However, there was an assumption that water added to powdered formula contained no additional fluoride (water in NZ may contain up to 1.1 mg/L fluoride). If water at this concentration was used to prepare infant formulae it may exceed the 0.4 ppm level.

The NHMRC Agricultural and Resource Management Council of Australia and New Zealand (1996) issued jointly drinking water guidelines for fluoride. Typical fluoride concentrations in unfluoridated water supplies range from <0.05 mg/L to 1.5 mg/L and in fluoridated supplies, the target concentration is between 0.7 and 1 mg/L.

The NHMRC suggested that the concentration of fluoride in the drinking water should not exceed 1.5 mg/L. This guideline level was set to protect children from the risk of dental fluorosis but it was recognised that there is a narrow margin between concentrations producing beneficial effects to teeth and those producing fluorosis. It was recommended that if the 1.5 mg/L value is exceeded (in circumstances where it is not practicable to defluoridate) then

parents should be advised to use rainwater or bottled water for children up to about 6 years of age to limit or prevent dental fluorosis.

It is noted that some manufacturers are manufacturing infant formula with low fluoride-containing water to reduce the fluoride levels in the final product (personal communication). This is consistent with a recent report that suggested that infant formula in Australia and New Zealand was being prepared using low fluoride water (Riordan, 1995).

In conclusion, the Authority considers that the issue of fluoride in infant formula is adequately covered by the current water quality guidelines and it is proposed not to specify a maximum level for fluoride in infant formula. However, due to the possibility of dental fluorosis, the Authority is proposing that infant formula powders containing fluoride levels >0.5 mg/L when reconstituted with fluorine free water (formulas with approx 17 microgram fluoride / 100kJ) and ready-to-drink formulas containing fluoride > 1.5 mg/litre should have an advisory statement on the label to advise carers of the potential risk of dental fluorosis. The advisory statement should recommend carers to specifically discuss the risk of dental fluorosis associated with the use of the product with a Doctor or health professional.

REFERENCES

National Research Council (1989) Recommended dietary allowances, 10th ed. Subcommittee on the Tenth Edition of the RDAs, Food and Nutrition Board, Commission on Life Sciences, National Research Council, National Academy Press, Washington, DC. In: Hunt CD and Stoecker BJ (1996) Deliberations and evaluations of the approaches, endpoints and paradigms for boron, chromium and fluoride dietary recommendations. *J. Nutr.* **126**: 2441S-2451S.

Riordan PJ (1995) Safe and adequate fluoride levels in infant formula. A paper prepared for the National Food Authority's Expert Panel on Infant Formula. March 1995.

Silver M and Reynolds EC (1996) Fluoride content of infant formulae in Australia. *Aust. Dent. J.* **41**: 37-42.

Vannoort RW, Cressey PJ, Thomson B (1977) Assessment of selected pesticides and the elements cadmium, lead, tin, iodine and fluoride in infant formulae and weaning foods. *ESR*, New Zealand.

LEAD

The current standard for lead in infant foods and formula is as follows:

Australia

Infant's foods, including foods for young children referred to in Standards R5 and R6	0.3 mg/kg
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New Zealand	
Foods that meet the special physiological needs of infants and young children	0.3 ppm

Proposed Codex levels (draft-step 5)	
Infant Formula	0.02 mg/kg

Diet and drinking water are considered to be the principal source of the total body burden of lead for non-occupationally exposed groups. The proportion of total lead intake derived from food is dependent on the concentration of lead in air, water and other sources. However, for infants and children lead from food and beverages may not be the predominate source of lead with dust and soil a significant source of lead exposure.

The risk assessment undertaken by the Authority has concluded that there is cause for concern about exposure to lead, even at very low levels particularly for susceptible groups such as infants and children. This is supported by the fact that lead exposure is ubiquitous in nature, is cumulative and the effects may not be reversible in children.

The 1996 Australian Total Dietary Survey (formerly the AMBS) found that 7 samples of infant formula contained lead with a mean level of 0.009 mg/kg and a maximum of 0.018 mg/kg.

It is proposed that a maximum limit of 0.02 mg/kg for lead in infant formulae be set. This is consistent with the draft Codex level of 0.02 mg/kg currently at step 5.

REFERENCES

Carrington, C.D., Sheehan, D.M., and Bolger, P.M. (1993). Hazard assessment of lead. *Food Addit. Contam.* **10**: 325 - 335.

Tahvonen, R. (1996). Contents of lead and cadmium in foods and diets. *Food Reviews International*. **12**: 1 - 70.

US EPA (1986). Air quality criteria for lead, North Carolina, Environmental Protection Agency.

WHO (1995). WHO Environmental Health Criteria 165: Inorganic lead, Geneva, World Health Organisation.

WHO/FAO (1996) *Trace elements in human nutrition and health*, Geneva, World Health Organisation. pp195 - 216.

NITRATES

Nitrate was considered by JECFA at the sixth (WHO, 1962), eighth (WHO, 1965) and seventeenth (WHO, 1984) meetings. At the 6th meeting an ADI of 5 mg/kg bw (expressed as sodium nitrate) was allocated. This ADI was based on a NOEL for sodium nitrate of 500 mg/kg bw/day derived from a long-term toxicity study in rats and a short-term toxicity study in dogs with an application of a 100 fold safety factor. Growth depression was observed at higher dose levels.

Since the previous evaluations new toxicological and epidemiological data has become available (WHO, 1996).

The toxicity of nitrate results from conversion to nitrite and the possible endogenous formation of N-nitroso compounds. The Committee evaluated the available new toxicological studies and considered that on the basis of a NOEL of 370 mg nitrate ion/kg bw/day in a long-term study in rats, an ADI of 5 mg/kg bw (expressed as sodium nitrate), or 3.7 mg/kg bw (expressed as nitrate ion) could be allocated.

In humans nitrate is converted to nitrite by microorganisms in the saliva (from 4-8% of ingested nitrate has been detected as nitrite in the saliva) with the concentration of salivary nitrite directly related to orally ingested nitrate. Other factors that may influence the oral microbial flora (and hence levels of nitrite) are nutritional status, infection, environmental temperature and age. In normal healthy adults a low stomach pH (1-2) is considered normal (although fluctuations can occur) and under these conditions bacterial nitrate reduction does not take place because of poor bacterial growth.

However, infants younger than 3 months are susceptible to gastric bacterial nitrate reduction because they have very little production of gastric acid. Furthermore, gastro-intestinal infections which frequently occur in infants may produce an additional increase in the reduction of nitrate to nitrite. Due to these facts the Committee considered that infants below the age of 3 months are more vulnerable to the toxicity of nitrite than adults, and that the above ADI did not apply to such infants.

The major toxicological effect of nitrite in humans is its involvement in the oxidation of normal haemoglobin to methaemoglobin which is unable to transport oxygen to the tissues. Therefore, as nitrate is reduced to nitrite the oxidation of oxyhaemoglobin to methaemoglobin occurs. Reduced oxygen transport has been noted clinically when MetHb levels in the blood reach

concentrations of 10% (normal range 1-3%). Infants younger than 3 months are susceptible to nitrate because foetal Hb is more readily oxidised to MetHb. Previous cases of infant methaemoglobinaemia have been reported in infants up to 6 months of age when nitrate in the water supplies exceeds 45 mg/l.

However, in humans the *in vivo* conversion of nitrate to nitrite is complex and the quantitative aspects are difficult to clarify because of endogenous synthesis of nitrate and nitrite, and the oxidation to nitrate of other nitrogen-containing compounds (eg ammonia). In addition, once nitrite is formed, it has a short biological half-life, being rapidly oxidised to nitrate in the blood.

The NHMRC Agricultural and Resource Management Council of Australia and New Zealand (1996) issued jointly, drinking water guidelines for nitrate. They have suggested the following measures:

"The guideline value of 50mg-NO₃/L (as nitrate) has been set to protect bottle-fed infants under 3 months of age. Up to 100mg-NO₃/L can be safely consumed by adults and children over 3 months of age. Where a water supply has between 50 and 100mg-NO₃/L nitrate, active measures are required to ensure that those caring for infants are aware of the need to use alternative water sources in making up bottle feeds for babies under 3 months of age."

The report also indicated that typical values in Australian water supplies range up to a maximum of 18 mg-NO₃/L, with typical levels usually <0.15-NO₃/L. The level of 50mg-NO₃/L (as nitrate) is also the maximum level set for New Zealand drinking water (1995).

Therefore, the Authority would consider that restriction of the level of nitrate in infant formula is essential and is being addressed in the current NHMRC water quality guidelines.

REFERENCES

WHO (1996) Toxicological evaluation of certain food additives and contaminants. Forty-fourth meeting of the Joint FAO/WHO Expert Committee on Food Additives, Geneva, World Health Organisation (WHO Food Additive Series, No. 35).

PESTICIDES

Agricultural and veterinary chemicals are registered for specific purposes and for use under stipulated conditions. In effect this means that the chemical can be used only for the purpose for which it was cleared. The conditions of use, such as the concentration of the chemical, the rate of application and other

restrictions are defined. This is an extensive process performed by the National registration Authority for agricultural and veterinary chemicals. Following this, a maximum residue limit for specific commodities is recommended. MRLs are legal limits which should result when the chemical is used according to good agricultural practices.

They should not be confused with biological or toxicological endpoints.

The best way of minimising chemical residues in foods is through good regulatory control. The State/Territory and Federal Governments monitor residues in agricultural produce through survey work such as the National Residue Survey and the Australian Market Basket Survey to ensure compliance with the regulations.

The 1996 Australian Total Dietary Survey (formerly the AMBS) analysed 70 pesticides of which none were detectable in infant formula.

Therefore, the Authority does not consider there is a need to have specific upper levels for pesticides in infant formula.

ALUMINIUM

The safety of aluminium intake for infants who consume infant formula was assessed at full assessment. It was then proposed that the aluminium content of infant formula be limited to 0.2 mg/L for non- soy-based formula, 1 mg/L for soy-based formula and deionised water be used in infant formula preparation.

Issues

There was widespread support for the setting of a maximum level for aluminium in infant formula. In general submissions considered there were no grounds to have different maximum permissions for non-soy and soy based formulae as the level should be determined on health and safety grounds.

Submissions request the maximum level for all formula be set at the level for soy-based formula (1 mg/L) as aluminium from glass containers, flocculant use for water purification and mineral salt contamination will contribute to the total aluminium content of the formula. Submissions note the aluminium levels in infant formula are below the PTWI set by FAO/WHO. However one industry submission requests the maximum level for lactose hydrolysed and proximate modified non-soy based formula be increased to 0.5 mg/L. Submissions were made that some specialty formula would not be able to limit aluminium content to 0.5 mg/L because of the use of aluminium containing ingredients.

Infant formula industry submissions claimed the limitations on aluminium levels would impose an additional quality assurance procedure for formulae sold in Australia only since the aluminium levels would require testing on each batch of infant formula.

It was claimed that the compliance with the maxima for aluminium (and fluoride) would cost one company approximately \$1300 per annum. It was further suggested the levels of aluminium could be better monitored and controlled by quality assurance procedures that ensure GMP such as control of ingredients, HACCP, minimisation of contamination from alum flocculants use in water purification, addition of calcium salts, etc. These issues could be addressed by an industry code of practice.

method of analysis

Submissions were made for a method of analysis to be specified as different methodologies can produce different results.

Assessment

As reported at full assessment, recommendations have been made by paediatricians in Australia, USA, UK and Canada to minimise the exposure of infants to aluminium.

Jensen (1995)* reports the levels of aluminium appear to reflect maternal exposure from both diet and environment and cites studies which indicate aluminium levels up to 30 ng/mL (0.03 mg/L) have been reported for breast milk in Australia. Jensen further reports the aluminium level in cow's milk from Australia has been reported as 95-100 ng/mL (0.09- 0.1 mg/L)

Whilst it is desirable that exposure to contaminants is minimised for infants, the maximum level proposed at full assessment for non-soy formulae for term infants could be raised to 0.5 mg/L, on the basis that there would be no risk to public health and safety. The level should not be raised to 1.0 mg/L as requested in submissions, because the aim is to minimise exposure to contaminants as far as possible, and a level of 0.5 mg/L in non-soy formulae is clearly attainable with good manufacturing practice.

However, the level should remain at 0.2 mg/L for pre-term infants as they may be at particular risk of aluminium toxicity because of their immature gastrointestinal tracts and limited ability to excrete aluminium through normal renal clearance.

There are safety concerns with the use of soy- based formula and it is now recommended these formulas should only be used by infants who have a medical reason which precludes milk based foods. The level of 1.0 mg/L for soy based formula is to be retained as it may not be currently possible to attain the lower limit possible for non- soy based formula. The risk of higher aluminium intake for these infants is less than the risk of consumption of a milk based formula.

Recommendation:

The maximum level set in the draft Standard for non- soy-formulae could be increased to 0.5 mg/L, the level in pre-term formula should remain unchanged at 0.2 mg/L and soy-based formula should remain unchanged at 1.0 mg/L .

Method of analysis for aluminium

The Authority's policy is to minimise prescription of methods of analysis in the Food Standards Code. Methods of analysis are being considered in a separate review project and therefore will; not be considered further in the review of infant formula.

Jensen RG (1995), *Handbook of milk composition*. Academic Press, Inc USA

TOXICOLOGICAL ASSESSMENT OF FOOD ADDITIVES IN INFANT FORMULA

CHROMIUM SULPHATE

Evaluation for permission for use in infant formulae

Chromium toxicology

Trivalent chromium (Cr III) is an essential trace element, a necessary component of the glucose tolerance factor (GTF). The role of chromium in glucose homeostasis is the only biologic role postulated for chromium. Diet represents the only source of chromium, obtained mainly from nuts, legumes and brewers yeast.

Limited information on chromium toxicity indicates that trivalent chromium has a low order of toxicity following oral exposure, and a relatively wide margin of safety between amounts ordinarily ingested and those likely to induce toxicity.

Absorption and excretion of chromium

There have been no studies on chromium absorption by infants and only a few in adults. The intestinal absorption of all inorganic forms of chromium is low, normally 0.5 - 2% in man (Anderson and Kozlowsky, 1985). Humans consuming self-selected diets had a chromium absorption of approximately 2% when dietary intake was 10 µg Cr/day and decreased to 0.5% when the diet provided 40 µg Cr/day (Anderson and Kozlowsky, 1985; Offenbacher *et al*, 1986). This inverse relationship between dietary chromium concentrations and absorption suggests that a homeostatic mechanism may regulate the levels of chromium body load; however, little information is available on such a mechanism. It has been suggested that various dietary factors such as oxalate, iron and high intakes of simple carbohydrates may influence the bioavailability or absorption of chromium, but data to support this supposition are meagre.

Chromium is excreted primarily via the kidneys and excretion rates reflect dietary intakes when a varied diet is consumed (Anderson and Kozlowsky, 1985).

Exposure levels

Infants fed human milk have access to approximately 0.05 µg Cr/kg bw/day (Zlotkin *et al*, 1995), as based on chromium content of human milk of approximately 0.3 to 0.5 µg/L (Zlotkin *et al*, 1995). Breast-fed infants do not appear to become chromium deficient and therefore this level is likely to be required for good health. The concentration of chromium in cows' milk and in cows' milk-based formulas is considerably higher than in human milk at 15 µg/L (Zlotkin *et al*, 1995), potentially providing 1.5 µg Cr/kg bw/day, a level 30 times higher than from human milk. Infants fed with cows' milk, or a formula based on it, have not been detected to suffer from any overt signs of chromium deficiency or toxicity.

Chromium requirements

Estimates of basal chromium requirements, (which are limited due to analytical problems), are based on observations that glucose intolerant adults consuming less than 20 µg Cr/day for 14 weeks respond to chromium supplementation by an improvement in glucose metabolism; glucose metabolism was unchanged in glucose tolerant subjects. (Polansky *et al*, 1990). Daily intakes of 24.5 and 37 µg Cr have been found adequate to maintain elderly people (Offenbacher *et al*, 1985; Bunker *et al*, 1984). It has been demonstrated, however, that active young adults excrete more chromium than sedentary adults, possibly indicating a greater requirement to maintain normal body store of this trace element in this sub population.

These data were extrapolated to calculate a basal need in adults of around 25 µg/day (0.4 µg Cr/kg bw/day). Extrapolation of this figure has given a tentative deduction that a 6 kg infant would have a predicted intake requirement of approximately 2.4 µg chromium per day (SHS International Report submitted to ANZFA).

This extrapolated basal need value in adults (0.4 µg Cr/kg bw/day) is significantly higher than the value of 0.05 µg Cr/kg bw/day provided to infants from breast milk. It is assumed that the content of chromium in human milk is at least, if not above the basal requirement level for infants. Two likely possibilities exist: either the chromium (and other nutrients) in breast milk are much more readily bioavailable than chromium available from the diet, or the basal values for chromium obtained from adult studies are inaccurate. It is less likely that infants have a lower requirement for chromium than adults. The value of 1.5 µg Cr/kg bw/day provided to infants from cow's milk or a cow's milk-based formula is therefore above the extrapolated basal need value.

NEOCATE*, as one type of infant formula, has a chromium content of 15 µg/100g of powder and it was calculated that this would provide 27 µg chromium/day to a 7.2 kg infant, (or 3.75 µg Cr/kg bw/day). This amount is 75 times higher than the chromium levels obtained from breast milk and almost 10 times higher than the requirement dose extrapolated from adult data.

At the upper level of chromium exposure, supplements providing 125 to 200 µg Cr/day, (approx. 18 to 28 µg/kg bw/day) in addition to normal dietary intake, have not been associated with toxicity when used in the treatment of adult patients with impaired glucose tolerance or in normal healthy adults. By extrapolation, and assuming that infants have a similar metabolic handling of this trace element to adults, this dose is unlikely to provide a toxicity hazard to infants.

Discussion on the setting of a minimum and maximum levels of chromium in infant formula

The Commission of the European Communities stated in its Report of the Scientific Committee on infant formula (1983) that: "the Committee took the view that the average composition of human milk should be used as a reference for determining the formulae of breast milk substitutes."

Infants fed breast-milk receive about 0.05 µg Cr/kg bw/day from that source. Basal requirement level of chromium extrapolated from adult diets is about 0.4 µg Cr/kg bw/day, or 8 times higher than the value obtained from breast-fed infants. Some infant formulae contain 3.75 µg Cr/kg bw/day, a value 75 times higher than the value obtained from breast-fed infants.

Based on a number of assumptions outlined in this report, it is probably reasonable to conclude, that levels of chromium present in infant formula are sufficiently high to prevent deficiency and retain adequate body levels of this element. It is also probably unlikely that these levels approach a toxic dose, which in case of chromium is relatively high. Therefore, based on available information, the level of chromium in infant formula (15 µg/100g of powder) is unlikely to present a toxicological hazard to the infant.

However, toxicological data on chromium is very meagre, especially in regard to the interaction with other trace metals; the recommended levels of exposure of infants are extrapolated from poor adult data; and the extrapolation of basal values for intake do not take into account the possibility of immaturity of the infants' metabolism or homeostatic mechanisms.

Therefore, although there is no toxicological evidence to limit the levels of chromium at the requirement values, the scarcity of data on chromium toxicity and the number of assumptions taken to obtain an extrapolation of a basal requirement value, suggests caution in giving permission for the addition of an open-ended amount of chromium in infant formulae.

It should also be noted that the Commission of the European Communities stated in its Report of the Scientific Committee on infant formula (1983) that: "the food of neonates and young infants should....not only supply them with all the materials and energy needed for growth and for the development....but also be capable of being metabolised and anything given in excess to be eliminated.

A reasonable safety margin should also be selected to allow for a possible further reduction in their tolerance in the event of illness and possible errors made by parents in the preparation...of bottled feeds".

Therefore the decision to set a minimum and maximum level for chromium in infant formula can only be partially based on toxicological considerations and must be a general policy decision on the desirability of exceeding the required levels of trace element in food that is the sole source of nutrition for this population.

Chromium sulphate

There are, potentially, wide variations in the bioavailability of trace minerals. Bioavailability may depend on the salt form of the metal, or any chemical complexation with organic molecules. For example, magnesium oxide is very poorly absorbed as compared to magnesium chloride and zinc picolinate is much more readily bioavailable than zinc chloride. The relative bioavailability of chromium sulphate as compared to bioavailability from a varied diet or from breast-milk is unknown. However, it is likely that the majority of inorganic forms of chromium have a comparable bioavailability, providing they are soluble. Based on available evidence, chromium sulphate is unlikely to pose a hazard to infants as a permitted form of chromium in infant formula. The use of chromium sulphate as opposed to other forms of chromium, eg. chromium chloride may need to be technologically justified.

REFERENCES

Anderson RA and Kozlowsky AS. Chromium intake, absorption and excretion of subjects consuming self-selected diets. *Am J Clin Nutr* 41: 1177-1183, 1985.

Bunker VW, Lawson MS, Delves HT and Clayton BE. The uptake and excretion of chromium by the elderly. *Amer J Clin Nutr* 39: 797-802

Offenbacher EG, Rinko, CJ and Pi-Sunyer FX. The effects of inorganic chromium and brewer's yeast on glucose tolerance, plasma lipids and plasma chromium in elderly subjects. *Am J Clin Nutr* 42: 454-461, 1985.

Offenbacher EG, Spencer H, Dowling HJ and Pi-Sunyer FX. Metabolic chromium balances in men. *American Journal of Clinical Nutrition* 44: 77-82, 1986.

Polansky MM, Bryden NA, Canary JJ and Anderson RA. Beneficial effects of supplemental chromium (Cr) on glucose, insulin and glucagon of subjects consuming controlled low chromium diets. *FASEB Journal* 4: A777 (abstr. 2964).

Zlotkin SH, Atkinson S and Lockitch G. Trace elements in nutrition for premature infants. *Clinics in Perinatology*. Volume 22 (1): 223-240, 1995

MOLYBDENUM

A review of the toxicity of molybdenum has been recently undertaken (WHO/FAO, 1996).

Molybdenum is an essential trace element for humans and animals (being a component of the enzymes xanthine oxidase, aldehyde oxidase and nitrate reductase) with an estimated requirement between 0.15mg-0.5 mg/day in adults.

Molybdenum toxicity is accompanied by a wide range of symptoms, possibly attributed to the induction of a deficiency in copper. Features of acute exposure include defects in osteogenesis (possibly by deranged phosphorous metabolism) leading to skeletal and joint deformities, spontaneous subepiphyseal fractures, and mandibular exostoses.

In ruminants, high intakes of molybdenum leads to copper deficiency, and in other species (including humans) the utilisation of copper may be impaired. Typical manifestations are the induction of anaemia, cardiac hypertrophy, and achromotrichia (arising from the development of defects in melanin synthesis in hair). Other consequences of high molybdenum intake in animal species include inhibition of active sulphate, inhibition of oestrus and interstitial testicular degeneration. However, the relevance to humans has not been studied.

The basis for the antagonistic effect of molybdenum on copper utilisation is, firstly the reaction of molybdate with sulphide generated by bacterial reduction of sulphate within the gastro-intestinal tract and, secondly, the reaction with copper of the thiomolybdates thus produced to yield derivatives in which the copper cannot be utilised.

Studies with animals and humans have been unable to establish a NOEL, however, a recent review of molybdenum toxicity has suggested that the lowest level at which adverse effects from high molybdenum levels are likely to be encountered in humans lies between 0.14-2 mg/kg bw if the ingested element is in the form of soluble molybdate. This is consistent with data from studies conducted in Armenia where molybdenum is present at high levels in food crops and it has been suggested that a high incidence of gout associated with defects in purine metabolism may be caused by consumption of natural diets providing up to 10-15 mg of molybdenum/day.

Data from several countries suggest that the molybdenum intakes of breast-fed infants 0-3 months of age varies from 0.1-0.5µg/kg bw/day. These intakes are substantially less than those recommended by the WHO (2µg/kg bw/day) and the United States National Academy of Sciences (30-60µg/day)

In conclusion, the data on molybdenum toxicity in animals suggests that there is only cause for concern at high levels of molybdenum intakes and there is considerable variability in the experimental results depending on the chemical nature of the compound and the animal species. However, further studies are needed before a maximum tolerable mean intake of molybdenum can be set.

Sodium molybdate VI dehydrate

There are limited toxicological studies on this compound, however, it is generally considered to be less toxic than other corresponding compounds of group 6B in the periodic table (Merk Index 11th edition, 1989). Generally, studies on the absorption and bioavailability of molybdenum and its inorganic compounds are based entirely on evidence from studies with ruminants or laboratory animals with limited or no studies in humans.

The only toxicological study that could be found on this compound was in a review document on molybdenum from the US EPA's Integrated Risk Information System. The effects of excess dietary molybdenum (added as sodium molybdate) in guinea pigs of unspecified strain was studied (Arthur, 1965). Groups of five guinea pigs were maintained for 8 weeks on diets with varying molybdenum content. At high doses of sodium molybdate (up to 320 mg/kg bw/day) weight loss and colour changes in the hair were noted. Approximately 75% of the animals receiving a dose between 240-320 mg/kg bw/day died.

In conclusion, there are limited toxicological studies on sodium molybdate VI dehydrate. However, assuming that there may be similarities in bioavailability of molybdenum compounds, oral toxicity from sodium molybdate VI would appear to occur only at high dose levels in animals. There are no available studies on humans and extrapolation from animal studies to infants is problematical.

Molybdenum is required to be added to some special purpose infant formulas as the formula ingredients may not contain innate molybdenum. The added proposed level is up to 3 micrograms/ 100kJ which is well below the level of identified toxicological concern in animals. Therefore sodium molybdate VI dehydrate could be permitted for use in special purpose infant formulas. Sodium molybdate has been added to enteral formulas for at least a decade at levels of 80 micrograms/L, without known adverse reports. However, given the very poor toxicological data base for molybdenum, especially in infants it would be prudent to restrict the addition to the ESADDI, ie 3 micrograms/ 100kJ.

References

WHO/FAO (1996) *Trace elements in human nutrition and health*, Geneva, World Health Organisation. pp144-154.

Arthur D (1965) Interrelationships of molybdenum and copper in the diet of the guinea pig. *J. Nutr.* 51: 295-304.

CARRAGEENAN IN INFANT FORMULA

Background

High molecular weight carrageenan, a sulphated polygalactan extracted from genera of the class *Rhodophyceae* (red algae), is used as a stabiliser, thickener and emulsifier in liquid infant formula. Ready-to-use liquid formula is primarily used in hospitals as a convenient source of nutrition for pre-term and term infants. Currently in Australia, the liquid formulae are not widely commercialised, with powdered forms, which do not contain carrageenan, in majority use. However, in the US, liquid formulae containing carrageenan have been commercially available for over 30 years. Industry sources advise that all of the liquid formulae are manufactured overseas (Europe and the US) and imported into Australia as ready-to-use products. At least one major supplier of infant formula intends to fully commercialise their liquid products containing carrageenan in Australia, expecting to retail them in pharmacies and supermarkets.

Carrageenan is generally a mixture of three molecular forms known as kappa, lambda and iota and is commercially prepared from a variety of red seaweed genera. In Australia, only conventionally refined carrageenan is approved as a food additive in infant formula. Semi-refined carrageenan or processed *Eucheuma* seaweed (PES) is also approved for use as a food additive in Australia, the European Community, the United States and Canada.

The Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) have reviewed data on carrageenan at the 13th, 17th, 28th, 44th and most recently 51st meetings. The 1998 JECFA report on carrageenan indicates that none of the studies considered at the 17th meeting of the committee has any indication of the origin of the seaweed providing the carrageenan used in infant formula. However, it is also stated in this report that the manufacturers know that it is kappa/lambda-carrageenan (The International Food Additives Council, 1997).

Current Regulations

Under the current standard R7, infant formula may contain not more than 0.3g per litre (0.03%) of carrageenan, in the case of liquid milk-based and soy-based varieties, and not more than 1.0 g per litre of carrageenan in the case of liquid hydrolysed protein-based and amino acid-based types.

Health issues raised in the UK and Europe

In an undated report, the UK Ministry of Agriculture, Fisheries and Food (MAFF) raised concern about possible immunological consequences following absorption of carrageenan, particularly by the immature gut. The results of a single, subsequent study were included in a report by the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (1991).

This study found that guinea pigs and newborn rabbits absorbed small amounts of carrageenan. Due to continuing concerns raised by these reports, in 1992 the Food Advisory Committee (MAFF) recommended that carrageenan should not be permitted in infant formula in the UK. The 1997 Annual Report of COT contains a summary of the current UK position but this is not yet available.

The EC Scientific Committee for Food (SCF), in its 1994 report, made a similar recommendation to restrict carrageenan use in infant formula. In 1997, the Committee considered carrageenan again but deferred opinion on its use in foods for special medical purposes (FSMP) for infants and young children pending completion of a current review in relation to food use generally.

A Canadian report (Tarlo *et al*, 1995) outlined the case of an anaphylactic reaction identified as being due to intestinal exposure to carrageenan during a medical procedure. The report details the case of a female adult who suffered from chronic irritable bowel syndrome whose medical condition was subsequently demonstrated to be an allergic response to dietary carrageenan ingested in milk and other food products. This single medical case study lead to speculation that carrageenan in infant formula could account for some of the gastrointestinal symptoms which occur in infants, often attributed to milk allergy or lactose intolerance.

On the basis of these concerns regarding the potential toxicity of carrageenan in infant formula, it was recommended in 1995 at Full Assessment, that Australia prohibit its use in the revised standard. In response to the comments received from public consultation, a review of the scientific data on the safety aspects of dietary carrageenan has been undertaken and presented below.

Toxicity of Carrageenan

A recent review of the toxicity of carrageenan was undertaken by the Joint Expert Committee on Food Additives (JECFA) and a temporary ADI was extended to include processed *Eucheuma* seaweeds in a group ADI 'not specified', pending future scientific data. The review, however, did not focus specifically on the potential adverse effects on infants, and instead it is stated specifically that its ADI does not apply to infants under 12 weeks. The following discussion focuses on those toxicity issues which may be relevant to the use of carrageenan in infant formula.

Gastrointestinal effects

The gastrointestinal effects of dietary carrageenan have been the subject of both short and long term studies in several species of laboratory animals, including primates. The findings in general do not form a consensus, vary according to the particular parameters of the study (for example, protein levels in the diet)

and indicate that the response of different species to carrageenan can vary markedly.

In general, the most frequent gastrointestinal effects in rats of dietary carrageenan, ranging between 30-1000 times the level prescribed for infant formula, are changes to the stools ranging from a softening to the presence of occult blood. Weight loss and retarded growth were reported in a few cases in which there were other dietary modifications such as a low protein diet. In contrast, a study where rats were administered 4% carrageenan in skim milk for six months showed no effect on growth rate, adsorption of protein, diet energy efficiency, and the utilisation of protein or iron. Furthermore, microscopic examination of the colon and caecum revealed no abnormalities.

Studies done in 1970 and 1973, indicate guinea pigs appear to be more susceptible than rats in that these animals developed small intestinal ulcerations after 3-5 weeks of exposure. In addition, it has been reported that carrageenan containing diets induce ulceration of the large intestine of the rabbit, although the dose has not been noted.

A primate study in 1977 found no adverse effects in infant baboons fed with infant formula containing carrageenan equivalent to 10-50 times the level currently permitted in standard R7. Furthermore, rhesus monkeys who were provided with carrageenan in their drinking water equivalent to an average intake of 1.3 g/kg bw/day also showed no gastrointestinal effects directly attributable to the carrageenan. Both reports corresponded to a period of study of no more than four months.

The following is a brief summary of the scientific data to hand:

- Several studies in rats - High levels of carrageenan (15-20%) in the diet produced changes in the stools (diarrhoea, presence of blood) of the laboratory animals. In addition, in a study where the carrageenan was supplied in a low protein diet, the animals displayed weight loss and retarded growth, while animals receiving carrageenan in a diet that was high in protein showed no adverse effects. (Hawkins & Yappe, 1965)
- Similar results were obtained for mice given a diet containing 25% carrageenan.
- In rats, 1-5% dietary carrageenan over 90-92 days had no effect on food consumption, body weight or faecal appearance.
- Guinea pigs appear to be more sensitive than rats, developing pin-point caecal and colonic ulcerations after 3-5 weeks of exposure to 5% carrageenan in the diet (Grasso *et al.*, 1973).

- Infant baboons provided with infant formula containing 300-1500 mg/L of carrageenan (approx 86-432 mg/kg bw/day), from birth to 112 days developed normally, and did not display any ill effects related to the consumption of a carrageenan containing diet (McGill *et al.*1977).
- Several medium to long term studies were conducted in rats but the results are conflicting. In one study, rats on dietary carrageenan at a level of 1-5% (approximately 0.5 - 2.5 g/kg bw) grew well but occult faecal blood was observed in a significant proportion of the animals. The animals on the higher amount also developed changes in the stools, which were soft or semi-fluid. A second similar study over 12 months reported a loss of weight in the rats at all doses. In contrast, in another study which provided rats with carrageenan in the diet at levels of 0.5, 2.5 or 5% for their lifetime, the animals developed soft stools but were otherwise unaffected by the presence of carrageenan in their diet.
- Pigs given 1-500 mg/kg bw/day carrageenan for 12 weeks showed no adverse responses, in particular in growth or food utilisation. Some changes were observed in the intestinal flora of one animal receiving 200 mg/kg bw/day, and at 500mg/kg bw/day two animals displayed some changes in the intestinal mucosa but none of the changes were considered to be significant (Poulsen, 1973).

Effects on the immune system

In general, the scientific concerns are based on several reports of the immunoreactive potential of carrageenan. While a response from direct injection is not unexpected (carrageenan has been used as an adjuvant), studies in rats indicate that ingestion of carrageenan at low doses reportedly induces immunosuppression at the level of the spleen. Of significant concern is the discovery that there is limited penetration of the intestine by high molecular weight native carrageenans. Although the relatively small amounts from dietary sources crossing the intestinal mucosa may not cause acute toxicity, there may be some chronic repercussions. In young animals that have relatively permeable intestinal epithelial barriers and not yet fully developed gut-associated lymphoid tissue, the indication is that infants may be particularly susceptible to these biologically active substances. Two earlier scientific studies in rats (Nicklin and Miller, 1989, and Pintauro and Gilbert, 1990) are reinforced by a 1998 report of a delayed and significantly reduced antibody response by rats given drinking water containing 0.5% carrageenan when compared to a control group.

Only limited information on the immunological effects in human infants is available. Sherry *et al* (1993) suggest no observable immunosuppression is found in association with the consumption of carrageenan-containing liquid infant formula, at least at the broad physiological level. This finding results

from an analysis of data collected following a large National Maternal and Infant Health Survey conducted in 1988 by the United States Department of Health and Human Services. The data was examined to determine whether there was an association between frequency of upper respiratory tract infections (URIs) in the first six months of life and type of formula (liquid containing 0.03% carrageenan versus powdered formula without carrageenan). The analysis found no association between type of formula consumed and the incidence of URIs in either preterm or term infants.

Carcinogenicity

The relationship between carrageenans and colon cancer is one that involves the promotion of chemically initiated carcinogenesis as well as intestinal mucosal cell proliferation. Long term feeding studies of identified carrageenans have been done in laboratory animals including mice, rats and monkeys without identifying any major adverse effects. However, rapid colonic cell proliferation characteristic of colon cancer was reported in rats supplied with a 5% ungraded carrageenan diet (Pintauro and Gilbert, 1990). Two other studies in rats to specifically address the relationship between tumourigenesis and carrageenans both found an increase in tumour formation in association with a specified dietary regime containing carrageenan. In the absence of further data, the possibility of a rat-specific effect cannot be excluded.

Conclusion

The intention of this review is to present any further recent scientific evidence of the potential toxicity of carrageenan in liquid infant formula.

While the detrimental health effects of degraded low molecular weight carrageenan are well known, the 1998 JECFA report notes that the type of carrageenan and its source used in the reported tests is often not indicated, making valid comparisons difficult. However, the report also notes that the results of parallel studies generally indicate no major differences between the effects of the various forms of high molecular weight carrageenan or its various sources. It is presumed that the kappa/lambda form is the type present in liquid infant formula for human consumption.

There is no evidence that carrageenans are broken down to smaller molecular weight molecules in the gastrointestinal tract. At high levels of intake, this property can cause adverse effects through the physical action on the gastrointestinal tract. Moreover, species variability is noted with specific mention of the particular susceptibility of the guinea pig. The most recent and reliable studies however, do not reveal any adverse effects of toxicological significance.

Studies on the carcinogenicity of carrageenan in rats have failed to demonstrate any definitive effect. Although a proliferative response occurred in rats, the

response at the highest dose (5% carrageenan) was reversible. It has been suggested that colon carcinogenesis in the rat is somehow dependent on the normal microflora in the intestine. The 1998 JECFA report notes advice that there is no evidence of tumour promotion by carrageenan in rats in which the intestinal microflora are derived from human donors who had been adapted to carrageenan.

Although there is evidence that carrageenan can cause an effect on the immune response in laboratory situations, the only epidemiological study in human infants suggests no immunotoxicity. In 1998, the JECFA Expert Committee on Food Additives reiterated its previous statement that the ADI should not be considered applicable to neonates and young infants below the age of 12 weeks.

This report also notes that the current specifications restrict the relative mass distribution of carrageenan for food use.

On the basis of the above considerations, there is not considered to be sufficient evidence of potential adverse effects of carrageenan to restrict its use in infant formula.

References

Huffman, F.G. and Shah, Z.C. (1995) Carrageenans - Uses In Food and Other Industries. *Nutrition Today*, 30(6), 246.

Tarlo, S.M., Dolovitch, J. and Listergarten, C. (1995) Anaphylaxis to carrageenan: A pseudo-latex allergy. *J. Allergy Clin. Immunol.*, 95, 933.

Nicklin, S. and Miller, K. (1984) Effect of Orally Administered Food-Grade Carrageenans on Antibody-Mediated and Cell-Mediated Immunity in the Inbred Rat. *Food and Chemical Toxicology*, 22(8), 615.

McGill, H.C. Jr, McMahon, C.A., Wigodsky, H.S. and Sprinz, H. (1977) Carrageenan in Formula and Infant Baboon Development. *Gastroenterology*, 73, 512.

Sherry, B. and Flewelling, A. (1993) Carrageenan: an asset or detriment in infant formula. Short communication, *Am. J. Clin. Nutr.*, 58(5), 715.

Evaluation of Certain Food Additives and Contaminants. Forty-fourth report of the JECFA, WHO Technical Report Series, number 859, 1995.

Safety evaluation of certain food additives and contaminants. Fifty-first report of the JECFA, WHO Food Additives Series, 1998.

RISK ASSESSMENT FOR MICROBIOLOGICAL SAFETY OF INFANT FORMULA

Scope

Any human milk substitute.

Hazards

The following microorganisms have been associated with infant formula or are of concern because their presence above certain levels would indicate inadequate processing or post process contamination.

Salmonella spp
Staphylococcus aureus
Listeria monocytogenes
Bacillus cereus
Clostridium perfringens
Yersinia enterocolitica (liquid samples only)
Enterobacter sakazakii

Hazard characterisation

The presence of food pathogens in a properly pasteurised and dried product is generally indicative of post-process contamination.

Salmonella organisms have their reservoir in the intestinal tract of animals, and all species are considered to be potentially pathogenic. With the wide distribution of *Salmonella* in the natural environment, stringent controls are required in food processing plants, and in the preparation of foods, because very few *Salmonella* cells are needed to cause infection and subsequent illness .

Staphylococcal organisms should be destroyed in the heat processes used to produce infant formula. Any organisms therefore present are a result of post-processing contamination or due to preformed toxins surviving the processing (ICMSF 1998). Although small numbers of *S. aureus* are not a health hazard, under the right storage conditions, these organisms may grow and produce enterotoxin, which can cause illness. There is also the risk of food poisoning if post-processing contamination is combined with infant formula being reconstituted and left at room temperature for several hours.

Although there have been no outbreaks of listeriosis linked to dry dairy products, the persistence of *Listeria spp.* in the dairy plant environment and the association of listeriosis with other dairy products clearly indicates the potential for contamination on dry dairy products (ICMSF 1998). It has been reported that *L. monocytogenes* can survive a typical spray-drying process (ICMSF 1998). However, dairy products used in infant formula are given a heat treatment greater than pasteurisation which will inactivate *Listeria* prior to spray drying. The product must also be protected against contamination between the pasteuriser, the drier and packaging operations (ICMSF 1998). *Listeria* should therefore not be present in infant formula. Although infant formula does not support microbial growth due to its low water activity, it is one of the few food borne pathogens that can grow at refrigeration temperatures and if present in the dried infant formula it could possibly multiply when made up and stored inappropriately. Neonates are one of the risk groups for contracting listeriosis.

B. cereus is a common contaminant in milk and dairy products. It is able to produce spores which can survive pasteurisation and even ultra-high temperature processing (Institute of Environmental Science & Research Limited, 1995). Food poisoning occurs as a result of the bacteria producing toxins. Most *B. cereus* strains isolated from dairy products are able to grow and produce toxins below 10°C (Institute of Environmental Science & Research Limited 1995). Although outbreaks of food poisoning due to *B. cereus* have not been directly attributed to dry dairy products, temperature abuse of reconstituted product is of major concern. (ICMSF 1998).

Clostridium perfringens is widely spread pathogenic bacteria in the environment and has been detected at some level in the majority of foods examined to date, indicating that all foods are a potential source of the organism. (AIFST, 1997). It produces heat resistant spores which may survive in cooked or processed foods. If infant formula is inadequately stored when made up, the spores will germinate and rapidly multiply, creating a potential health risk. The illness resulting from ingestion of contaminated food is caused by an enterotoxin, which is produced in the intestine by organism.

Yersinia enterocolitica is often present in foods, particularly those of animal origin including milk. *Yersinia enterocolitica* should be destroyed by pasteurisation as it is heat sensitive, therefore its presence would probably result from post-process contamination. *Y. enterocolitica* can survive and multiply at temperatures as low as 0°C (AFIST 1997).

Enterobacter sakazakii has been implicated with infant formula in neonatal meningitis (Nazarowec-White and Farber, 1997). Studies have failed to identify an environmental source for the organism, and the reservoir and mode of transmission has not been clearly identified. Health Canada, studied the potential for *E. sakazakii* to grow in infant formula. Average generation times were 40 min at 23°C but *E. sakazakii* strains did not grow at refrigeration

temperatures (Nazarowec-White and Farber, 1997).

This short generation time of *E. sakazakii* in reconstituted dried infant formula at room temperature shows how quickly this organism can grow. *E. sakazakii* would not survive the pasteurisation process, however post-processing contamination is possible and there is no heat treatment in reconstitution of the formula in the home (Nazarowec-White and Farber, 1997).

Exposure evaluation

Infants are an especially vulnerable group because of their underdeveloped immune systems and because infant formula may represent their sole source of nutrition (ie. the frequency of consumption is very high).

As the 1995 National Nutrition Survey did not survey children under the age of two, it is difficult to obtain data on the consumption of infant formula in Australia. However, it has been reported that in the years 1991-1992 in Victoria, 45 - 49% of infants at six months of age from rural areas, and 42% of infants at six months of age from metropolitan areas, were breastfed (Wahlqvist, 1997). Therefore the approximate percentage of infants at six months who consumed infant formula would be around 52 - 58%.

The final quality of infant formula depends on the quality of raw ingredients, correct processing and ensuring product is not contaminated during handling after processing.

The extent of microbial destruction during drying depends on the types of microorganisms present and on the drying temperature of the exit air in spray-dried or roller-dried powder. Dairy products for drying must be given a heat treatment equal to or greater than pasteurisation, and the products must be protected against contamination between the pasteuriser, the drier and the packaging operations. After dehydration, the products will not support microbial growth.

As dried milks do not wet or disperse easily when added to water they are subject to an instantizing process. This rewets the surface of dried particles in steam or atomised water droplets, causing them to agglomerate in clusters. The product is then redried to 5% moisture or less. Accidental microbiological contamination can occur during rewetting or after it is reconstituted, since the water activity of the dried product is too low to permit growth. Subsequent processing steps such as cooling, intermediate storage, mixing and packaging may also influence the microbiological quality by recontamination from the line or the environment. During storage of infant formula, surviving organisms slowly die, but spore-formers, being the most resistant, retain viability for long periods of time (ICMSF 1998).

Infant formula is specifically designed as a human milk substitute for infants. Infant formula is consumed after being made up with boiled water. Infant

formula powder is normally stored at ambient temperatures.

However once made up it may be stored for considerable periods before consumption and there is the potential for temperature abuse if preparation and storage instructions are not correctly followed. The presence of any pathogens in the infant formula powder may therefore present a risk to infants.

Risk characterisation

Salmonella presents a high risk to infants if found in infant formula as *Salmonella* bacteria can multiply in a host and cause an infection, which can be fatal for an infant.

Outbreaks of *Salmonella* infections after consumption of contaminated infant formula were reported in the United Kingdom in 1985 (Committee on the Microbiological Safety of Food, 1990) and in Canada in 1992 from infant formula produced in the United States (ICMSF 1998). Another outbreak occurred in Spain in 1994 (Usera et al, 1996). These outbreaks were traced back to contamination from processing equipment.

Staphylococcal toxins in infant formula indicates unhygienic ingredients or unacceptable processing conditions during the manufacture of the formula. There is therefore a high risk to infants if infant formula was made up and left at room temperature for extended periods. Survival of staphylococcus enterotoxigenic strains has been indicated in dried milk used for infant formulas (Olszyna-Malzysa, 1983). Milk powder has also recently reported to be contaminated with staphylococcus aureus, which may have been due to the preformed toxin surviving processing (ICMSF 1998).

As neonates are at susceptible to listeriosis, and *Listeria* is able to grow at refrigeration temperatures, *Listeria* presents a high risk for infants if found in infant formula. Generation times for *Listeria* have been reported between 29 and 45 hours for milk and milk products at 4°C (AIFST, 1997), however at temperatures of 13°C and 35°C generation times for whole milk have been reported at 5.9 hours and 0.69 hours respectively (Doyle, 1985). Although gradual die-off has also been reported for dried milk product after the drying process (ICMSF, 1998), there is the risk of post-heat treatment contamination as *Listeria* is ubiquitous by nature. To date, surveys have not been performed to assess the incidence of *Listeria spp.* contamination in dry dairy products (ICMSF, 1998), however a survey conducted in New Zealand did not detect *Listeria* in any of its samples of Infant Formula (Institute of Environmental Science & Research Limited, 1995).

As *Bacillus cereus* and *Clostridium perfringens* spores can survive heat-treatment processing, there is a high risk to infants if spores were present in the formula and the formula made up and inadequately stored. As *Bacillus cereus* can also be psychotropic, spores present in the formula pose a high risk to infants when the formula is made up and refrigerated. The presence of *B. cereus* at low levels

in dry milk has been reported in several publications (ICMSF 1998). Survival of *Bacillus cereus* enterotoxigenic strains has been indicated in dried milk used for infant formulas (Olszyna-Malzysa, 1983).

If post-process contamination has occurred *Yersinia enterocolitica* could be of concern to liquid infant formula as the organism can multiply in product at refrigerator temperatures. If liquid infant formula is ultra heat treated/sterilised correctly, there should be no risk from *Yersinia enterocolitica*.

It has been clearly established that *E. sakazakii* can be found in dried infant formula (Nazarowec-White and Farber, 1997). With low levels of *E. sakazakii* being found in dried infant formula in combination with its relatively short generation times, the improper storage of reconstituted dried infant formula may be a cause for concern (Nazarowec-White and Farber, 1997). There has been no published work on the mechanisms of pathogenicity or associated virulence factors of *E. sakazakii*, however it appears to produce an enterotoxin-like compound (Nazarowec-White and Farber, 1997). Until more is known about *E. sakazakii*, care must be taken in the manufacture of infant formula to safeguard the microbiological quality of the finished product. It must also be noted that *E. sakazakii* is a coliform and a general criterion for coliforms will ensure that the risk from this bacteria is minimised.

Overall, the risk ranking for infant formula is high due to the vulnerability of the consumer group and the history of the product.

Risk management

Ensuring infant formula is free of food borne pathogens is the most effective measure for ensuring the final product is safe.

In determining suitable microbiological criteria and pathogen management strategies for infant formula it is preferable to adopt the approach that all infant formula should be safe to consume by infants when made up.

Pathogen free infant formula relies upon the bacteriological quality of the raw materials, adequate cleaning regimes at time of manufacture, adequate heat treatment, and packaging in hygienic conditions. It also relies upon the consumer making up the formula according to correct instructions and not storing the product at elevated temperatures.

Tests for SPC and coliforms can indicate the adequacy of processing and possible post process contamination. High SPC numbers may indicate underprocessing. Sufficient numbers of coliforms can indicate inadequacy of general hygiene in a food plant (ICMSF, 1986).

Tests for specific pathogens should be applied when the history of a product shows that the presence of the pathogen has caused illness or when moderately

hazardous organisms may constitute a severe hazard, such as an infant becoming seriously ill, or dying from salmonellosis. Testing for these pathogens is therefore an effective means of consumer protection (ICMSF, 1986).

As infants are more susceptible to food poisoning than adults, very stringent criteria are required.

POWDERED INFANT FORMULA

The suggested criterion for infant formula is as follows:

where:

- n = the number of sample units
- c = the maximum number of sample units allowed to exceed the microbiological criterion (m)
- m = the acceptable maximum level of an organism
- M = the level of an organism above which the food is unacceptable

POWDERED INFANT FORMULA

SPC (/g)	n=5	c=2	m=10 ³	M=10 ³
Coliforms (/g)	n=5	c=0	m=0	
Bacillus cereus (/g)	n=5	c=1	m=10 ²	M=10 ³
Coagulase positive staphylococcus (/0.1g)	n=5	c=1	m=0	M=0
Salmonella (/25g)	n=10	c=0	m=0	

POWDERED INFANT FORMULA WITH ADDED L⁽⁺⁾ PRODUCING LACTIC ACID CULTURES

SPC (/g) prior to the addition of Lactic acid

cultures	n=5	c=2	m=10 ³	M=10 ³
Coliforms (/g)	n=5	c=0	m=0	
Bacillus cereus (/g)	n=5	c=1	m=10 ²	M=10 ³
Coagulase positive staphylococcus (/0.1g)	n=5	c=1	m=0	M=0
Salmonella (/25g)	n=10	c=0	m=0	

POWDERED INFANT FORMULA AND POWDERED INFANT FORMULA WITH ADDED L⁽⁺⁾ PRODUCING LACTIC ACID CULTURES - guidelines only

Clostridium perfringens(/g)	n=5	c=2	m=<1	M=10
Listeria monocytogenes (/25g)	n=5	c=0	m=0	

UHT/STERILISED LIQUID INFANT FORMULA

The suggested criterion for liquid infant formula is as follows:

The product shall be sterilised or ultra heat treated and shall show no microbial growth. (This should preclude any risk of *Yersinia enterocolitica* in infant formula).

Existing microbiological provisions for infant formula are as follows:

Australian Food Standards Code

SPC (/g)	n=5	c=2	m=10 ³	M=10 ³
Coliforms (/g)	n=5	c=2	m=0	
Bacillus cereus (/g)	n=5	c=1	m=10 ²	M=10 ³
Coagulase positive staphylococcus (/0.1g)	n=5	c=1	m=0	M=0
Salmonella (/25g)	n=5	c=0	m=0	

New Zealand Microbiological Reference Criteria for Food

APC at 35°C (/g)	n=5	c=2	m=10 ³	M=10 ⁴
Faecal coliform (/g)	n=5	c=0	m=0	
Presumptive coliform (/g)	n=5	c=0	m=0	
Bacillus cereus (/g)	n=5	c=2	m=10	M=10 ²
Clostridium perfringens (/g)	n=5	c=2	m=<1	M=10
Coagulase producing staphylococcus (/g)	n=5	c=2	m=<1	M=10
Listeria monocytogenes (/25g)	n=5	c=0	m=0	
Salmonella (/50g)	n=5	c=0	m=0	

Codex

Mesophilic aerobic

bacteria (/25g)	n=5	c=2	m=10 ³	M=10 ⁴
Coliforms (/g)	n=5	c=1	m<3	M=20
Salmonella (/25g)	n=60	c=0	m=0	

ICMSF

APC (/g)	n=5	c=1	m=10 ⁴	M=10 ⁵
Coliforms (/g)	n=5	c=1	m=10	M=10 ²
Salmonella (/25g)	n=60	c=0	m=0	

Prepared by: Narelle Marro

References

- AIFST 1997 *Food borne Microorganisms of Public Health Significance*. 5th edn. AIFST (NSW Branch) Food Microbiology Group, Australia.
- Committee on the Microbiological Safety of Food 1991 *The Microbiological Safety of Food, Part II*, HMSO, London.
- Doyle, MP (ed) 1989 *Food borne Bacterial Pathogens*. Marcel Dekker Inc., New York.
- ICMSF 1986 *Microorganisms in Foods 2, Sampling for microbiological analysis: Principles and specific applications*, 2nd edn., Blackwell Scientific Publications, Oxford.
- ICMSF 1996 *Microorganisms in Foods. 6 Microbial Ecology of Food Commodities*, Blackie Academic and Professional, London.
- Institute of Environmental Science & Research Limited 1995 *Chemical & microbiological composition of infant formula. A report for the Ministry of Health/Public Health Commission October 1995*.
- Nazarowec-White, M. and Farber, J. M. 1997 '*Enterobacter sakazakii*: a review', *International Journal of Food Microbiology*, 34 pp 103-113.
- Nazarowec-White, M. and Farber, J. M. 1997 'Incidence, Survival, and Growth of *Enterobacter sakazakii* in Infant Formula', *Journal of Food Protection*, 60:3 pp 226-230.
- Nazarowec-White, M. and Farber, J. M. 1997 'Thermal resistance of *Enterobacter sakazakii* in reconstituted dried-infant formula', *Letters in applied Microbiology*, 24 pp 9-13.
- Olszyna-Marzysa, Dr A. E. 1983 *Conditions of Storage and Distribution, and their impact on the Nutritional value and safety of products specifically intended for infant and young child feeding*, WHO.
- Usera, MA; Echeita, A; Aladuena, A; Blanco, MC; Reymundo, R; Prieto, MI; Tello, O; Cano, R; Herrera, D; Martinez-Navarro, F 1996 'Interregional food borne salmonellosis outbreak due to powdered infant formula contaminated with lactose-fermenting *Salmonella virchow*', *European Journal of Epidemiology* 12:4 pp 377-81.
- Wahlqvist, Mark. L. (ed), 1997 *Food and Nutrition*, Allen & Unwin, Sydney.

REPORT: LABELLING PROVISIONS FOR INFANT FORMULAS

1. PRINT SIZE, FORM AND CONTENT OF MANDATORY STATEMENTS

Current requirements

Australian Food Standards Code

Standard R7 - Infant formula currently requires mandatory statements to appear in the label of infant formula in standard type of 3 mm. Small packages of less than 1 kg may declare this information in standard type of 1.5 mm. Declaration in the label relating to the direction for use of the product are required to appear in standard type of 1.5 mm.

The form of mandatory statements is currently prescribed. Manufacturers must use the wording prescribed by the Code.

New Zealand Food Regulations

The NZFR does not specifically prescribe the format of required statements in the label of infant formula and it does not specifically indicate the print size of mandatory statements. The form of the mandatory statement is not prescribed.

Codex requirements

The proposed Codex Standard for Infant Formula does not specifically stipulate the required print size, form or content of mandatory statements. Where mandatory statements are required the intent of the statement is given but the wording is not prescribed.

Issues raised in submissions

Use of upper case lettering and print size

Heinz stated that consideration be given to permitting the use of upper and lower case characters. They claim that the current upper case statements are difficult to read, which negates the intent of the statements.

The FSC currently requires statements prescribed in Standard R7 to be in 'standard type' of 3 mm or 1.5 mm. Standard type requirements (Clause 4(c) of the Preliminary Provisions) permit the use of:

- bold-face sanserif capital letters of not less than the specified size;
- bold-face or semi-bold letters the smallest of which is not less than 1.5 the specified size; or
- letters other than bold-face or semi-bold letters the smallest of which is not less than twice the specified size.

Therefore, manufacturers currently have the choice of using upper or lower case lettering for the statements prescribed in Standard R7. If the manufacturer chooses to use lower case letters then the smallest letter must not be less than 6 mm (twice the specified size of 3 mm).

There is evidence that statements written in upper case are difficult to read and that the use of lower case and other printing techniques such as bolding, underlining and a combination of upper and lower case can make the statements more noticeable and easier to read.

Codex does not require any mandatory statements to be in upper case letters. It would create a barrier to trade and would not align with the principles of the WTO if labelling requirements for infant formula are implemented in Australia and New Zealand that are not consistent internationally.

The Authority is conducting a Review of Print Size and Quality, P142, as a part of the Review of Labelling Requirements in the Food Standards Code. P142 is recommending that:

- current provisions relating to print size and quality be deleted and replaced with the simplified requirements that all prescribed information on a food label must be legible and in English;
- standard type (upper or lower case) and print size no longer be specified;
- due to their direct link to public health and safety, warning statements should be in a size of type of not less than 3mm, or 1.5 mm for small packages. The case of a warning statement will not be specified. Print size for advisory statements should not be prescribed; and
- small packages be defined as a package with a total surface area of less than 100 cm².

The outcomes of this review will extend to the required statements in Standard R7. In the meantime it is proposed that the printing style (upper case or lower case) of any warning or advisory statement required by the revised Standard R7 should not be prescribed. The manufacturer is responsible for ensuring that such statements are presented in a manner that is clear and noticeable to the consumer.

In addition the issue of print size for mandatory statements must be considered. At present standard type size is 1.5 mm and most warning statements are required to appear in the label of infant formula in 3 mm type size. -Until the review of print size and quality is complete, and the Joint Food Standards Code is adopted, it is proposed that any mandatory warning or advisory statements required in the label of infant formula appear in type of not less than 3 mm, that is the smallest letter should be not less than 3 mm, as is currently required. All other mandatory labelling requirements should appear in standard type of not less than 1.5 mm.

Until such time as the joint ANZ FSC provisions for print size come into force, print size for all mandatory statements should continue to be classified as set out in clause 4(c) of the preliminary provisions of the Food Standards Code.

Small packages

Scientific Hospital Supplies (SHS) indicated that due to cost, hospitals only buy small quantities of specialised formulae, therefore the maximum package size produced by SHS is 500g. They explained that there is insufficient space to include the amount of information and warning statements required by Standard R7. They also expressed concern that having so many statements on a label will result in consumers ignoring the information.

While P142 is recommending that a small package be defined as having a total surface area of less than 100 cm², due to the large amount of information required to appear on the label, small packages of infant formula should be considered separately. It is reasonable that small packages should be permitted to use a smaller print size for mandatory statements than is required for larger packages. It is proposed that packages of infant formula which weigh less than 1 kg may present mandatory advisory and warning statements in type of not less than 1.5 mm.

Prescription of wording

SHS suggested that there should be a general requirement for various warning statements, as in the EU Directive, with the exact wording at the discretion of the manufacturer. They expressed concern that the prescriptive nature of statements may have space constraints. They warned that if each country were to develop its own specific statements, there could be a barrier to trade in highly specialised formulae, leading to higher costs and delays in the supply of these products in emergency situations.

The Authority is currently conducting a Review of Specific Labelling Statements, Proposal P161. P161 is considering the use of warning and advisory statements in the label of foods where there is a public health and safety concern. At the present time it is proposed that:

- a warning statement should be used if the risk to health is life threatening and it can be reasonably assumed that the general population or the specific target group is unaware of the potential risk to their health and a statement is needed to alert them to the risk;
- an advisory statement should be used when the general public or the sub-population is exposed to a significant potential risk to health but the risk is not life threatening, or when guidance about use of a food is needed to protect public health and safety; and
- all warning and advisory statements should be mandatory. The form of a warning statements should be prescribed, whereas the form of advisory statements should not be prescriptive.

Statements required in the label of infant formula should be consistent with statements required in the label of other foods. Where a statement is considered necessary because there is a potential life threatening risk to the infant or a specific group of infants in the community then the wording of the statement should be prescribed in the Food Standards Code.

However, if the statement is considered to be providing advice where there is a potential significant public health and safety risk to an infant but that risk is not life threatening then the Code should simply prescribe the intent of the statement.

The Authority proposes that any mandatory statements required to be declared in the label of infant formula be consistent with the definition of either an advisory statement or a warning statement.

Need for and content of specific statements

The following statements were proposed for mandatory declaration in the label of infant formula at the full assessment of P93:

(a)'ATTENTION - BREAST MILK IS BEST FOR BABIES. BEFORE YOU DECIDE TO USE AN INFANT FORMULA, CONSULT YOUR DOCTOR OR CHILD HEALTH CLINIC FOR ADVICE.'

(b)'WARNING - UNBOILED WATER, UNBOILED OR UNSTERILISED BOTTLES AND TEATS CAN MAKE YOUR BABY ILL. PREPARE ONLY ONE BOTTLE AT A TIME. FOLLOW INSTRUCTIONS EXACTLY.'

(c)'USING MORE OR LESS [POWDER OF LIQUID CONCENTRATE use whichever is applicable] THAN INDICATED MAY EITHER LEAD TO DEHYDRATION OR DEPRIVE YOUR BABY OF PROPER NUTRITION. DO NOT CHANGE PROPORTIONS WITHOUT MEDICAL ADVICE.'

(d)'FOR INFANTS OVER THE AGE OF 6 MONTHS, IT IS ADVISABLE TO INTRODUCE OTHER FOODS'

(e)'IF CORRECTLY STORED AND MADE UP IN ACCORDANCE WITH THE DIRECTIONS CONTAINED IN THE LABEL, NO FURTHER VITAMIN OR MINERAL SUPPLEMENTS ARE NECESSARY'

(f)'USE ONLY THE ENCLOSED SCOOP'

(g) The label of proximate modified human milk substitute must include the statement:

'THIS PRODUCT HAS BEEN SPECIFICALLY FORMULATED FOR INFANTS WITH SPECIAL DIETARY NEEDS AND SHOULD BE USED UNDER MEDICAL SUPERVISION'

Various comments were received in submissions on the suitability of these statements. Each statement is assessed separately below.

(a)

'ATTENTION - BREAST MILK IS BEST FOR BABIES. BEFORE YOU DECIDE TO USE AN INFANT FORMULA, CONSULT YOUR DOCTOR OR CHILD HEALTH CLINIC FOR ADVICE.'

The International Code of Marketing of Breast milk Substitutes requires that there be in the label of infant formula:

- a statement of the superiority of breast-feeding; and
- a statement that the product should be used only on the advice of a health worker as to the need for its use)

This requirement is the basis for including the above statement in the draft standard. The proposed draft Codex standard for infant formula states that labels should not discourage breast feeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

- (a) the words "important notice" or their equivalent;
- (b) a statement of the superiority of breast feeding;
- (c) a statement that the product should only be used on advice of a health worker as to the need for its use and the proper method of use;

Assessment

The above prescribed statement proposed for inclusion in the Food Standards Code covers the intent of the Codex requirements and the requirements of the

International Code of Marketing of Breast Milk Substitutes. However, the Authority considers that it is not necessary to prescribe the exact wording of the statement. It is considered that the code should only indicate the intent of the statement.

This statement is considered to be an advisory statement because it advises the user of the infant formula, that for optimal health of the baby breast milk is best and that if they are considering using infant formula instead they should talk to their health worker about it. This statement is not intended to protect the infant from a life threatening situation but encourages the care giver to consider if infant formula is the correct choice of feed for their infant.

Submissions did not specifically comment on the statement however, there was a concern over the proposed required statement "SUITABLE FROM BIRTH" which was proposed to be required in the label of infant formula following the prescribed name. Similar consideration applies to the statement for follow-on formula.

The concern with the statement was that it may be "legally indefensible". It was argued that the Authority has a legal responsibility to ensure that mothers are suitably informed about the very considerable health risks to the infant and to the mother if anything other than breast milk is consumed by the infant in the first six months of its life.

The team considered that the desirability of breast feeding, in preference to bottle feeding, is adequately reflected in the statement required by the International Code of Breast Milk Marketing and Codex and that it would be desirable for this statement to be placed near the 'age suitability' statement. It was further considered that the word 'suitable' could be construed as giving approval for the use of formula, and that removal of this word would make the statement more 'matter-of -fact'.

The team concluded that :

- the word "SUITABLE" should not be used and there should be a statement on the label indicating the infant formula product may be used from birth and if a follow-on formula is used it should not be introduced before the infant is 6 months or older.

RECOMMENDATION

It is recommended that the proposed Codex requirement as outlined above be adopted into the Food Standards Code, and that an additional criteria be included, that there should be a statement indicating in the case of an infant formula, the product may be used from birth and if a follow-on formula is used it should not be introduced before the infant is 6 months or older'.

(b)

'WARNING - UNBOILED WATER, UNBOILED OR UNSTERILISED BOTTLES AND TEATS CAN MAKE YOUR BABY ILL. PREPARE ONLY ONE BOTTLE AT A TIME. FOLLOW INSTRUCTIONS EXACTLY.'

(c)

'USING MORE OR LESS [POWDER OF LIQUID CONCENTRATE use whichever is applicable] THAN INDICATED MAY EITHER LEAD TO DEHYDRATION OR DEPRIVE YOUR BABY OF PROPER NUTRITION. DO NOT CHANGE PROPORTIONS WITHOUT MEDICAL ADVICE.'

No similar requirements exist in the NZFR or the Codex proposed standard for infant formula. However, there is a requirement for a statement that the product should include instructions for appropriate preparation and a warning against the health hazards of inappropriate preparation.

Issues raised in submissions

Douglas, Heinz, Wyeth, InforMed Systems and the Dietitians Association of Australia (DAA) all expressed concern over the required statement, "Prepare only one bottle at a time". Douglas suggested that it creates confusion. They argued that as long as formula is prepared according to instructions, refrigerated during storage and used within 24 hours, the practice of making up 24 hours' supply at a time does not pose any microbiological hazard. Heinz suggested that if the intent of this statement is that the formula should be used within 24 hours, and unused formula should be discarded, then this could be covered in the storage instructions.

Heinz, InforMed and the DAA commented that in practice bottles are rarely made up one at a time. Heinz stated that to some care givers this statement may mean each bottle should be individually sterilised.

InforMed noted that preparing more than one bottle at a time is considered safe, as long as there are instructions about clean preparation and storage under refrigeration for not more than 24 hours. They suggested that it may be more to the point to reinforce advice about cleansing of bottles prior to filling and to prohibit the reuse of formula left in the bottle from a previous feed. The DAA stated that it is more of a concern that parents may not be receiving advice for such common practices as preparing multiple bottles or feeding away from home or tips when travelling.

Wyeth recommended that in place of the statement "Prepare only one bottle at a time" there should be the following: "Prepared formula should be refrigerated and used within 24 hours". Their rationale was that the vast

majority of Australian homes have refrigerators and it is not logical to insist on the preparation of only one bottle at a time, when a day's supply can easily be prepared at a time provided that the prepared product is refrigerated.

Wyeth suggested that the product label instructions should be consistent with the instructions given by health workers and cited the final draft of the NHMRC Infant Nutrition Panel Guidelines for Health Workers which states, "Store all made up formula in the centre back of the fridge where it is coldest, not in the door where it is warmer," and "Put formula straight back into the refrigerator as soon as it is made."

The DAA indicated that it may be confusing to some parents to have "unboiled or unsterilised bottles", and that the term "unsterilised" would suffice. They also noted that the phrase "more or less" (14(c)) may be difficult to grasp immediately.

One submission commented that many mothers have great difficulty following the instructions for preparation of bottles, and since it's very important that formula is prepared correctly, manufacturers should be required to demonstrate that their instructions are user-friendly or alternatively provide a simple dipstick to test the strength of the formula.

HSH suggested that there needs to be a cautionary statement on the label as to the use of mineral or bore water. They said they were unsure whether the reference to 'de-ionising water' in para 10(3), relating to "Limit on fluoride" was expected to cover this.

Assessment

There are two separate issues linked to these clauses: the potential to inadvertently alter the concentration of the formula by bulk preparation and the microbiological safety of the formulas.

Correct formulation

Infant formula that is not prepared to the correct formulation may be a life threatening risk to an infant due to the consequences of dehydration and solute load on the kidneys. Deprivation of proper nutrition may also be a life threatening risk. It is usual to include advice about the number of scoops of formula powder (or concentrate) required to prepare each feed. Therefore it is important carers make up bottles individually even if several bottles are made at one time and therefore it is recommended that manufacturers advise carers of the need to prepare bottles individually.

Microbiological safety

It is considered safe, in microbiological terms, to make up several bottles at a time provided they are stored in the fridge for not more than 24 hours.

Information on the label should be consistent with and complimentary to the information provided by health professionals. The proposed advisory statement would align with the instructions in the NHMRC Infant Nutrition Panel Guidelines for Health Workers.

The problem raised by InforMed and Heinz, of the reuse of formula left in the bottle from a previous feed could be solved by requiring manufacturers to ensure their product contains adequate directions for use and storage and an indication that left over formula should not be reused.

DAA has commented that in clause 14(1)(c) of the draft standard, the term "...unboiled or unsterilised bottles..." may be confusing and that the term 'unsterilised' should suffice.

The term 'unsterilised' is not included in the current Standard. It was introduced into the draft standard in recognition of the fact that bottles may be sterilised by methods other than boiling. However, the use of sterilising tablets may alter formula content

According to the criteria for inclusion of a prescriptive warning statement in a food label as outlined in Proposal P161 - Specific Labelling Statements, the risk to the health of the consumer must be life threatening for a prescriptive statement to be required. Incorrect preparation of bottles for infant formula presents a significant health risk to infants which, depending on the circumstances, may be life threatening. The person preparing the bottles needs to be informed that the bottles need to be sterilised. It is the manufacturers responsibility to ensure they provide adequate directions for use to ensure the safety of the product. In addition to these directions for use and storage, the label of infant formula should contain a warning statement against the health hazards of inappropriate preparation.

This warning statement should indicate that bottles and teats should be sterilised as shown in the instructions to prevent the baby from becoming ill.

The Authority considers that the manufacturer should not have to demonstrate that the instructions for preparation are user-friendly, but it is their responsibility to ensure that the product can be made up as intended by ordinary consumers. Whilst it is considered inappropriate to require manufacturers to provide a method of testing the strength of the formula after it is prepared by the consumer, manufacturers may do so if they wish.

In regard to the request for a cautionary statement on the use of mineral or bore water to reconstitute formula, it is noted that some manufacturers use the term 'fresh' water or 'fresh drinking water' in the preparation instructions. The Authority regards it as the manufacturers' responsibility to ensure that clear directions for use are given, and this would presumably include the type of water to be used. Codex indicates, in the proposed draft revised standard for infant formula, in the product description section, that infant formula requires safe, potable, and previously boiled water for preparation.

Recommendation

The Authority recommends that the following warning statement should appear in the label of infant formula.

“Warning - Follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder or concentrate (- use whichever is applicable)

except on medical advice. Inappropriate use or preparation can make your baby very ill.”

As indicated previously in this paper this warning statement should appear in type of 3 mm, that is the smallest letter should be no less than 3 mm.

In addition the Authority proposes that there be a requirement for infant formula in a powdered or liquid concentrate form to contain words and pictures as to its use and preparation. The directions for preparation and use should include the following that:

- each bottle of formula should be prepared individually;
- if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours;
- potable, previously boiled water should be used; and
- formula left in the bottle after a feed must be discarded.

(d)

‘FOR INFANTS OVER THE AGE OF 6 MONTHS, IT IS ADVISABLE TO INTRODUCE OTHER FOODS’

Currently Standard R7 of the Food Standards code currently requires the statement:

‘AFTER 4-6 MONTHS OF AGE YOUR BABY MAY NEED ADDITIONAL NOURISHMENT. CONSULT YOUR DOCTOR.’

There is no similar requirement in the NZFR. The proposed Codex standard for infant formula indicates that the label of infant formula should contain information that infants (over six months of age) should receive supplemental foods in addition to the formula.

No specific comment was received about the need for this statement.

Assessment

Under proposal P161 such a statement would be classed as an advisory statement because it is providing advice to the consumer that additional foods should be included in the diet in order to reduce the risk of ill health due to poor nutrition. Therefore, there is no need to specifically prescribe the wording of the statement.

Such a statement is useful information for consumers and it aligns with Codex to provide such a statement. It is recommended that the Codex requirement be adopted.

Recommendation

An advisory statement should appear in the label of infant formula providing information that infants (over 6 months of age) should receive other food in addition to the formula.

(e)

'IF CORRECTLY STORED AND MADE UP IN ACCORDANCE WITH THE DIRECTIONS CONTAINED IN THE LABEL, NO FURTHER VITAMIN OR MINERAL SUPPLEMENTS ARE NECESSARY'

This statement is required currently in the Food Standards Code and it was proposed as a requirement in the new standard for infant formula. The NZFR currently require the following label on each package of infant formula to bear the words 'An infant being fed this formula does not require additional vitamin or mineral supplements', or words of similar meaning. Such a statement is not required currently by Codex in the proposed draft standard for infant formula.

Assessment

Specific comment was not received in regard to this statement by submissions. Such a statement provides useful information to consumers and may assist in protecting the infant from ill health related to toxicity of vitamins and minerals.

However, it does not align internationally to prescribe the use of such a statement in the label of a food. Such a statement currently presents a trade barrier and will continue to present a trade barrier. Consideration needs to be given to the need for this statement and whether the information about the use of vitamins and minerals in addition to infant formula could be provided by means other than the food label.

Such information could be provided by a health worker. One of the proposed required statements already discussed in this paper indicates that a health worker should be consulted before the use of infant formula. Such information could be provided by the health worker at that stage.

Manufacturers may voluntarily provide such information in their label or in information provided to consumers, eg leaflets, about the product. A guideline or editorial note in the Code, could be developed to encourage manufactures to provide such information to consumers.

Recommendation

Proposal P93 has recommended that a guide for manufacturers on the maximum levels of vitamins and/or minerals in infant formula be developed. It is proposed that an additional guideline recommending manufacturers

indicate in the label that additional vitamin or mineral supplementation is not needed be incorporated into the guideline document.

(f)

'USE ONLY THE ENCLOSED SCOOP'

The above statement is a current requirement in the Food Standards Code and is proposed as a requirement in the new proposed draft standard. Codex and the NZFR do not have a similar requirement except that the label should contain adequate storage instructions and directions for use.

Summary of submissions

Francis and the former Department of Human Services and Health (DHS) recommended introduction of a standard scoop size, whilst Heinz noted that scoop sizes for different infant formulae cannot be standardised, due to different product densities. The DHS mentioned that difference in scoop sizes is a common cause of incorrect reconstitution of powdered formula.

Francis recommended that the scoop size be such that 1 level scoop of powder is added to each 30 mL of water. She claimed that this is a dilution which is convenient, avoids excessive increments in volume when extra formula is needed and is the most common dilution of the current powder formulae on the market. She advocated that liquid concentrate also be standardised to 50 mL liquid concentrate to 50 mL water.

Recognising that this an opportune time to achieve consistency in the preparation of infant formula, Francis explained that the design of the scoop is important, a deeper scoop being more accurate than a shallow one and that it is important to have standardised instructions regarding filling and levelling of the scoop with a knife edge and the amount of water to which a level scoop should be added.

Assessment

The purpose of this statement is to advise the consumer that they should use only the scoop enclosed in the package to measure the powdered infant formula to ensure that the concentration of the infant formula is correct.

The Authority acknowledges that there is a problem associated with varying scoop sizes in different brands of infant formula and different dilution factors. It would be possible for the Authority to require a standard scoop size for all formulae, or a standard dilution but this would set up a trade barrier. To standardise both scoop size and dilution factor would be to required all formulae to have the same density which would not be possible.

It was noted by the project team that the use of sachets could solve the problem. However, it was considered that to require all infant formula to be in sachets would impose a cost on manufacturers that is not warranted and it is not environmentally sound.

The Authority considers that the only practical solution is for manufacturers to advise consumers that they should only use the scoop provided by the manufacturer. However, it is considered that this kind of information should be provided in the instructions for use provided by the manufacturer and should not have to be a separate mandatory statement required by the Food Standards Code. There is no public health and safety reason for specifically requiring the statement 'Use only the enclosed scoop'. There is public health and safety justification, however, for providing statements advising the consumer to follow instructions exactly as indicated previously.

Recommendation

It is proposed that where a measuring scoop is provided, the instructions for use of powdered infant formula should contain information that only the enclosed scoop should be used. This will assist consumers in making up the correct proportions and should be required because it is linked to the previously discussed warning statement about appropriate use of the product and use of the correct proportion of powder or concentrate.

(g)

The label of proximate modified human milk substitute must include the statement:

'THIS PRODUCT HAS BEEN SPECIFICALLY FORMULATED FOR INFANTS WITH SPECIAL DIETARY NEEDS AND SHOULD BE USED UNDER MEDICAL SUPERVISION'.

The NZFR does not specifically require such a statement. The proposed draft Codex standard for infant formula indicates that a product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirements for which the formula is to be used and the dietary property or properties on which it is based. It also indicates that no health claims shall be made regarding the dietary properties of the product.

Assessment

The above statement, as currently proposed, is very prescriptive and there is a concern amongst team members that the use of the term 'special dietary needs' may be misleading to consumers.

Infant formulas formulated for metabolic and immunological needs are intended for infants who are unable to tolerate breast milk or normal infant formula due to a medical problem. The proposed standard indicates that in addition to the above statement that the label must also include a statement indicating the medical conditions for which the food has been specially formulated and the nutrient modification which applies to the food.

Such infant formulas are not expected to be generally available and should not be used except under medical supervision. If consumed by an infant without a specific medical problem that required the use of such products, the risk to the infant's health could be significant. The Authority considers that there needs to be an indication in the label of such products that they should only be used under medical supervision and that these formulas are not suitable for general use.

The Authority also considers that there is a need to indicate under what circumstances such a formula should be used and the dietary properties on which it is based as proposed by Codex.

The use of a declaration indicating the circumstances under which such a formula should be used may be seen as a health claim. As is proposed in Codex no specific health claims should be made by manufactures in regard to the dietary properties of the product; however, there is a need to indicate the intended use of the product for the benefit of consumers and medical practitioners.

RECOMMENDATION

It is proposed that infant formula specially formulated for metabolic and immunological need contain the following warning statement in the label:

- the product is unsuitable for general use and should only be used under medical supervision'

and an advisory statement indicating:

- the special requirements for which the formula is to be used; and
- the dietary property or properties on which it is based.

It is proposed that there be an indication that this statement should not be made in the form of a health claim in regard to the dietary properties of the product.

(h)

The label of pre-term infant formula must include the statement:

“SUITABLE ONLY FOR PRETERM INFANTS UNDER SPECIALIST MEDICAL SUPERVISION” for pre-term infant formula.

Assessment

There are no international regulations for Pre-term formula. This formula type is not designed for infants with 'normal' requirements and levels of nutrients are not likely to be suitable for term infants. Therefore the statement proposed at full assessment should be included in the joint ANZ standard for infant formula.

WARNING STATEMENT FOR INFANTS WITH GALACTOSEMIA.

This issue is addressed under essential composition at Appendix 1

2. NUTRITION INFORMATION TABLE

The current Codex position on the provision of nutrition information on infant formula is that :

The declaration of nutrition information shall contain the following information in the following order:

(a) the amount of energy, expressed in kilocalories (kcal) and /or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as 100 milliliter of the food ready for use, when prepared according to the instructions on the label.

(b) the total quantity of each vitamin, mineral, choline and any optional ingredient as listed in paragraphs 3.1.2 and 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label. In addition, the declaration per 100 kilocalories (or per 100 kilojoules) is permitted.

The proposed revised Standard R7 differs from Codex in that:

- 1 the revised Standard R7 is proposing that minimum levels for nutrients be stated in the nutrition information table (NIT) whereas Codex require weighted average values;
- 2 the revised Standard R7 make no allowances for choline and optional ingredients to be included in the NIT whereas Codex do;

- 3 the revised Standard R7 require nutrient information per 100mL whereas Codex require the information per 100 mL as ready to use and per 100g of the food as sold.
- 4 there are differences in nutrient order of the tables and in the units of measurement.

1 Minimum Nutrient Levels

Analysis of the submissions shows strong support for recommending the declaration of average or optimal nutrient contents rather than minimum values. It is believed that this information is more useful to both the consumer and health professional as it more truly reflects the actual composition of the product. This information will be used by some health professionals in the calculations of ideal nutrient intakes for some infants.

Consistency with both international regulations and other standards within the joint FSC would support a position that requires the declaration of average or typical nutrient composition rather than minimum.

Recommend: that the nutrient values in the NIT be average or typical nutrient values.

2 Allowances for choline and optional ingredients

The draft proposed at full assessment makes no allowance for choline or other ingredients not listed in the proposed NIT. This is inconsistent with the current Codex standard and does not provide any flexibility for ingredients in the formula. The Codex standard requires that the declaration of nutrition information shall contain information on optional ingredients where optional ingredients are other nutrients that may be added when required in order to provide nutrients ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrients in the label.

New Zealand exempt special purpose foods, including infant formula, from needing to meet minimum requirements to include nutrition information on the label, because it is often important for consumers and health professionals for special medical conditions.

It is believed that all nutrients added to infant formula should be declared as part of the NIT.

Recommend: that the NIT be amended to include choline and other ingredients in its list so that all nutrients in infant formula are listed in the NIT.

3 Per 100g as sold and per 100mL ready to drink

There were no comments in the submissions regarding this difference with Codex. The NZFR also require the information as sold and as consumed. It is recognised that the information of use to the consumer and health professional is primarily as consumed. People may be interested in the composition of the dry powder if wanting to modify feeds but there is potential for causing an imbalance of nutrients if feeds are modified by a non professional.

Recommend: that the NIT include nutrients as purchased (per 100g dry powder) as well as per 100mL ready to consume formula.

4 Differences in units and order of nutrients.

In the present draft there are differences in the order of nutrients and the units, both with Codex and with other tables within the current draft. It is particularly important that the order of nutrient be consistent within the standard. This means that the order of nutrients in the NIT should be consistent with schedule 3 and schedule 4.

Units of vitamin E should be in mg not mcg.

Recommend: that the order of nutrients in the NIT be consistent throughout the standard.

3. FEEDING GUIDE

The purpose of a feeding guide on infant formula products is to require manufacturers to provide guidance to care givers on both the preparation of the formula and the recommended number of feeds each day. The current draft guide proposes a guideline that is quite detailed by age breakdown.

There is no such precedent in Codex or in the NZFR.

Most feedback from consultation was that the proposed guide was too inflexible and had the potential to provide parental anxiety because of prescriptiveness. The guide does not provide consistency with the current infant feeding recommendations of breastfeeding, which is to demand feed.

Manufacturers do currently provide guidance on preparation of formula and suggested feeding but the proposed guide is too prescriptive in both quantity and number of feeds. It is not clear as to why the recommendation for a prescriptive feeding guide was made as there is no argument made for the public health and safety of the infant. It is not believed that providing information in the format suggested is going to safeguard the health and safety of the infant any more than the current regulations do.

Most manufacturers provide information on the feeding of infant formula both because it is important in the successful promotion, sale and end use of their product and because most regulations for infant formula, including Codex and the NZFR, require directions as to the preparation and use of the food on the label. It is recommended that the joint ANZ standard for infant formula use the same approach in requiring provision of directions on preparation and use on the label.

Recommendation: That the joint ANZ standard for infant formula require the provision of directions as to the preparation and use of the product but do not prescribe the format of those directions.

4. DATE MARKING, STORAGE INSTRUCTIONS AND DIRECTIONS FOR USE

Issues

In general, date marking is not required for products with a long shelf life ie a minimum durable life of 2 years or longer. Infant formula products are frequently available as powders which have a long shelf life.

Human Services and Health makes the claim that in the very hot areas of Australia, opened cans or packages deteriorate before the expiry date.

Assessment

Codex requires the infant formula products to be marked with a 'best before' date. In addition to the date, any necessary special conditions for storage of the food are required to be indicated if the validity of the date depends these. The Codex standard provisions require that the expiry date must take into account the conditions in each country where infant formula is sold.

Codex also requires directions for storage and keeping after the product has been opened to be provided for infant formulas.

The provisions in the draft proposed at full assessment require storage instructions for the periods before and after opening of the package to be given on the label.

Date marking

The date marking requirements apply to the shelf life of an unopened product. The date marking provisions for infant formula products should be required regardless of product shelf life as there will be loss of some micro nutrient potency with extended shelf life, particularly from light exposure for those products in transparent containers.

Directions for use

Once an infant formula product is opened it may start to deteriorate rapidly. Therefore it is critical that instructions be provided for storage after the product is opened.

Recommendation:

That provision be made in the joint ANZ standard for infant formula to require the manufacturer to provide:

- storage instructions for after the product is opened and
- date marking in accordance with date marking requirements for all infant formula products regardless of shelf life.

An editorial note should be included in the standard to advise manufacturers that the storage instructions must be valid for the full range of climatic conditions in Australia and New Zealand.

DRAFT EXPLANATORY NOTES

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 to the Explanatory Notes.

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 B₆, 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.

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 \geq 20)	2
- Arachidonic acid (20:4)	1
Long chain omega 3 series fatty acids (C \geq 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 \geq 20) should be double the total long chain omega 3 series fatty acids (C \geq 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 novel 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 4

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 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>.

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 macronutrient 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
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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 \leq 8%	No limit given	Trans \leq 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 contaminants	None specified	None specified in reg 242	Max for Al, Pb Specific labelling for formulas with high fluoride content.
Microbiological 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

Labelling - prescribed names	None, although prescribed text for 'infant formula'	Infant formula; follow-on formula or other appropriate designation	Infant formula; follow-on formula
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Element	Current Standard R7	Current NZ Regulation 242	Draft Standard 2.9.1 compared to Std R7)
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
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

PUBLIC COMMENT RECEIVED
P93 - INFANT FORMULA PRODUCTS
P93 Infant Formula
Summary of Submissions

1. Abbott Australasia (Abbott)

Maximum level of aluminium

upper limit for non-soy formulae should be same as for soy formulae (1.0 mg/L):

- limit of 0.2 mg/L unnecessarily low;
- studies have shown no difference between breast and formula fed infants wrt blood levels of Al;
- level in formula is well below safe level established for humans by JECFA; and;
- processing infant formula in glass raises the Al content.

Maximum level of fluoride

upper limit for non-soy formulae should be same as for soy formulae (2.0 mg/L):

- limit of 0.5 mg/L unnecessarily low;
- illogical to set lower level for non-soy based formulae; and
- proposed maximum would be difficult /impossible to adhere to in specialty formulae where addition of fluoride-containing ingredients (eg. tricalcium phosphate salts) are required.

Concern over soy formulae concerns over health hazards raised in NZ not well founded:

- insufficient supporting data to justify warning statement;
- soy based infant formula available for over 60 years and no adverse effects related to phytoestrogens have been identified; and
- data from controlled clinical trials have demonstrated that infants fed soy formulae develop and grow normally.

Use of minimum levels in NIT:

- prefers average to minimum values;
- they give more accurate determination of the quantity of nutrient to be consumed by infant.

Need for prescribed format for non-warning statements:

- these are a guide, and manufacturers should be required to convey the desired intent without having the wording prescribed.

Prohibition on carrageenan:

- seeks reassessment of proposed prohibition;
- should align with Codex;
- prohibition is unwarranted and unnecessary;
- no evidence of health problems with its use in infant formula, despite extensive clinical studies and many years of experience; and
- concern has only been raised in UK.

Maximum level of nucleotides:

- maximum levels should be increased to achieve the average total potentially available nucleotides (TPAN) in breast milk;
- maxima are same as in draft EC Directive;
- maxima are too low, reflect research carried out in 1985, rather than a 1995 paper which suggests traditional methods underestimate the (TPAN) in breast milk by more than 50%.

Maxima for vitamins and minerals:

- setting maxima justified for nutrients which have an adverse effect when consumed in large quantities;
- only nutrients deliberately added to infant formula should have upper limits (eg Fe as ferrous salts, vitamin B6 as pyridoxine);
- do not need maxima for nutrients which are coincidental components of other ingredients and have a wide margin of safety (eg vitamin K in soy oil, riboflavin in cows milk, tocopherols in vegetable oils);
- Codex, EU and US FDA do not have maxima for water-soluble vitamins
- harmonisation should be an important consideration;
- ranges for water soluble vitamins will cause major manufacturing difficulties in setting specifications to meet the requirements at the expiry date of the product;
- there are cost implications associated with the introduction of such maxima for infant formula sold in Australia.
- levels of selenium supports having an upper limit, but 0.89 mg/100 kJ is too low, given the variation in raw materials used in manufacturing infant formula;
- maximum level of Se if added to infant formula should be 1.1 mg/100 kJ, consistent with levels in human milk in Se adequate areas
- no evidence of problems with this level of intake.

Permitted forms of selenium:

- sodium selenate should be permitted as a form of Se, as well as sodium selenite.

Maximum level of manganese:

- request that the limit be 13 ug/100 kJ for all human milk substitutes;
- protein hydrolysate and soy formulae have higher inherent Mn levels and would therefore exceed the proposed maximum of 7.2 ug/100 kJ;
- extremely difficult to manufacture within the range proposed for pre-term formula, 1.2 - 1.8 ug/100 kJ.

Ratio of zinc:copper:

- a maximum of 12:1 would enable manufacturers to more closely achieve the proposed 10:1 ratio;
- it is accepted that Cu and Zn carry significant risks if in excess;
- most infant formulae have ratios of approx. 10:1;
- most research in infant feeding has been done with such a ratio.

Energy value for carbohydrate should be 17 not 16 kJ/g, to harmonise with Codex and EU:

Requirement for 80% carbohydrate to be lactose :

- not consistent with the permitted use of soy protein isolate as a protein source;
- if intent is to control amount of added sucrose, then limits for sucrose should be set.

Definition of medium chain triglycerides:

- requires clarification to distinguish between added MCTs and those inherent in the fat source.

Prohibition on medium chain triglycerides:

- should not have been prohibited in pre-term formula;
- improvement in fat absorption in pre-term infants is well documented in scientific literature.

Ratio of linoleic to alpha linolenic acid:

- request range of 5:1 to 15:1, rather than the proposed 4:1 to 10:1;
- to harmonise with the EU;
- to avoid major manufacturing difficulties and significantly increased cost, without significant clinical benefit.

Minimum level of alpha linolenic acid:

- the level (2% total fatty acids) cannot be achieved with typically used vegetable oils (eg soybean);
- levels typically reported in human milk: 0.45 - 1.85% ; mean = 0.95%

Fat profile and ratios:

- suggest adoption of EU requirements -these allow for more flexibility in sourcing of fat blends while being similar in requirements.

Use of amino acid score to determine protein quality:

- supports adoption of this method, but requests comment on fortifying the protein source to obtain required amino acid levels.

Definition of protein-modified:

- the reference to synthetic amino acids in this definition requires clarification.

Definitions of partially and extensively hydrolysed protein:

- these definitions are unnecessary, because hydrolysed protein (regardless of the extent of hydrolysis) is permitted as protein-modified.

Title of Standard R7:

- changing the title of the Standard to “Human Milk Substitutes” does not support international harmonisation efforts.

Definition of human milk substitute:

- should be amended to include the presentation (liquid, liquid concentrate and powder).

Definition of follow-on infant formula:

- because follow-on formula is not always intended to be the 'sole source of food', the definition should be amended to 'a nutritionally complete formula which forms a substantial part of the source of food'.

Definition of pre-term human milk substitute:

- should include a reference to body weight as well as age, to include low birthweight babies.

Definition of proximate-modified:

- should make reference to modifications to protein, fat or carbohydrate;
- definition is inconsistent with 'modified cow's milk protein';
- reference to specific medical conditions is inappropriate, as they are not inclusive of all situations.

Need for regulations to cover special formulae:

- if incomplete formulae are to be covered by an as yet undefined standard, this should be clearly stated;
- omission of clause 2(b) of the current Standard R7 from the draft Standard R7, means it does not cover formulae with specific modifications appropriate to meet the nutritional needs of medically supervised infants.

Scope of Standard R7:

- supports the creation of a Standard which contains reference to a range of complete formulae.

Regulatory Impact:

- the restrictiveness of Standard R7 compared with the infant formula standards of NZ, Europe and the US, would necessitate the production of formulae specifically for the Australian market. Because this is so relatively small, costs would be greatly increased;
- the restrictiveness of the Standard would also exclude Australia from receiving the latest advances in nutritional research available overseas -

reformulation for sale solely in Australia would be commercially non viable;
- the very narrow ranges of some nutrients would also increase manufacturing costs.

Need for more flexibility in the Standard:

- the regulatory review process needs to be flexible to encompass future changes in scientific data, thus maintaining relevance;
- if new ingredients can be shown to add to the nutritional benefits provided by infant formula, the composition of formula should be able to change to accommodate them.

2. Australian Food and Grocery Council (AFGC)

Title of Standard R7:

- 'human milk substitute' is a misnomer - nothing can be a true substitute for breast milk; the term has negative connotations, better avoided;
- more consistent to name Standard 'Infant Formula' and have 'infant formula' in the name of each division.

Definitions of partially and extensively hydrolysed protein:

- definition of 'extensively hydrolysed' should be tied to a method of analysis, as it contains a zero requirement;
- need to examine product specifications and analyses to determine whether A 'less than x%' may be appropriate;
- with partially and extensively hydrolysed, the source of protein is not stated and they are not listed as protein sources. They are only referred to in clause 44(2)(b) and in the definition of protein modified, a definition which could be omitted.

Definition of follow-on infant formula:

- replace 'principal' with 'significant';
- 'represented as being suitable for' should be 'suitable for' - similarly in other definitions relating to formula and human milk substitutes.

Definition of pre-term human milk substitute:

- does not go far enough - these are also used for low birthweight infants.

Need for regulations to cover special formulae:

- until provision is made for products covered by clause 2(b) of the current Standard, a subclause (c) should be inserted in the definition of proximate - modified human milk substitute, eg:
'(c) some other well recognised physical or physiological condition which renders other products within this standard unsuitable as the principal source of food';
- would also need to insert in Division 3, suitable provisions controlling the degree of deviation from the other compositional requirements.

Energy value for carbohydrate:

- value of 16 kJ/g is inconsistent with other Standards in AFSC, EU and Codex;
- preferable to relate energy values to those in Standard R2. This would ensure that any future changes in energy values would automatically apply across all standards.

Maximum level of aluminium:

- should be set on health and safety grounds and therefore be the same for all formulae;
- should consider specifying a method of analysis.

Maximum level of fluoride:

- should be set on health and safety grounds and therefore be the same for all formulae;
- should consider specifying a method of analysis.

Prohibition on medium chain triglycerides:

- prohibition should be on 'added triglycerides', because MCTs occur naturally;
- the health and safety reason provided - unknown health effects of long term consumption of a high percentage of saturated fats - is not valid because:
- these products are not consumed long term; and
- clause 22(d) limits the amount of saturated fatty acids

Ratio of linoleic to alpha linolenic acid:

- too restrictive;
- reformulation would be necessary;
- at this time have not established a combination of fats which would achieve this;
- EU level, 15:1, is more appropriate.

Requirement for 80% carbohydrate to be lactose:

- not appropriate for soy formulae;
- not needed at all if lactose added to list of permitted carbohydrates - clauses 20(a), (b) and (c) control carbohydrate content sufficiently.

Permitted forms of selenium:

- sodium selenate should also be permitted - would require specification in A11.

Maximum level of manganese:

- should maximum in pre-term formula be 18 ug/100 kJ instead of 1.8?

Maxima for vitamins and minerals:

- opposed the imposition of upper limits on all vitamins and minerals;
- cited the following manufacturing difficulties:
- because formula is made from a premix of fixed composition containing the micronutrients for which there is a prescribed minimum, with overages of

certain vitamins, under the draft Standard one single premix would no longer be an option;

- the base food may contain certain nutrients at levels exceeding their maximum permitted levels in the draft Standard, eg sodium, potassium, calcium and phosphorus in cow's milk and magnesium, phosphorus and potassium in soya beans;

- control of the level of micronutrients within a narrow range, particularly at the mg level, is difficult, especially when using dry mixes where the variation throughout is $\pm 15\%$.

Consistency of terminology:

- there is a lack of consistency:
- 'to mean' in 15, 'to be' in 4.

Definition of carbohydrate-modified:

- should omit the definition of 'carbohydrate-modified' and the reference in 44(2)(b);
- 'low lactose' or 'lactose free' would be more appropriate in the appropriate designation of proximate-modified formulae and are required by clause 37(1);
- draft Standard would require, for a formula designed for infants with both lactose intolerance and protein allergy, both terms 'lactose free' and 'carbohydrate-modified'.

Definition of fat-modified:

- unnecessary definition;
- only required by clause 44(2)(b), and it would be more precise to describe the nutrient modification as 'added medium chain triglycerides' (most fats and oils would contain some MCTs).

Permission to add MCTs to proximate-modified formulae:

- there is no express permission and they should be permitted.

Definition of glucose polymers:

- since this term only appears in the list of permitted sources of carbohydrate for pre-term formula (clause 32), its definition could be omitted from clause 1 and used in a modified form in clause 32.

Problems with subclause 2(1) - refs. to a human milk substitute:

- it is impossible for both a powder or concentrate and the same product when diluted, to comply with parameters set on a per litre or per Kg basis;
- compliance with clause 12 is not possible for a powder, and possibly also a concentrate (ie 'being suitable for feeding through a soft teat').

Problems with subclause 2(2):

- simpler to omit this clause and instead modify clause 15 (relating to the NIT).

Sources of carbohydrate:

- the following additional permissions are required:
- lactose hydrolysate and glucose polymers (in all formulae, not only pre-term)
- sucrose (in all formulae, not only infant formula)
- any natural starch (not only pre-cooked or gelatinised)
- corn syrup (as both glucose syrup and dried glucose syrup are permitted)

Ratio of Ca:P:

- natural variations in raw materials will make it difficult to remain consistently within this range.

Ratio of alpha tocopherol equivalents to PUFA:

- the figure of 0.9 should be used throughout (clause 42(3) and Schedule 3 specify 0.5).

Permissions for additives:

- permissions for citric and lactic acids should be included in the Table to 25(c).

Requirements relating to use of product:

- not necessary to specify instructions for 'preparation and use' (clauses 34(1)(b) and 44(1)(b)), 'directions for use' will suffice.

Levels of selenium:

- minimum should be 0.42 ug/100 kJ, the same as for infant formula, or alternatively there should be a maximum only;
- for follow-on formula (FOF), range (0.79 - 0.89 ug/100 kJ) is too narrow ;
- unreasonable for FOF to have higher minimum than infant formula, because would expect other foods used in conjunction with FOF to supply reasonable amount of Se.

Need for prescribed format for non-warning statements?

- clause 34, relating to the labelling of proximate-modified formulae, should be less prescriptive eg. 'the label should have a feeding guide', omitting 'in the form specified in Table 5 of Schedule 5';
- rationale:
- these pre-term formulae are only dispensed through hospitals; and
- most of these would be imported, and a label unique to Australia would constitute a non-tariff trade barrier

Use of amino acid score to determine protein quality:

- the same minimum score should apply to all products, if the rationale is health and safety.

Levels of zinc:

- minimum level in follow-on formula should be the same as that in infant formula (0.12 not 0.18 mg/100 kJ);
- rationale:
- other foods introduced with FOF will supply additional Zn.

Calculation of protein:

- subclause 4(a) should include modified cows' milk protein as well as cow or goat milk protein;
- subclause 4(b) should refer to protein substitute instead of protein hydrolysates - would then include amino acids;
- questions where extensively and partially hydrolysed proteins fit, ie what factor is used.

Prohibition on gluten:

- clause 5 should be worded in a manner consistent with paragraph 3(b)(i) in Standard R1.

Entries in NIT:

- there is no indication in clause 15 as to where optional ingredients should be listed in the NIT;
- if they were listed in the NIT, their presence there would constitute a nutrient claim - they therefore need to be exempted from the requirements relating to nutrient claims in A1(13);
- there is no indication as to whether chromium and molybdenum can be declared in the NIT.

Measuring scoop - requirement for:

- clause 11 should be amended to “other than a single serve sachet or a package containing single serve sachets”, otherwise a scoop would be required in a package containing more than one single serve sachet.

Use of minimum levels in NIT:

- prefers average to minimum values.

Consistency of terminology:

- the word 'fat' should be used throughout the Standard, rather than 'fat' in some places and 'lipid' in others.

Statement containing advice to introduce other foods:

- current provision, “after 4-6 months of age”, is preferable to “over the age of 6 months” in paragraph 14(1)(d) - the latter is open ended.

Minor amendments:

- subclause 31(d) should be amended to “must comply with the limits, if any, ...”;
- subclause 33(1) should be amended to “in relation to each vitamin, mineral or electrolyte”;
- in Schedule 1, the heading in Column 1 should refer to L amino acids and the footnote should refer to cystine not cysteine;
- subclause 35(2) needs amending in the light of any decision taken in relation to problems with subclause 2(1);
- subclause 36(1), which is headed “Composition”, contains a reference to labelling requirements which should be moved to clause 37, which is headed “Labelling”;
- subclause 39(2) (pertaining to addition of amino acids solely to achieve the specified amino acid score) is a non sequitur, because the definition of a protein substitute (which is permitted in proximate modified formulae) includes L amino acids.

Lactose free/low lactose claims:

- a method of analysis should be prescribed for 'lactose free'.

Warning statement for infants with galactosemia:

- this requirement should be tied to galactose content;
- if a zero level for galactose was required, a method of analysis for galactose would need to be specified;
- the requirement for a warning statement should also apply to low lactose formulae.

Sources of protein:

- why are soya and goat milk protein not permitted in proximate-modified formulae?

Consequential amendments:

- in the draft Standard the following changes need to be made under Consequential Amendments.
in Standard A1 (b):
 - “appropriate alphabetical and numerical order” needs to be inserted;
 - additional entries for Choline chloride 1001 and possibly Choline bitartrate with the same number need to be included.
- in Standard A11(a):
 - (zf), the reference to USP (1990), will need to be (zh);
 - a definition of Addendum 3 will need to be included as (zi).
- in Standard A11 (b):
 - “appropriate alphabetical order” needs to be inserted;
 - specifications for taurine, chromium and molybdenum salts need to be included.

Regulatory impact:

- the highly prescriptive and detailed nature of the Standard, and its narrow tolerances, may mean that it is not possible to produce a product that consistently complies with it;
- it may cause some manufacturers to not enter, or withdraw from, the marketing of pre-term and modified formulae, where the demand is small.

Lack of harmonisation:

- the Standard does not harmonise with the infant formula standards of Codex, the US FDA or the EU.

3. ALK

Need for rules for manufacturers (GMP):

- manufacturing rules (some sort of GMP rules) and acceptance limits would be appreciated.

Prohibition on medium chain triglycerides:

- prohibition is too strong a word and should be modified to “minimized”.

Levels of selenium:

- in connection with Se amounts, “if added” should be added, because the level of Se in milk is very variable.

Hypoallergenic claim:

- the criterion of molecular size is not sufficient to determine whether or not a product is hypoallergenic;
- need to use immuno chemical methods with antibodies of verified cow-milk allergenic infants;
- the statement “should not be for infants with cow milk allergy” should be used if the immuno chemical criteria are fulfilled.

Use of minimum levels in NIT:

- there needs to be clarification of which amounts should be entered in the NIT, and their acceptance limits.

Sources of carbohydrate:

- sucrose is only permitted in infant formula, why is it not permitted in other formulae?

Definitions of partially and extensively hydrolysed protein:

- the ESPACI Position paper definition should be used.

Concern over soy formulae:

- cannot be used for cow milk allergic infants as it can cause allergic reactions in cow milk allergic infants.

Osmolality value:

- this should not be raised over 325 mOsmol/ kg.

Fat profile and ratios:

- limits are very tight.

Permissions for additives:

- mono- and di-glycerides of fat-forming fatty acids should be permitted to a level of 4 g/L, as in the EU Directive.

Schedule for vitamins and minerals:

- this is lacking for proximate-modified human milk substitutes.

Problems with clinical studies:

- in Australia is it possible, from an ethical point of view, to run clinical studies with infants?

4. Anchor (NZ Dairy Group)

Maximum level of protein:

- the maximum protein level should be reviewed;
- protein content of formulae far exceeds that of human milk, providing a safety margin for the less abundant sulphur containing amino acids;

- most important determinant for improving the amino acid profile is lowering the protein content;
- since L amino acids can be added to achieve the minimum amino acid score, a lower protein level would be possible.

Use of amino acid score to determine protein quality:

- the use of an amino acid profile as an indicator of protein quality is to be commended;
- the range 0.8-1.2 (proposed for proximate modified formulae) should be adopted for all milk protein sources because;
- the minimum value for formulae in Codex and EU regulations is 0.8;
- to require the higher minimum of 1.0 for cows' milk, although readily achievable, is discriminatory.

Prohibition on medium chain triglycerides:

- need clarification as to whether it is the synthetic oils that are being prohibited, or whether it is intended to limit the use of oils with a high MCT content (eg. coconut oil) - many current products contain vegetable oils that have C8-C12 fatty acids;
- regulation to prevent the use of synthetically produced MCT oil for formulae for normal term infants is supported, because an appropriate fatty acid profile can be achieved with blends of vegetable oils;
- no longer permitting MCTs in pre-term formula is unreasonable, given that an improvement in lipid absorption has been documented with MCTs, and there is no evidence to the contrary;
- it is of concern that there is evidence that preterm infants fed MCT oils may have an increased excretion of dicarboxylic acid and may be more oxygen dependent;
- although it is stated in the full assessment report that MCTs are "not normally present in human milk", - it is very probable that women in the Pacific Islands produce milk with considerable amounts of MCT, because of their diet.

Permission to add MCTs to proximate-modified formulae:

- formulae designed for infants with fat malabsorption should be permitted to contain MCT oil, provided that the formula is supplemented with essential fatty acids;
- MCTs can play an important role in infants with pancreatic insufficiency or impaired bile secretion.

Ratio of linoleic to alpha linolenic acid:

- proposed range not substantiated by sound scientific evidence.

Fat profile and ratios:

- the rationale for the proposed lipid profile is to align more closely with human milk, but the human milk profile depends on the maternal diet, and human milk fatty acids have a superior mechanism for absorption (in particular, the fatty acids in human milk triacyl glycerols have a highly specific positional

distribution);

- unless the triacyl glycerol structure of infant formula lipids is modified (using methods such as 1,3-enzymic interesterification) it is not rational for the profile to be so prescriptive, and there is insufficient scientific justification for it;
- it is noted that maxima for saturated, cis-monounsaturated and cis-polyunsaturated fatty acids are not substantiated by sound scientific evidence;
- although the oil blend could be modified to meet the requirements, it is noted that major changes in the relative proportions of saturated to unsaturated fatty acids may:
 - influence the melting point of the blend; and
 - affect properties of the powder, eg emulsion stability, solution appearance, powder flowability, wettability and dispersibility;
 - cis-polyunsaturated fatty acid levels should be expressed to 2 significant figures (or a level of 1.8% can count as 2%);
 - it is noted that the current methodology does not allow unambiguous identification of 18:1 isomers.

Maximum level of thiamin (B1):

- recommended maximum - 40 ug/100 kJ (Schedule 3, 22 ug /100 kJ)
- range narrower than for other B vitamins;
- not very stable, need to allow for losses over time;
- no safety concern.

Maximum level of riboflavin (B2):

- recommended maximum 100 ug/100 kJ, Schedule 3, 86 ug/100 kJ;
- formula can contain 100 ug/100 kJ without fortification due to the high levels which may be inherently present in milk.

Maximum level of vitamin B12:

- recommended maximum 0.2 ug/100 kJ, Schedule 3, 0.13 ug/100 kJ;
- given the inherent level in the base food (2-3 ug/100 g, equivalent to 0.13 ug/100 kJ in formula), and the fact that vitamin B12 is a microbiological assay with a standard deviation of 40%, it is recommended that the maximum be raised to 0.2 ug/100 kJ.

Ratio of alpha tocopherol equivalents to PUFA:

- the 0.5 mg/g PUFA ratio should apply across the Standard (in line with the EU and Codex).

Maximum level of iron:

- recommended maximum 0.48 mg/100 kJ ; Schedule 3 max. 0.5 mg/100 kJ;
- the maximum should not be raised even marginally because as iron intake increases, percentage absorption decreases and unabsorbed excess iron may:
 - increase the risk of gastro-intestinal infection;
 - interact with other divalent cations eg. Cu and Zn.

Maximum level of phosphorus:

- recommended maximum 25 mg/100 kJ (as in the current R7);
- Schedule 3 max. is 22 mg/100 kJ varying inherent levels present in milk provide higher than the maximum permitted level.

Levels of selenium:

- supplementation of formula with Se is supported;
- recommended minimum for follow-on formula 0.42 ug/100 kJ, the same as for infant formula;
- the narrow range proposed (0.79-0.89 ug/100 kJ) is beyond the capability of our process;
- although the Australian RDI for infants 7-12 months is 15 ug / day, higher than it is for infants 0-6 months of age (10 u g/day), it should be remembered that the older infants will be consuming foods other than milk, so may be obtaining Se from other sources;
- If further research were to show that infants >6 months obtain very little Se from the weaning diet, then a range with a raised minimum and maximum above the range for infants <6 months may well be justified.

Permission to add nucleotides:

- permission to add nucleotides is supported;
- regarding inosine monophosphate (IMP), given that there is only one paper suggesting that IMP may be a sample preparation artefact, the Authority should review the decision to include IMP only if there is further evidence to substantiate this claim.

Maximum level of choline:

- recommended maximum, 7-8 mg/100 kJ;
- maximum proposed in draft Standard 5.4 mg/100 kJ;
- natural choline levels above the maximum permitted in the draft are obtained
- seasonal variation of choline in milk solids is 55 - 95 mg/100 g (measured in whole milk powder);
- in addition to the choline in milk, a maximum of 5 g/L of lecithin must be accounted for in setting the choline maximum.

Osmolality value:

- recommended maximum 350 mOsm/kg, for follow-on formula;
- proposed maximum in draft Standard is 325 mOsm/kg for infant formula and follow-on formula;
- follow-on formula is higher in protein and has inherently higher levels of minerals and it might not be possible to comply with a maximum of 325 mOsm/kg;
- a level of 350 mOsm/kg would not pose any risk to infants over 6 months of age.

Maximum level of carnitine:

- the maximum level in the draft Standard , 0.42 mg/100 kJ, is less than the natural level of carnitine typically in formulae, 0.6-0.8 mg/100 kJ;
- it is not clear whether more than the specified maximum is permitted if it is from a natural contribution.

Use of minimum levels in NIT:

- typical or optimal levels of nutrients would be preferred to minimum levels because:
- these would more accurately reflect the composition of the formula;
- they would be more meaningful to consumers and health professionals (especially for the macronutrients, which are used in calculations for dietary manipulation and to determine the energy level of infant feeds).

Maximum level of aluminium:

- supports the levels set.

Maximum level of fluoride:

- supports the levels set.

Maximum level of nitrates:

- recommended maximum, 0.3 mg/100 kJ;
- there is a need to set a maximum for nitrates, as they can occur at significant levels in some water supplies and are potentially toxic to infants.

Microbiological requirements:

- Australian and NZ Standards differ;
- NZ methods have been recently reviewed and are now based on the internationally recognised IDF methods;
- recommended that both Australia and NZ should follow the IDF methods and that a committee of experts be established to review Australian and NZ microbiological methods and standards for infant formulae and dairy foods.

Concern over soy formulae:

- soy protein isolate has been used in infant formulae for over 30 years;
- no side effects, including no evidence of oestrogenic effects, have ever been reported;
- this observation, in the absence of any scientifically validated data to the contrary, tends to support the view that they are safe;
- requirement for a warning statement would only be warranted if some reasonable, objective, scientific evidence was brought forward.

5. Informed Systems Ltd

Permission to add nucleotides:

- recommend that no action be taken to exclude inosine monophosphate (IMP) until/unless there is further substantiation of the work suggesting it is an artefact.

Prohibition on medium chain triglycerides:

- if the definition of MCTs was changed to include only synthesised triglycerides, there would be no problem with the prohibition;

- there might be some reason to prevent the use of pure MCT oil, as there is some evidence that this may present a problem in preterm infants, but it is curious to prohibit the inclusion of medium chain triglycerides when:
- the main source these lipids, coconut oil, is a common component of formulas today; and
- medium chain fatty acids are present in quite significant amounts in some breast milk (eg. that of Pacific Islands women, where coconut oil is a common dietary component);
- it is recommended that the prohibition (based on the definition of MCTs in the draft Standard) serves no useful function and should be deleted:-
- lauric acid (C12) is controlled by the requirement that it constitute less than 15% total fatty acids;
- fatty acids C8 and C10, the other constituents of coconut oil, are not usually thought of as saturates (do not affect plasma LDL).

Definition of medium chain triglycerides:

- should encompass only “triglycerides solely containing fatty acids of 10 carbons or under”.

Fat profile and ratios:

- recommended maximum level of trans fatty acids, 12-15%;
- maximum proposed in draft Standard, 8%;
- there should be no difficulty in achieving a maximum of 12%, unless substantial amounts of hydrogenated oils are used;
- trans fatty acids should be counted as saturates.

Use of minimum levels in NIT:

- prefer to use “optimum” level for all label nutrient claims, as long as the label value represents the approximate level at the time of manufacture, and the actual level never falls below the regulatory minimum during the shelf life;
- if use minimum levels in the NIT, the information is meaningless from a nutritional viewpoint.

Hypoallergenic claim:

- permission to use the claim “hypoallergenic” or “suitable for infants allergic to cow milk protein” should be granted when it can be demonstrated that at least most infants who react to regular cow's milk protein formulas do not react to peptides say below 1000D, or some similar value

Maximum level of aluminium:

- the introduction of maximum levels for aluminium is supported, especially for preterm formula;
- aluminium may come from water (eg. if alum is used as a flocculant in water purification) or as a contaminant of mineral salts (eg. calcium salts) - these contaminants can be minimized.

Prohibition on carrageenan:

- prohibition should not cause any problems as there is no compelling reason for its addition;
- not sure whether unmodified carrageenan can cause immunological problems in the gut, degraded form can.

Concern over soy formulae:

- there is no scientific data to support any contentions about safety issues;
- a warning about phytoestrogens would raise public concerns, which have at present no scientific justification;
- consideration could be given to requiring a statement to the effect that soy formulas should be used on the advice of a health provider for specific indications.

Definition of fat-modified:

- this is pointless and should be deleted;
- what fat has been modified, since effectively all formulae use a blend of vegetable oils?

Statement on preparation of bottles:

- there seems to be little point in insisting on a statement, "prepare only one bottle at a time", which is widely ignored and is safe, as long as there are instructions about clean preparation and storage under refrigeration for not more than 24 hours;
- more to the point to reinforce advice about cleansing of bottle prior to filling and to prohibit reuse of formula left in the bottle from a previous feed.

Prohibited representations:

- supports the prohibition in subclause 18(e) on "information relating to the nutrient content of human milk", on the basis that comparisons are at best meaningless and at worst misleading.

Microbiological requirements:

- there are considerable differences between the Australian and NZ regulations especially in methodology;
- recommend the issue be debated, for harmonisation purposes.

Ratio of Ca:P:

- recommended minimum 1.2:1 (as in the current R7) not 1.1:1, as in the draft Standard
- very low ratios are theoretically undesirable (human milk tends to be around 2:1).

Permissions for additives:

- the reduction in the maximum level of mono- and di-glycerides of fat-forming fatty acids from 4 to 2 g /L should not pose any problem.

Maximum level of carnitine:

- no mention is made of carnitine under “Other permitted additions” ;
- should be permitted to 75 u moles /L.

Maximum level of protein:

- support the reduction in the maximum level for follow-on formula from 1.2 to 1 g/100 kJ - high levels have no nutritional foundation.

Levels of selenium:

- recommended range for follow-on formula, same as for infant formula;
- range prescribed in draft Standard, too narrow for compliance;
- although the RDI is higher for infants >6 months old, at that time formula is no longer the sole or even dominant source of nutrients and Se should be acquired from other sources.

Ratio of linoleic to alpha linolenic acid:

- why is the ratio in the range 4:1 to 10:1 for ordinary formula and 4:1 to 15:1 for pre-term formula?

Lactose free/low lactose claims:

- better to set a limit (e.g.50 mg/L) for 'lactose free' than to state “must not contain any detectable lactose”.

Use of amino acid score to determine protein quality:

- this method is endorsed.

Maximum level of vitamin A:

- recommended maximum, 37 ug/100 kJ, as in the current Standard;
- there is no justification for raising it to 54 ug/100 kJ.

Maximum level of vitamin D:

- recommended maximum, 0.48 ug/100 kJ, as in the current R7;
- there is no justification for raising the maximum to 0.61 ug/100 kJ in the draft Standard.

Maximum level of trans fatty acids:

- recommended max level 12-15%;
- max. proposed in draft Standard, 8%;
- there should be no difficulty in achieving a maximum of 12% , unless substantial amounts of hydrogenated oils are used;
- trans fatty acids should be counted as saturates.

6. CAFTA Victoria (CAFTA Vic)

Definition of protein source:

- 'protein source' needs to be carefully defined in clauses 4 and 17.

Calculation of protein:

- the Kjeldahl factor of 6.38 is very general, may not be accurate and may be dependent on formulation (references supplied).

7. Royal Hospital for Women (Knight, David)

Concern over soy formulae:

- isoflavones, the type of phytoestrogens in soy, were found to be present at the following levels:
- infant formulas (including soy) - 0.001 - 3.0 mg/L
- cow's milk - 0.1 - 1.0 mg/L;
- in the medical literature over the past 35 years, there are no documented disturbances in reproductive function, development of sex organs, sexual behavioural patterns or predisposition to cancer development secondary to infant exposure to phytoestrogens;
- warning statements inappropriate, especially as the overall assessment is that phytoestrogens are beneficial.

8. Dietitians' Association of Australia (DAA)

Definition of proximate-modified:

- another description may be more appropriate.

Categorisation of hms for special dietary use:

- groupings not appropriate;
- lactose-modified formulae could also be proximate-modified formulae.

Warning statement for infants with galactosemia:

- the value of a warning statement is questioned, as galactosemia is often not diagnosed until later in infancy;
 - if formulae are to have warning statements, should PKU or other metabolic disorders be mentioned?
 - as an alternative strategy, could label suitable formulae "Suitable for infants with galactosemia" (and similarly with PKU)
- recommendation: galactose levels of currently suitable formulae should be measured and a maximum level of galactose set for the management of galactosemia;
- lactose-free formulae not meeting this criterion could then be labelled with the warning statement.

Maximum level of aluminium:

- there is concern that a higher limit has been permitted for soy-based formulae;
- if soy formulae are unable to conform to the general standard they should not be categorised for normal use.

Maximum level of fluoride:

- there is concern that a higher limit has been permitted for soy-based formulae;
- if soy formulae are unable to conform to the general standard they should not be categorised for normal use.

Definitions of partially and extensively hydrolysed protein:

- need to be more precise.

Definition of follow-on infant formula:

- should not be defined as the principle source of food for all infants over 6 months;
- need recognition that by 9 months, food should be the principle nutrient source rather than formula.

Statement on preparation of bottles:

- confusing to some parents to have “unboiled or unsterilised bottles”, “unsterilised” would suffice;
- preparation of only one bottle at a time is the ideal, but not common practice;
- it is a concern that parents may not be receiving advice for such common practices as preparing multiple bottles or feeding away from home or tips when travelling ;
- the phrase “more or less” (14(c)) may be difficult to grasp immediately

Declaration of sources of ingredients:

- the requirement to declare the source of protein is supported;
- would be beneficial to label sources of carbohydrate and fat also.

Sources of carbohydrate:

- starch should be listed as corn starch, to fulfil prohibition on gluten.

Requirement for 80% carbohydrate to be lactose:

- would exclude soy formulae.

Sources of protein:

- 35(2) excludes soy formulae from the “low lactose HMS” category, because the protein source (soy) is not derived from any of the stated sources, cows' milk, modified cows' milk or goats' milk.

Prohibition on medium chain triglycerides:

- exclusion of MCT as a fat source for pre-term formula is of concern;
- the rationale for not permitting it is unclear, not clearly justified scientifically and contradictory in the full assessment report;
- it would exclude most formulae currently available in Australia which may unnecessarily threaten supply.

Fat profile and ratios:

- the lowering of permitted saturated fat unnecessarily excludes other formulae currently on the market, is not clearly justified scientifically and is not supported by the profile of breast milk.

Feeding guide:

- should be presented as a guide;
- a range rather than a single volume for age would alleviate parental anxiety and be more consistent with advice to feed infants on demand.

9. Dairy Goat Co-operative

Maximum level of thiamin (B1):

- request an increase in the maximum level to 40 ug, to allow for the natural level of vitamin B1 in goat milk based follow-on formula.

Maximum level of vitamin B12:

- request an increase in the maximum level to 0.3 ug, to allow for the natural level of vitamin B12 in goat milk based follow-on formula.

Maximum level of vitamin C:

- request an increase in the maximum level to 7.5 mg, to allow for the natural level of vitamin C in goat milk based follow-on formula.

Maximum level of vitamin K:

- request an increase in the maximum level to 5 ug, to allow for the natural level of vitamin K in goat milk based follow-on formula.

Maximum level of phosphorus:

- request an increase in the maximum level to 25 mg, to allow for the natural level of phosphorus in goat milk based follow-on formula.

Maximum level of magnesium:

- request an increase in the maximum level to 4.5 mg, to allow for the natural level of magnesium in goat milk based follow-on formula.

Maximum level of potassium:

- request an increase in the maximum level to 65 mg, to allow for the natural level of potassium in goat milk based follow-on formula.

Maxima for vitamins and minerals:

- vitamin maxima are established to allow for decay over the shelf-life of the product;
- there is a natural variation in the vitamin and mineral content of goat milk which needs to be accommodated in setting maxima.

Osmolality value:

- goat milk based infant formula can have a naturally occurring osmolality of up to 350 mOsm/kg;
- suggest this would be a more appropriate maximum.

Prohibition on medium chain triglycerides:

- MCTs occur naturally in goat, cow and human milk;
- do not believe that any milk based formula can satisfy the requirement for no MCTs.

Maximum level of lactose:

- the maximum level of lactose should be the same, 2.4 g/L, for goat and cow milk "low lactose" formula, because both cow and goat milk have the same level of lactose.

10. Prof. Roger Short

Concern over 'suitable from birth' statement:

- published data shows considerable health risks to the infant and mother if anything but breast milk is consumed by infant during first 6 months of life;
- information regarding known risks should be made available to mothers via a label on packages;
- it is legally indefensible to state as in section 26(a) pg 13, that infant formula is 'suitable from birth' rather than, as in section 28 pg 14, 'suitable only for infants over 6 months'.

Health warnings:

- there should be a general health warning on all infant formulae: "Warning - Infant Formula is potentially hazardous to the health of your baby in the first 4-6 months of its life";
- there should also be a statement, in the form of a packet insert, that documents its proven health risks, namely:
"Feeding an infant on artificial formula instead of breast milk during the first 4-6 months of life puts the baby at much greater risk of:
diarrhoea, respiratory infections, SIDS, allergies in later life, necrotising enterocolitis, early age onset diabetes and lowered intelligence in later life.
Failure to breastfeed also has adverse effects for the mother who is at increased risk of developing breast cancer in later life and denied the contraceptive effect of lactational amenorrhoea";
- numerous case control studies have shown links between increased risk of SIDS in bottle-fed babies.

Concern over oestrogenic effects:

- all infant formula contains appreciable amounts of oestrone sulphate (a very potent orally active oestrogen) because most milk is supplied by pregnant cows which secrete oestrone sulphate and some oestradiol into their milk;
- concentrations in infant formula are similar to that found in fresh cows milk.

Concern over advice to consult doctor/health clinic:

- revised Standard R7, pg 7 sect 14 1(a) - do mothers actually consult a doctor or child health clinic for advice before starting their child on infant formula?;
 - are doctors aware of the information about health risks of infant formula to mother and child?;
 - do consumers understand nutritional information supplied?;
- would be better to summarise information by appropriate labelling of the products.

11. Hatrick Chemicals (Hatrick)

Prohibition on carrageenan:

- strong concern against banning carrageenan;
- not supported by scientific literature;
- strongly endorses the views of IFAC and IFC;
- Codex permits the use of carrageenan;
- 30 years of clinical experience by IFC shows no evidence of health problems associated with the use of carrageenan in any commercially prepared infant formula. Literature by Russell W. Steele, an expert on infant immune systems, in 1992 concluded "There is no direct evidence that carrageenan exerts any detrimental effect on the immune system of humans."

12. Infant Formula Council (IFC)

Prohibition on carrageenan:

- prohibition is unwarranted and unnecessary;
- members of the US IFC have over 30 years of clinical experience and actual commercial use with carrageenan in infant formulas, including extensive clinical studies in the US and Canada. The industry's total clinical experience shows no evidence of health problems from the use of carrageenan in any commercially prepared infant formula;
- a 1992 review of published data does not support a prohibition against the use of carrageenan. Russell W Steel MD Professor and Vice Chairman of the Department of Pediatrics, Louisiana State University School of Medicine and Childrens Hospital in New Orleans, an expert on the infant's immune system, conducted a 1992 literature review on the effects of carrageenan on the immune system (a copy of the report was enclosed). Dr Steele concluded there is no direct evidence that carrageenan exerts any detrimental effect on the immune system of humans;
- Codex permits carrageenan.

Concern over soy formulae:

- concerns about "alleged hazards associated with the consumption by infants of soy-based formula" containing phytoestrogens are not well-founded and are contradicted by scientific data;
- there is insufficient information to support a warning statement on soy-based formula;
- scientific data have demonstrated that infants fed soy-based infant formulas develop and grow normally;
- the FDA have recently reaffirmed their position that soy-based infant formulas are safe, in light of current allegations.

Maxima for vitamins and minerals:

- a strong rationale exists for establishing upper limits for those nutrients which have adverse effects when consumed in excessive quantities;
- neither Codex, the EC, or the FDA has set maximum values for water soluble

vitamins in infant formulas, due to the low toxicity of these vitamins;

- the FDA includes upper limits for protein, fat, sodium, potassium, chloride, iron, iodine, and Vitamins A and D in infant formula;
- Codex have upper limits for protein, fat, sodium, potassium, chloride and vitamins A and D;
- appropriate to review and revise those upper limits and to establish new limits where there is adequate scientific evidence to suggest that limitation is warranted;
- if upper limits for nutrients in infant formulas designed for normal term infants are unnecessarily restrictive, the result could be a severe limitation on the ability of manufacturers to make available improved formulations for premature infants and other infants with special nutritional needs;
- the establishment of upper limits of nutrients as regulatory limits can have far reaching medical, regulatory and economic implications, especially if such upper limits are unreasonable or unnecessarily restrictive;
- when upper limits are warranted, they should be based on the evidence of potential toxicity and biochemical changes which are associated with abnormal or adverse consequences;
- guidelines for upper limits in infant formula should be implemented via GMP, so that infant formulas can be designed and manufactured to comply with such guidelines;
- in the absence of toxicity, guidelines for upper limits apply only to those nutrients which are deliberately added to an infant formula, but not to nutrients which are coincidental components of other ingredients and which have a very wide margin of safety and are difficult to predict and control;
- the American Academy of Paediatrics Committee on Nutrition has reviewed the findings from the 1988 symposium on Upper Limits of Nutrients in Infant Formulas, held in the USA, and has made no suggested changes regarding infant formula nutrient requirements;
- the FDA also has reviewed the 1988 symposium findings, but has not set any additional maximum limits for infant formula nutrients.

Levels of selenium:

- appropriate to limit the amount of added selenium in infant formulas, but the proposed maximum limit of 0.89 μ g/100kJ total selenium is too low;
- the level of selenium in soils varies, and therefore the levels vary in raw materials used to manufacture infant formula;
- a higher maximum level for selenium is needed in infant formula;
- it is important to remember that the selenium in human milk also varies, depending on the geographic region and maternal selenium intake;
- IFC proposes a maximum level for selenium of 1.1 μ g/100kJ; this is consistent with the level found in human milk from women consuming foods from selenium adequate areas and, most importantly, their infants have no problems associated with this level.

Maximum level of manganese:

- IFC questions the rationale behind proposed manganese maxima for preterm formulas and proximate modified human milk substitutes;
- they assume that the proximate modified human milk substitutes would include protein hydrolysate formulas. these as well as soy isolate formulas, have higher inherent manganese than milk based formulas and will exceed the proposed maximum level of 7.2 ug/100kJ, but would not exceed the 13 ug/100kJ maximum proposed for infant formula.

Maximum level of aluminium:

- proposed upper limit for aluminium in non-soy infant formulas is too low;
- aluminium in infant formula is not of concern for infants with normal kidney function, since the human body absorbs very little aluminium;
- aluminium levels in infant formula are well below the Provisional Tolerable Weekly Intake established for humans by the Joint FAO/WHO Expert Committee on Food Additives;
- if infant formulas are processed and then distributed in glass bottles, the glass will increase the aluminium content of the infant formula;
- if an aluminium maximum is set for non-soy products, it should be 0.5mg/L.

Maximum level of fluoride:

- IFC believe the proposed maximum for fluoride in non-soy formulas is too low;
- given the possible addition of fluoride-containing ingredients to specialty formulas, the proposed maximum would be difficult if not impossible to adhere to in some of these life-sustaining formulas;
- IFC propose that infant formula for special dietary use have a maximum fluoride level of 2.0 mg/L, which is the same level proposed for the soy formulas.

Minimum level of alpha linolenic acid:

- the proposed minimum level of these is too high;
this level cannot be accomplished by the use of typical vegetable oils, such as soy bean oil;
- the proposed 2% minimum is a marked departure from the reported average level of alpha-linolenic acid in human milk, which has a typical range of 0.45 to 1.85%.

Ratio of linoleic to alpha linolenic acid:

- proposed ratio is too narrow;
- such restricted ratios would increase the cost of infant formula without any clinically significant benefit;
- recommend that broader ratios be considered as recommended by the EU, which allows linoleic acid to alpha-linolenic acid ratios of no less the 5:1 and no greater than 15:1.

Ratio of zinc:copper:

- recommends increasing the zinc to copper ratio to 12:1 from the proposed 10:1;
- although human milk and most infant formulas have a zinc to copper ratio of approximately 10:1, this ratio would be extremely difficult not to exceed when manufacturing formula; a maximum ratio of 12:1 would enable manufacturers to more closely achieve the 10:1 ratio;
- there are no valid concerns associated with zinc to copper ratios.

Permitted forms:

- IFC do not believe it is necessary to have a prescriptive list of nutrients, which prohibits the use of any nutrient not on the list;
- such a list could disrupt and impair the development and provision of special infant formulas for those vulnerable infants who critically need them;
- any standard should be based on practical and timely criteria which would allow new nutrients based upon science to be used.

Fat profile and ratios:

- IFC question the rationale for the very narrow fat range allowed for infant formula;
- Codex allows lower minimum values as does the FDA;
- the maximum proposed value is more consistent with Codex and FDA;
- there is extensive, ongoing research, as well as controversy, regarding fats in infant formulas;
- unnecessary restrictions on fat levels and sources of fat for infant formulas could prevent significant progress in infant nutrition.

Prohibition on medium chain triglycerides:

- IFC believe the prohibition on MCT is inappropriate, particularly for pre-term formulas;
- improvement of lipid absorption with MCTs in the pre-term infant has been documented in the scientific literature;
- MCTs are more easily absorbed by infants who may have malabsorption problems, therefore the addition of MCT to infant formulas is necessary for these sensitive populations.

Microbiological requirements:

- the microbial standard for powdered infant formula is unnecessarily restrictive;
- the standard for coliforms is of particular concern;
- clarification is needed regarding the methodology provided for coliforms;
- (IFC was instrumental in the development of microbiological guidelines for powdered infant formula in the US).

Definition of human milk substitute:

- the term “ infant formula” is preferable, in order to harmonise with other international standards.

Definition of proximate-modified:

- from an international perspective , 'proximate modified human milk substitutes' are more appropriately termed 'medical foods' for infants with a certain disease or condition; the proposed definition for 'proximate modified' is not consistent with 'modified cow's milk protein';
- perhaps the use of specific terms, such as hydrosylates or amino acids would clarify the point.

Definition of fat-modified:

- IFC believe the definition of fat modified is inappropriate. there are other means of modifying the lipid component than through the use of MCTs.

Energy value for carbohydrate:

- the Draft states that 1g of carbohydrate yields 16kJ. This is inconsistent with the international value of 17kJ/g cited by Codex and the EU.

Concern over soy formulae:

- the draft Standard permits the use of soy protein isolates in the preparation of soy-based formulas;
- the Standard should clarify that other forms of soy protein could also be utilised in the production of soy-based infant formulae.

Maximum level of carnitine:

- proposed maximum limit of 0.42mg/100kJ for added carnitine is too low;
- carnitine is naturally present in cow's milk, particularly in the whey fractions;
- carnitine is usually added to soy-based formulas at levels of 0.48 - 0.72mg/100kJ;
- IFC propose the maximum level be increased to 1.0mg/100kJ of added carnitine.

Amino acid profile:

- note the Standard's valine content , 5.5g/100g of protein, in the reference amino acid composition of human milk is much higher than the reference cited by the EU, 4.5g/100g of protein;
- believe 4.5g/100g of protein is a more accurate value.

Maximum level of Vitamin E (Tocopherols):

- not appropriate to prohibit the addition of tocopherols as anti oxidants beyond the maximum level;
- tocopherol esters are added to infant formula to meet the infant's nutritional requirements for Vitamin E because these esters are stable in infant formula, but they are not antioxidants that will prevent oxidation of oils in a powder formula;
- free (non-esterified) tocopherols are added to prevent the oxidation of oils, but in protecting the oils' activity, their vitamin activity may be lost;
- if maximum unneeded requirements for tocopherol esters and free tocopherols are set, they should be separate, to ensure both nutritional and antioxidative needs are adequately met.

13. International Food Additives Council (IFAC)

Prohibition on carrageenan:

- a loss to explain the scientific basis to support the plan to prohibit the use of carrageenan;

- examination of the carrageenan database would indicate the NFA's conclusion on carrageenan to be conjecture at best;
- lab studies which show degradation of carrageenan have used aqueous buffers only. Buffers do not represent liquid foods - where no evidence of degradation has been reported;
- thermal processing studies, which show heating times and temperatures required for carrageenan degradation, far exceed processing conditions of canned liquid infant formula. Should significant degradation of carrageenan occur, suspending capabilities of the carrageenan would be lost;
- studies of absorption of carrageenan in laboratory animals indicate such is seen in herbivores, but not omnivores;
- there are data in the literature indicating lack of absorption of carrageenan in primates;
- studies in which immunotoxic responses are reported are of questionable validity due to the methods and protocols employed. In these studies amounts required to induce effects were 10-100 times the carrageenan amounts used in foods;
- in 1992, FAC made available a review document to MAFF officials and users of carrageenan in infant formula, summarising the literature, which clearly responded to these concerns of alleged degradation and concomitant loss of safety.

14. Douglas Nutrition (Douglas)

Maximum level of vitamin K:

- proposed maximum (3.6 ug/100 kJ) should be increased to 5.0 ug/100 kJ, to allow for levels in goats' milk of up to 5.0 ug/100 kJ;
- vitamin K toxicity is rare, probably because the vitamin is so poorly stored.

15. Hartmann, Peter

Definition of follow-on infant formula:

- providing a definition justifies the existence of this product;
- is not convinced that there is any physiological basis for a different, slightly modified infant formula to be introduced at 6 months;
- the manufacturer should be required to validate the physiological justification for the product, and this requirement should be in Standard R7

Maximum level of aluminium:

- if levels are a problem, then soy-based formula should meet the same standards as cow's milk based formula.

Maximum level of fluoride:

- if levels are a problem then soy-based formula should meet the same standard as cow's milk based formula.

Maximum level of iron:

- limits should be stated for lead contamination for eg. from soldered cans and particulate iron contamination eg. from welded cans.

Contaminants other than Al and F:

- since it is possible for infant formula to be contaminated with chemicals such as pesticides during manufacture, limits for such contamination should be defined.

Concern over soy formulae:

- there is concern over phytoestrogens and other plant metabolites that may interfere with an infant's metabolism;
- cow's milk may also introduce an unacceptable level of plant phytoestrogens into the diet;
- until more research is carried out, the Standards in this area should be conservative and soy-based formula should be on restricted sale.

Statement on preparation of bottles:

- many mothers have great difficulty following the instruction for preparation of bottles and since its very important that formula is prepared correctly, manufacturers should be required to demonstrate that their instructions are user-friendly or that they provide a simple dipstick to test the strength of the formula.

Feeding guide:

- have concerns with regard to feeding instructions eg. defining frequency of feeding and quantity of infant formula to be consumed per feed is educationally desirable but nutritionally incorrect (such focus may encourage obesity);
- energy intakes are not balanced feed by feed or even day by day so correct advice would be that over a period eg 5 days that a particular aged infant should consume a volume of infant formula within a particular range;
- unfortunately although impossible to publish dietary research based on intake per meal or per day, almost all educational material focuses on daily intake;
- standards should require feeding instruction to be research evidence based.

Maximum level of nucleotides:

- some nucleotides eg ATP bind strongly to milk proteins and may be difficult to measure;
- these compounds could be released and have biological activity in the gut;
- care must be used since current chemical analysis may not detect particular added nucleotides.

Storage instructions:

- should relate periods before and after opening the package to storage temperature esp important for northern Australia.

Amino acid profile:

- Alison Darragh, Massey Uni has provided very good data on amino acid composition of human milk.

Fat profile and ratios:

- are fatty acid percentages presented as percentage by weight or percentage by moles?

Statement of oligosaccharide content:

- a statement on oligosaccharides should be included 'there is more oligosaccharide than protein in human milk'.

Health warnings:

- may need to consider a Health Warning on infant formula labels because:- there is potential for formula to contain minor components which may cause infants harm; and
- formula may not contain minor components which are beneficial to infant development (eg DHA).

Protein precipitable lactose:

- storage lactose binds to milk protein and eventually produces a brown discolouration;
- lactose bound to protein may ferment in large intestine, therefore limits to protein precipitable lactose should be stated.

Sources of carbohydrate:

- there is a case for including galactose in all infant formula since it is rapidly removed by the liver;
- caution is required in regard to including fructose in the diet of premature and young infants since although little evidence in human infants it is very poorly metabolised in young piglets;
- fructose is more readily utilised for fat synthesis in adipose tissue so there may be an exaggeration in perceived tolerance by human infants.

16. Human Services & Health (HSH)

Title of Standard R7:

- infants are the sole user group of infant formula and we do not agree with the change in the name from infant formula to Human Milk Substitutes;
- this infers an equivalent substitute for human milk, which infant formula is not;
- at best infant formula is a better option than unmodified cow's milk, but is not a substitute for human milk

Permission to add nucleotides:

- Is it necessary to consider the addition of IMP to infant formula when the status of IMP in human milk has not been proven?

Use of minimum levels in NIT:

- it appears that the minimum amount of nutrients will be on the NIT, but the maximum amount of contaminants will be on the label somewhere. Won't this give rise to confusion?

Definition of medium chain triglycerides:

- is it necessary to provide definitions of substances that are not going to be permitted?

Prohibition on gluten:

- a definition of gluten should be provided if definitions of substances that are not permitted are to be included in the Standard, eg. MCT

Maximum level of fluoride:

- para 10(3), relating to the limit on fluoride 'Is to be reconstituted according to directions and using de-ionising water'. Is this a direction to the consumer and will therefore appear on the label? If so, will there be an explanation of 'de-ionised water'.

Measuring scoop:

- requirement for this is an opportunity to introduce a generic sized scoop; - difference in scoop size has been found to be a common cause of incorrect reconstitution of powdered formula.

Minor amendments:

- Paragraph 14 (1) d the wording in this instruction is incorrect. It is not 'advisable' but 'necessary' for other foods to be introduced after 6 months;
- do not agree with the statement that infant formula are nutritionally complete, because infant formula will only provide adequate nutrients to approximately six months of age;
- Paragraph 3 - Because of the frequent misuse of 'Lactose reduced' and 'lactose free' formulae we suggest insertion of the words 'medical conditions which require special dietary modifications' after 'infants with'

Expiry date:

- mention should be made of the fact that, in the very hot areas in Australia, opened cans or packages of formula deteriorate before the expiry date.

Statement containing advice to introduce other foods:

- labels on 'follow-on' formula should include a statement that for infants more than 6 months the inclusion of other foods in their diet is necessary
NZ Ministry of Health (NZH) definition of human milk substitute the definitions of human milk substitute and infant formula need to be described as not only being suitable as the 'principal' but also as the 'sole' source of nutrition for infants.

Statement on preparation of bottles:

- there needs to be a cautionary statement on the label as to the use of mineral or bore water, or is the reference to 'de-ionising water' in para 10(3), relating to "Limit on fluoride" expected to cover this?

17. NZ Ministry of Health (NZH)

Definition of follow-on infant formula:

- the definition of follow-on infant formula is considerably more restrictive than that of the UK or Codex;
- follow-on formula does not fit the definition or standard for infant formula in the current NZ Food Regulations 1984; given that infants for which this is intended are at least 6 months of age and consuming other weaning foods, it would seem that a broader definition would be more suitable.

Maximum level of aluminium:

- support the introduction of an upper limit for aluminium;
- notes that the levels are set so that intakes will be well below the FAO/WHO Provisional Tolerable Weekly Intake for aluminium

Maximum level of fluoride:

- supports the introduction of an upper limit for fluoride as a measure to prevent fluorosis in infants;
- the Ministry's dental specialist is pleased that fluoride levels in infant formula will be limited in future because some Australian products have been found to have high fluoride levels;
- imported infant formula, fluoridated toothpaste and fluoride tablets have been responsible for fluorosis in NZ.

Advertising/promotional materials:

- there is differentiation between requirements for the label and advertising/promotional materials. In NZ the food legislation currently applies to both the label and advertising/promotional material and the provisions of the Fair Trading Act would also apply. Therefore, this position would need to be fully evaluated before it could be considered acceptable to NZ.

Microbiological requirements:

- NZ has revised the Microbiological Reference Criteria for Foods, which includes criteria for infant formula (An extract was supplied with the submission);
- the draft Standard has not included two bacteria that NZ considers important and relevant to infant formula, *Clostridium perfringens* and *Listeria monocytogenes*;
- the Ministry do not consider the absence of reported associations of listeriosis in infants consuming infant formula as adequate justification for excluding this bacterium;
- NZ includes both presumptive and faecal coliforms, compared to coliforms in the Australian draft standard.

Lactose free/low lactose claims:

- unclear as to why a standard for lactose free and low lactose formula is included, when there is no such standard for a range of other infant formula for infants with inborn errors of metabolism;
- is it the intention to develop such standards in the future?

Levels of selenium:

- NZ soils are selenium deficient, locally grown food is low in selenium, but human health has not been affected;
- NZ people have adapted to a low selenium intake and there are no proven health effects as a result of the low selenium intakes;
- selenium is not a permitted additive in infant formula in NZ or in the Codex standard;
- the proposal refers to NZ infant formula which are selenium - fortified. These products would be considered to be non-complying under the current food legislation;
- selenium is an essential nutrient and we do not believe that the proposed levels are likely to cause any problems;
- note that the Authority does not appear to be requiring scientific justification as a basis for permission to add selenium to infant formula.

Permission to add nucleotides:

- in 1993 NZ declined a manufacturer's application to add nucleotides to infant formula;
- the recommendation was declined on the basis that there was inadequate scientific justification and no assurances that appropriate purity standards would be achieved for the nucleotides;
- the Ministry has not considered the matter recently, and it is unclear from the NFA proposal whether these requirements have been met for the draft Standard.

Entries in NIT:

- the Draft appears to permit the inclusion of nutrients in the table only if the minimum requirements listed in Column 3 in Schedule 3 are met;
- does this apply to optional ingredients only or is it intended to apply to all nutrients?
- NZ exempt special purpose foods, such as infant formula from needing to meet minimum requirements to include nutrient information on the label, because this is often important to consumers and their health professionals for special medical conditions.

Concern over soy formulae:

- for the past year, NZ has been assessing the allegations that the consumption of soy products has adverse health effects;
- provided two articles to reflect their position in terms of when it is appropriate to use a soy based infant formula;
- NZ does not believe there is any justification for warning statements on soy infant formula, based on the current scientific literature.

Maxima for vitamins and minerals:

- the Ministry supports maximum and minimum nutrient levels in infant formula;
- it notes that nutrient levels for folate, sodium, vitamin C, vitamin E, pantothenic acid and iron differ from the levels specified in the Codex standard;
- given that Codex is revising its Standard and that the Ministry considers alignment with Codex as important, does Australia propose to ensure alignment with the revised Codex Standard?

Permitted forms:

- NZ noted that some permitted forms in Schedule 3 in the draft standard differ from those specified by Codex.

Minor amendments:

- NZ suggested that the units for pantothenic acid be expressed in ug consistently in all standards, as in the nutrition information table;
- at present the Standard is presented in ug and the pre term standard in mg

Permission to add flavouring:

- agree with the NFA's position that flavourings should not be permitted in follow on formula.

18. Minchin, Maureen

Maximum level of protein:

- concerned that the protein level of all infant formula should be lowered;
- is researching the issue for herself.

Fat profile and ratios:

- the practicality of achieving this fatty acid balance in a tinned product is moot;
- it may be that supplementation with a product which can be packed in a form not susceptible to oxidation would be a better prescription;
- blister packs of PUFAs could be packed with the can;
- this may be complicated for the consumer to make up, but if the nutrition for the infant is improved, it may be an option to consider.
- Is interested to know what the group took as the standard composition of breast milk.

Lactose free/low lactose claims:

- the term 'low lactose' adequately describes all modified-lactose formulas on the Australian market;
- what does 'detectable' mean in article 35.1? what tests are used to detect it?; if a product contains any lactose it should not be able to be labelled 'lactose free'
- . A standard should not legitimise inaccurate label claims;

- until it can be shown by long term RCTs of cognitive ability, that the long term use of low lactose formula is safe, this product should be prescription only, and restricted in availability. Warning labels on the cans should be considered;
- we have no proof of safety and efficacy for long-term feeding of normal infants, now occurring because of the availability, sampling and advertising of this product.

Sources of fat:

- the use of peanut oil should be banned, given the evidence of its sensitising capacity;
- research should be set afoot to ascertain whether other fat sources are also implicated in the increased rates of allergy in Australian children.

Declaration of source of ingredients:

- labels should state the source of all components used, not just protein;
- "Phospholipids derived from egg yolk" would serve to alert atopic parents to potential hazards;
- other concerns arise from inadequate sourcing information eg: Jewish people do not recognise oleo as destearated beef fat;
- until it can be shown that cooked starch and gelatinised starch are totally non antigenic, the source of these components should be stated.

Permission to add nucleotides:

- if the safety of nucleotides is in any way dubious, addition should wait until properly controlled trials of safety in the short and long-term are conducted;
- IMP are banned in some countries.

Concern over soy formulae:

- concerns re the safety of soy formula exist: the high levels of manganese, phyto-oestrogens and more;
- the products still provide very real benefits to infants intolerant of bovine products;
- if safety warnings are put on soy-based formula, such warnings should also be applied to bovine-based formula.

Measuring scoop - requirement for:

- some infant illness would be avoided if Australian standardisation of scoop:water ratios occurred;
- Industry should consider this world wide.

Definition of human milk substitute:

- why is 'human milk substitute' being used when WHO has consistently used breastmilk substitute? are the two synonymous?;
- 'human milk substitute', written without a hyphen, is technically a human substitute for milk. Bovine or vegetable protein based artificial formulas have nothing human about them;
- why not use breastmilk, accepted internationally?;
- labelling requirements ban the use of words like 'humanised' or 'maternalised', 'artificial substitute for breast milk' would be more accurate.

Statement containing advice to introduce other foods:

- concerned over recommended age (6months) of introduction of solids;
- this is desirable for atopic breastfed infants, but not for the artificially-fed, whose diet should be widened earlier, to decrease the risk of depending on a sole source of nutrition after body stores have been depleted.

Declaration of sources of ingredients:

- concerned as to why proximate-modified formula has an exemption from stating the source of protein;
- modification does not remove all risk of reactivity;
- parents are entitled to know what their children ate and reacted to, particularly when proximate-modified formula can include unmodified cows milk protein.

Maximum level of aluminium:

- parents will not understand that soy formula are permitted to have higher levels of aluminium;
- if toxicity is dose-dependent, then the Standard should be the same for all formulas;
- setting a strict standard and giving reasonable cut off dates for compliance seems the way to go.

Maximum level of fluoride:

- parents will not understand that soy formula are permitted to have higher levels of fluoride;
- if toxicity is dose-dependent, then the Standard should be the same for all formulas;
- setting a strict standard and giving reasonable cut off dates for compliance seems the way to go.

Contaminants other than Al and F:

- what testing has ever been done on cadmium, and other heavy metal contamination of Australian formula, shown to be a problem in Canada in the late 1980's?

19. H. J. Heinz Co (Heinz)

Expert panel:

- Heinz supports the role of an expert panel to advise on specific compositional aspects of the revised Standard, but consider it surprising that the names and positions of the expert panel members were not publicly documented in the explanatory notes.

Prohibition on medium chain triglycerides:

- does not support this prohibition for the following reasons:
- MCT are present in the coconut oil used as part of the oil blend used in the majority of infant formulas on the Australasian market, a prohibition of which would have serious economic and trade implications for both the infant formula industry and Heinz;
- MCT's are present in human breast milk;
- MCT levels in breast milk may be enhanced in females consuming a diet high in ruminant fat or coconut oil;
- the C8:0 and C10:0 fatty acids in coconut oil are metabolised differently to saturated fatty acids (ie no effect on plasma LDL cholesterol);
- the prohibition is redundant given the limitations on lauric acid and total saturates;
- the majority of preterm infant formula contain MCT as an easily digestible form of lipid;
- the European Society of Paediatric Gastroenterology and Nutrition recommendations allow up to 40% of fats in pre-term formula to be MCT and;
- the rationale "no convincing evidence that the inclusion in human milk substitutes has conferred any benefit to infants" seems to be applied on an ad-hoc basis throughout the Standard, ie in comparison with the lack of scientific rationale for adding nucleotides to infant formula. MCT appears to have been treated as "guilty until proven innocent" compared with nucleotides which are "innocent until proven guilty".

Definition of infant formula:

- Heinz disputes that infant formula is designed to be the sole source of nourishment of infants, given that, as defined on page 3 of the revised standard "infant" means a child under the age of 12 months;
- at greater than 6 months solid foods are nutritionally important and have additional functions in introducing taste, texture and variety of foods to the infant and assisting the infants oral development.

Criteria for setting nutrient levels:

- Heinz is concerned that the main considerations of setting nutrient levels were not:
- harmonisation with NZ and formulae available on the NZ market; and
- consideration of the Recommended Dietary Intakes for use in Australia for infants as established by the NHMRC.

Use of minimum levels in NIT:

- Heinz does not support the declaration of nutrient content in the NIT as the minimum amount for the following reasons:
- it does not seem to be recognised in the review of the Standard that manufacturing specifications for formulae set a minimum, optimum, and maximum level for nutrient levels. This provides a realistic range within which the optimum is the target, but levels of the nutrient are acceptable within the range from minimum to maximum in order to account for natural variation in source ingredients etc. and cannot be exactly controlled;
- levels of nutrients in the formula are controlled as precisely as possible, for example a nutrient may be supplemented only when required due to seasonal variation in source ingredients;
- the 'minimum' level of a nutrient will vary throughout the season, and to specify the 'minimum' on the label claim will only reflect the lowest point in the seasonal production, not the true optimum/average level;
- nutrient levels must also be above the label claim levels for the entire shelf-life of the product (2 years for Heinz infant formula). Vitamins will degrade over the shelf life of the product, so that there is usually 'overage' of vitamins to ensure that the label claim is always met;
- a minimum level for vitamins would therefore be realistic and supported;
- the optimum or average level should be the basis of the label claim for all other nutrients.

Maximum level of fluoride:

- Heinz does not support the inclusion of a the limitation on fluoride within the revised Standard R7.

Minor amendments:

- Heinz supports 'Purpose' and 'Table of Provisions' and the use of schedules, but it would be useful in Part 2 and 3 if the Divisions which describe each type of infant formula could each begin on a new page, for easier cross-referencing and readability;
- the title in column in Schedule 1 should read "L-Amino acid"; note that the sulphur-containing amino acid cystine is readily reduced to two molecules of cysteine.

Amino acid profile:

- Heinz Company Australia supports the use of the amino acid score and agrees with the definition.

Definition of carbohydrate-modified:

- Heinz does not support the inclusion of a definition for 'carbohydrate modified' for the following reasons:
- the term 'carbohydrate modified' is used in Standards A8 and R3, is included in the name of Standard R3, and is defined differently in Standard R3;
- the term is unnecessary given the definitions of 'lactose free human milk

substitute' and 'lactose human milk substitute' in revised Standard R7; and
- the term is not used with the revised Standard R7.
The definition should be deleted.

Definitions of partially and extensively hydrolysed protein:

- Heinz does not support the inclusion of a definition for 'extensively hydrolysed protein' unless the definition is further clarified by:
 - stating an amount of protein fragments that have a molecular weight greater than 5000 daltons, such as less than 1 percent;
 - the definition is tied to a method of analysis; and
 - the method has a defined level of sensitivity.
- Similar comments apply to the definition of 'partially hydrolysed protein'.

Definition of fat-modified:

- Heinz does not support the inclusion of a definition for 'fat modified' for the following reasons:
 - the term is inconsistent with clauses 22(b) and 31 (c) of the revised Standard;
 - the term is unnecessary, given medium chain triglycerides are defined;
 - the use of medium chain triglycerides should not, and cannot, be excluded from infant formula, if it is to emulate breast milk composition; and
 - the term is not used within the revised Standard R7.
- This definition should be deleted.

Definition of follow-on infant formula:

- Heinz does not support the definition for 'follow-on infant formula' unless the words "the principal" are replaced with 'a substantial' source of food for the following reasons:
 - food should be the principal source of nutrients for older infants; and
 - this is in contrast with the warning statement prescribed in paragraph 14(10(d)) for infants over the age of 6 months, it is advisable to introduce other foods'.

Definition of glucose polymers:

- Heinz does not support the inclusion of the definition 'glucose polymers' in Standard R7;
- this would be better defined in Standard K1 and a reference made to all carbohydrate definitions to refer to K1;
- this would ensure that all updates to definitions are encompassed within the one Standard.

Definition of human milk substitute:

- it should be noted that some health professionals do not consider infant formula as a breast milk substitute, but rather as a cow's milk alternative.

Definition of infant:

- Heinz supports the definition of 'infant' which is harmonised to the Codex Standard for infant formula.

Lactose free/low lactose claims:

- Heinz supports the definition of 'lactose free/low lactose human milk substitute' provided that the definitions in clause 35 of the revised Standard are:
 - tied to a method of analysis; and
 - the method has a defined level of sensitivity.

Definition of medium chain triglycerides:

- Heinz does not support the inclusion of the definition 'medium chain triglycerides' for the reason as discussed above. It is assumed that the intent of the MCT definition is to define synthetic, added MCT.

Definition of modified cow's milk protein:

- Heinz does not support the inclusion of the definition 'modified cows' milk protein' for the following reasons:
 - the definition is unnecessary, as the intent is covered by the amino acid score; and
 - it is suggested that 21(1)(a)(i)&(ii); 30(1)(a)(i)&(ii); be combined and simplified to 'cows' milk protein'.

Definition of protein equivalent:

- Heinz supports the definition of 'protein equivalent'.

Definition of protein-modified:

- Heinz does not support the definition for 'protein modified' as the intent is regulated by sub-clause 39(2).

Definition of proximate-modified:

- Heinz does not support the inclusion of the definition 'proximate-modified human milk substitute' for the following reasons:
 - what do the words "proximate-modified" mean? Proximate in the dictionary means near, close, next, immediate or present;
 - the definition is too narrow as it only regulates semi-elemental and hypoallergenic formulae, not all specialist formulae;
 - the definition is insufficient to cover current infant formula on the market that would be illegal with the removal of clause 2(b) of the current Standard R7 - Infant Formula; and
 - presumably the remainder of the specialist infant formulae would be covered in the proposed Standard R10 - Foods for Special Medical Purposes. This is an assumption, as no mention was made of this issue in the explanatory notes. It is difficult to comment on the inclusion of two categories of specialist infant formula in the draft Standard R7 without knowledge of how the remainder are categorised in Standard R10.

Concern over soy formulae:

- Heinz supports the definition of soy-based human milk substitute'.

Problems with subclause 2(1) - refs. to a human milk substitute:

- Heinz supports the intent of subclause 2(1), however the present drafting excludes ready-to-feed infant formulae from any reference made to a human milk substitute in Standard R7;
- it is suggested that this clause is included as part (ii) of the definition of 'human milk substitute'.

Calculation of energy:

- Heinz does not support the inclusion of the calculation of energy within Standard R7 for the following reasons:
- the energy value for one gram of CHO should be updated to 17 kJ as per the amendment made to Standard R2 in 1994;
- clause 23 of the draft Standard R7 permits up to 20% of the carbohydrate in infant formulae to be of sources other than lactose and thus a range of carbohydrates should be reflected by an energy value of 17kJ for 1 gram of carbohydrate;
- an energy value of 17kJ would harmonise with international standards including the EU Directive on Infant Formula;
- note that in altering the energy value to 17Kj that some consequential reworking of other nutrient limits as prescribed per 100kJ in the draft Standard R7 may be required; and
- all calculations of energy should be referenced to Standard R2. This ensures that all updates to definitions are encompassed within the one standard and makes individual standards shorter in length and easier to read.

Calculation of protein:

- Heinz supports the conversion factors used to calculate protein content which is harmonised to the Codex standard for infant formula.

Prohibition on gluten:

- suggest that the intent of clause 5 would be more accurately worded as "A human milk substitute must not contain any detectable gluten when examined by the method prescribed by subclause 3(h) of Standard R1".

Maximum level of choline:

- Heinz supports the proposed minimum of 1.7 mg choline per 100kJ which is consistent with Codex;
- does not support the maximum permitted amount of 5.4mg choline per 100kJ;
- this proposed maximum is too low for whey-based formulae to comply with, due to whey-based formulae having intrinsically higher levels of naturally occurring choline;
- a more realistic maximum level would be 7 - 8 mg choline per 100kJ.

Maximum level of inositol and taurine:

- Heinz supports the proposed minimum and maximum permitted amounts for inositol and taurine and their inclusion as optional ingredients.

Maximum level of carnitine:

- does the specification for L-Carnitine specify free carnitine or total?;
- assume that the minimum and maximum limits apply to added carnitine as an optional ingredient, and not to naturally present levels of intrinsic carnitine for which no claim nor ingredient listing would be made.

Permission to add nucleotides:

- Heinz has the following comments regarding the inclusion of nucleotides in infant formulae:
- the inclusion of nucleotides as optional ingredients is supported. however it is noted that due to marketing forces, this 'option' can become 'mandatory' if all of the competitors formulations include nucleotides;
- internationally some infant formulae already contain nucleotides, such as Wyeth formulations sold in the USA, EEC and Japan;
- scientific evidence, although building, seems to be premature, as to the forms of nucleotides that may be added, limitations on levels added, safety and stability etc.

Optional ingredients claim:

- Column 3 of table to clause 7 specifies a minimum amount in mg/100kJ of an optional ingredient that may be added for a claim to be made. Heinz makes the following comments:
- it is understood that should an infant formula contain less than the minimum amount of an added optional ingredient specified in column 3, then the optional ingredient could be listed in the statement of ingredients, but not in the NIT, and that this would not constitute a claim; and
- how would this apply to information leaflets produced for medical detailing purposes?

Maximum level of aluminium:

- Heinz does not support the inclusion of the limitation on aluminium and fluoride for the following reasons:
- there are no specifications for levels of aluminium and fluoride in infant formulae in the current Standard R7, Codex or NZ and the limitations do not support international harmonisation of food standards;
- if the limitations on levels of aluminium and fluoride are of such public health and safety significance that they should be included in the revised Standard R7, then surely the public health and safety risk should apply equally to soy-based infant formulae and other infant formulae, and the limitations for both types of formula should be the same;
- if there is to be discrimination between types of formula and the limitations on levels prescribed, then the lower levels should apply to pre-term formulae only, where there is scientific validation of pre-term infants inability to metabolise the levels of aluminium or fluoride in pre-term formulae currently available on the market;
- the 1992 Australian Market Basket Survey completed, reported and published by the NFA states “ Although the soy based formulas contain higher

concentrations of aluminium than other formulas or human milk, no matter what type of milk or formula is consumed the estimated dietary intake of aluminium of an infant is well below the international limit;

- the limitations should be tied to a method of analysis and the method must have a defined level of sensitivity;
- what is the justification for the higher levels of fluoride permitted in soy-based formula compared with other formulae?
- the limitations on aluminium and fluoride levels would impose on the infant formula industry, for formulae sold in Australia only, an additional quality assurance procedure where the aluminium and fluoride levels would require testing on each batch of infant formula. This economic and trade restriction would cost Heinz app \$1300 per annum; and
- consultation with the infant formula industry on this matter appears to have been ad-hoc, particularly with regard to practical implementation of achievable legislation;
- the levels of aluminium could be better monitored and controlled by quality assurance procedures that ensure GMP such as control of ingredients, HACCP, minimisation of contamination from alum flocculants use in water purification, addition of calcium salts, etc. These issues could be addressed by an industry code of practice.

Maximum level of fluoride:

- see maximum level of aluminium.

Measuring scoop - requirement for:

- Heinz supports clause 11 and notes that different scoop sizes for differing infant formulae cannot be standardised to the one size, due to different product densities.

Required statements:

- Heinz supports the inclusion of the required statements in clause 14 provided that:
 - consideration be given to permitting the use of upper and lower case characters, based on an increase in font sizes as per clause 4 of the Preliminary Provisions of the Food Standards Code. The current uppercase statements are difficult to read, which negates the intent of the statements;
 - some health professionals believe that before deciding to use an infant formula, a child health clinic would be the preferable place to seek advice due to their updated knowledge and expertise and thus the order for 'doctor and 'child health clinic' should be reversed in the warning statement in paragraph 14(1)(a);
 - in paragraph 14(1)(b), some children may use a feeding cup, or a cup, rather than a bottle, particularly for follow-on formula;
 - in paragraph 14(1)(b), bottles are rarely prepared one at a time, and to some care givers this statement may mean each bottle should be individually sterilised . If the intent of this statement is that the formula should be used within 24 hours and unused formula should be discarded, then this could be

covered in the storage instructions;

- in paragraph 14(1)(d), the age range for the introduction of other foods should be between 4 - 6 months.

Microbiological requirements:

- Heinz notes that although the microbiological requirements are unchanged from the current Standard R7, the requirements are inconsistent with the NZ regulations.

Ratio of linoleic to alpha linolenic acid:

- Heinz does not support the ratio of linoleic to alpha - linolenic acid of not more than 10:1;
- this maximum ratio is difficult to meet within production limits and is inconsistent with the EEC maximum ration of 15:1; Heinz would support a ratio of not more than 15:1.

Fat profile and ratios:

- Heinz does not support the minimum and maximum limitations place on fatty acids for the following reasons:
- these limitations are specific to regulation in Australia only and inconsistent with harmonisation with NZ, Codex etc;
- these limitations are far too prescriptive and would present practical difficulties in the manufacture of infant formula. The current Heinz infant formulae would require reformulation to meet these limitations;
- no scientific substantiation nor rationale is provided as to why these limits have been prescribed. These limits are not internationally reflective and are different to those prescribed by the EEC for example; and
- these limitations could be discussed at a forum/workshop with all interested parties present and at which substantiation could be provided as to how the levels were determined. Heinz would support and participate in the process of developing realistic levels which were sufficiently flexible for the infant formula industry to comply with.

Maximum level of thiamin (B1):

- vitamin B, thiamine, has the most narrow range of all vitamins specified;
- as thiamine is extremely heat labile, it is difficult to estimate consistency in processing losses during manufacture, particularly during a spray drying operation;
- Heinz supports a maximum of 40 ug/100kJ to ensure that all product can achieve the minimum requirement for thiamin.

Levels of selenium:

- Heinz does not support the minimum and maximum amounts of selenium for the following reasons:
- the range is extremely narrow at +/-10%;
- the range is beyond the capability of the production process used for Heinz infant formulae; and
- the limits are beyond the sensitivity and accuracy of testing method limits

Levels of zinc:

- Heinz does not support the minimum and maximum amounts of zinc for the following reasons:
- the minimum level of zinc has been raised from >120ug/100kJ to >180ug/100kJ which would require reformulation to enable the currently available product to achieve fortification rates at higher levels; and
- the higher zinc level prescribed for follow-on formula dictates that copper levels in these products must also be raised, if the ratio of these two elements is to be regulated.

Feeding guide:

- feeding guides are exactly that - a guide only and individual infants can vary the number and volume of feeds taken;
- Heinz supports flexibility in allowing manufacturers to determine the format of feeding guides, particularly since the prescribed guides do not harmonise with international standards.

Need for regulations to cover special formulae:

- without clause 2(b) of the current Standard R7, the remaining specialist infant formulae will be illegal in the time period between the adoption of the revised Standard R7 and the introduction of the new Standard R10.

Regulatory impact:

- the total estimated cost of product reformulation to meet the proposed fatty acid profile would be \$57,250 this would impose economic and trade restriction on infant formula sold within Australia only;
- this would be contrary to the principles of APEC and GATT and imply restrictions to free trade;
- this additional production cost may eventually force an increase in the retail price for infant formulae;
- the economic and trade restriction of having to comply with upper limits for aluminium and fluoride would cost Heinz app \$1300 per annum;
- this additional production cost may eventually force an increase in the retail price for infant formulae, so that consumers would be paying for the cost of legislation.

Problems with subclause 2(2):

- The intent of subclause 2(2) is unclear. It also excludes ready-to-feed infant formulae.

Ratio of alpha tocopherol equivalents to PUFA:

- Clause 24(3) and 33(3) specify a minimum of 0.9mg of d-alpha-tocopherol equivalents, however clause 42(3) and Schedule 3 specify a minimum of 0.5mg;
- this is inconsistent and the same level should appear in all four areas

Maximum level of nucleotides:

- the levels nominated in the revised Standard are reflective of levels normally present in human breast milk, but do these account for polymeric or cellular nucleotides?;
- the total limit on nucleotides in clause 8 of less than 1.2mg/100kJ is lower than the sum of maximum permitted levels of individual nucleotides specified in the table to clause 7. Is this intentional?

Methods of analysis:

- the specifications on vitamins, minerals and electrolytes should be tied to a method of analysis and the method must have a defined sensitivity, particularly for B vitamins.

Maximum level of riboflavin (B2):

- NZ milk powder may have intrinsically occurring levels of riboflavin at up to 100 ug/100kJ;
- Heinz supports a maximum of 100 ug/100kJ, to ensure that all product can achieve the maximum requirement for riboflavin.

Maximum level of vitamin B12:

- supports a maximum of 0.2 ug/100kJ, to enable the currently available product to maintain fortification rates at existing levels.

Maximum level of phosphorus:

- does not support the lowering of the maximum level of phosphorus from 25 to 22 mg/100kJ;
- it will be impossible to formulate an infant formula based on skim milk powder without restricting manufacture to between the months of January to May only to account for intrinsically higher levels of phosphorus outside these three months;
- the trade and economic ramifications of this restriction in production are enormous;
- Heinz supports maintenance of the existing maximum level of phosphorus at 25mg/100kJ.

Ratio of Ca:P:

- Heinz supports the specifications for the ratio of calcium to phosphorus prescribed in paragraph 24(2)(a), but notes that the lower ratio must be at least 1.1, due to seasonal variation in source ingredients.

Ratio of zinc:copper:

- Heinz does not support the ratio of zinc to copper as this is inconsistent with the ratios of maximum amounts prescribed in Schedule 3; supports a maximum ratio of zinc to copper of 12:1.

Definition of protein substitute:

- supports the definition.

20. Douglas Nutrition (Douglas)

Use of minimum levels in NIT:

- more practical to declare typical values of nutrients as both consumers and health professionals assume declared quantities are typical quantities;
- some vitamins are added with overage, therefore not practical to declare these as minimum values;
- most countries require that measured values fall within a + range of label claim
- easier to comply with this if optimum values are declared.

Concern over soy formulae:

- concerns are based on the possible effects of isoflavones on the infant;
- isoflavones have 1/1000 to 1/10,000 the activity of endogenous or ingested oestrogens;
- infants fed soy formulas grow and develop like cows' milk formula-fed infants;
- the breast milk of mothers taking soy products has never caused any deleterious effect on infants;
- there is no evidence in the scientific literature of deleterious effects of soy based formulae in infants, although they have been fed to millions of babies worldwide for over 30 years;
- some animal species are known to be adversely affected if fed soy based feeds, but until proper clinical trials are undertaken in infants, there is insufficient evidence to warrant any amendment to the labelling or distribution of soy based infant formula.

Definition of infant:

- in NZ an infant is defined as being aged 0-6 months
- NZ's interpretation of the WHO Code therefore differs from that of Australia*;
- interpretation of the age of an infant should be confined to R7;
- *NOTE: WHO Code - infant formula ...“to satisfy the normal nutritional requirements of infants up to between 4 and 6 months of age”;
- Codex defines an infant as “a person not more than 12 months of age”

Maximum level of choline:

- maximum level should be increased from 5.4 mg/100 kJ (draft Standard R7 level) to 10 mg/100 kJ;
- existing level may not be technically feasible because levels of free choline in whey proteins are naturally high and vary seasonally.

Maximum level of carnitine:

- maximum level should be increased from 0.42 mg/100 kJ (draft Standard R7 level) to 1.0 mg/100 kJ;
- specified maximum may not be technically feasible in milk-based formulations, because level of carnitine in milk is so naturally high that

fortification is not always required;

- levels should be for total carnitine, not free carnitine, which is not tested

Permission to add nucleotides:

- supported

Maximum level of fluoride:

- next step is to examine varying concentrations of fluoride in local water supply used for reconstitution.

Entries in NIT:

- declaration of fluoride content in the NIT would not be required;
- assume that optional ingredients, kcal content, fatty acid profiles and whey:casein ratios may also be declared in the NIT, as per the current Standard;
- this information is requested frequently by health professionals

Osmolality value:

- maximum osmolality value for all formulae should be 350-360 mOsm/kg;
- maximum for proximate-modified formula is 360 mOsm/kg, and goat milk formula may naturally have values between 325 and 350 mOsm/kg.

Microbiological requirements:

- the term "aerobic plate count" is preferred to "standard plate count", as this is the term used by international convention (international dairy federation (IDF) terminology);
- internationally recognised methods of analysis should be followed because:
- a large portion of infant formula distributed in Australia is manufactured in NZ;
- the NZ Dairy Industry generally utilises IDF methods;
- currently dual test methods are required for formulae sold in Australia.

Requirements relating to use of product:

- the statement "Prepare only one bottle at a time" creates confusion;
- as long as formula is prepared according to instructions, refrigerated during storage and used within 24 hours, the practice of making up 24 hours' supply at a time does not pose any microbiological hazard.

Advertising/promotional materials:

- as a consequence of some health professionals misinterpreting the WHO Code, care givers may not receive information on the safe preparation and usage of infant formula;
- manufacturers and health professionals should be able to disseminate freely, to care givers who are bottle feeding, information on the safe preparation of formula.

Use of amino acid score to determine protein quality:

- should be standardised at a minimum of 0.8 for all formulae;
- extensive use of formulas with AA score of > 0.8 (eg. casein-dominant formulas) for several decades has demonstrated the adequacy of these formulas for infant growth and development.

Definition of medium chain triglycerides:

- there needs to be clarification of this term and whether it refers to MCT oils.

Prohibition on medium chain triglycerides:

- medium chain triglycerides are readily absorbed and present in a number of infant formulae, and in human milk (in small quantities);
- pre-term formulae, and special formulae for infants with disorders of fat absorption, should be permitted to contain MCT oil.

Fat profile and ratios:

- profile is very prescriptive;
- should be noted that the absorption of fats from cows' milk differs from that of human milk;
- functionality or physical properties of products can be affected by any radical change in oil blend;
- analytical capability should be a consideration for any new substances permitted in infant formula.

Requirement for 80% carbohydrate to be lactose:

- this requirement excludes soy formulae from division 1 - infant formula;
- the provision for soy based formulae to contain carbohydrates other than lactose as the majority of their carbohydrates should be made clear.

Category for soy-based formulae:

- it is not clear which category soy-based infant formula and follow-on infant formula come under - they cannot be classified as infant formula, lactose free or low lactose or proximate-modified.

Sources of carbohydrate:

- starch should be specified as corn starch because of the gluten-free requirement.

Maxima for vitamins and minerals:

- maxima for some nutrients are not practical or feasible because:
- overages of vitamins are sometimes used to compensate for any decay over the shelf life period;
- there is natural variation, sometimes seasonal, in vitamin and mineral content in cow and goat milk;
- levels in follow-on infant formula may be higher than in infant formula, due to the higher protein content; and
- the EC, USFDA and Codex do not specify maxima for all vitamins.

Maximum level of thiamin (B1):

- proposed maximum (22 ug/100 kJ) should be increased to 40 ug/100 kJ, to allow for frequently high levels in milk;
- thiamin hydrochloride is also very heat susceptible, so that end measured levels are less than initial levels;

- the increased maxima would pose no toxicity problems;
- urinary excretion rates of oral thiamine are high.

Maximum level of riboflavin (B2):

- proposed maximum (86 ug/100 kJ) should be increased to 110-120 ug/100 kJ, to allow for frequently high levels in milk;
- because of the relatively low solubility of riboflavin, it is rare for higher intakes to result in toxic levels in the blood (US RDA 1989).

Maximum level of vitamin B12:

- proposed maximum (0.13 ug/100 kJ) should be increased to 0.2 ug/100 kJ, to allow for high levels which occur in milk in Autumn;
- vitamin B12 is not considered toxic - no toxic effects have been found in man;
- excess vitamin B12 (not bound by serum and tissue protein) is excreted in the urine.

Maximum level of vitamin C:

- proposed maximum (5.4 mg/100 kJ) should be increased to 7.5 mg/100 kJ;
- overage added to allow for decay from oxidation and heat processing (dehydroascorbic acid is less stable in heat).

Ratio of alpha tocopherol equivalents to PUFA:

- minimum value specified in Schedule 3, 0.5 mg, is inconsistent with the minimum level listed in 24(3), 0.9 mg;
- EEC requirement is for 0.5 mg;
- 24(3) should be amended to 0.5 mg.

Maximum level of iron:

- proposed specifications permit iron levels of between 6 and 14 mg/L, but a moderate level of iron, 7-8 mg/L, has been shown to be adequate;
- ascorbic acid in formulae increases effectiveness.

Maximum level of magnesium:

- proposed maximum (3.6 mg/100 kJ) should be increased to 4.5 mg/100 kJ, to allow for the seasonally higher level of magnesium in goats' milk;
- adverse effects have not been attributed to higher magnesium concentrations in infant formula.

Feeding guide:

- proposed feeding guides should be much less detailed, with indications only of volumes and frequency of feeds;
- should take into account weight as well as age;
- there should be a statement to the effect that it is a guide only, and that infants may vary in the volume and number of feeds taken.

Maximum level of potassium:

- proposed maximum (50 mg/100 kJ) should be increased to 65 mg/100 kJ, to allow for naturally higher levels that may occur in goats' milk.

Maximum level of phosphorus:

- proposed maximum (22 mg/100 kJ) should be increased to 25 mg/100 kJ, as in the current Standard R7, to allow for higher levels in follow-on infant formula;
- follow on formulae have higher protein levels and in cows' milk, 22% of the phosphorus is present in protein.

Levels of selenium:

- strongly supports the proposal to allow fortification of selenium in the forms and levels quoted in Schedule 3;
- reasons:-
- formulas manufactured in NZ and not supplemented with selenium may contain as little as 15% the selenium levels quoted for human milk;
- in countries with normal selenium status, studies have shown that infants fed low Se formulas have lower blood Se levels and glutathione peroxidase activities than infants fed human milk;
- NZ manufactures a large number of infant formulae distributed in Australia;
- range for follow-on formula should be the same as for infant formula, 0.42 - 0.89 ug/100 kJ, because by 6 months most infants are consuming solids which contribute to selenium intake;
- the range for Se in proximate modified formula should be the same as it is for infant formula.

Sources of carbohydrate:

- soy based follow-on infant formula should be permitted to contain corn syrup solids as their main source of carbohydrate.

Minimum level of copper:

- the minimum level of copper in all sucrose free infant formulae should be 14 ug/100 kJ, as in Codex and the current R7;
- the minimum levels proposed are 14 ug/100 kJ for non-soy formulae and 21 ug/100 kJ for soy based formulae. The rationale for the different requirements is unclear, as the phytate present in soy protein affects zinc absorption but not copper;
- it has been reported in the literature that sucrose can interfere with copper nutritional status. If this is the rationale for increased copper requirements in soy based formulae, then the higher minimum should not apply to those soy based formulae which are sucrose free.

Maximum level of lactose:

- should be the same for both cows' milk and goats' milk formula, 2.4 g/L, because both types of milk contain approximately 4.7 g/100 mL lactose (Visser et al (1991). Composition of New Zealand Foods. 3. Dairy Products. Palmerston North; DSIR).

Maximum level of manganese:

- if soy based formulae are to be classified as proximate- modified (and this is not clear), the maximum level for Mn in proximate-modified formulae should be the same as it is for infant formula, 13 ug/100 kJ , not 7.2 ug/100 kJ. (The rationale for the lower Mn maximum is not clear).

Permission to add chromium and molybdenum:

- the permission for these to be added to proximate-modified formulae is supported;
- molybdenum is noted in the UK DRV as essential;
- only at extremely high intake levels has toxicity been observed;
- Cr 3+ is bioavailable and of very low toxicity, even at extremely high intakes.

Consequential amendments:

- specifications should be given for sodium selenite;
- Standard A1 should list potassium and sodium hydroxide as permissible food additives in the required schedule.

21. Francis, Dorothy

Need for regulations to cover special formulae:

- clause 2(b) should be retained, and the warning statement in 44(1)(a) should be included on these products;
- there is no other standard to cover these products, many of which are used in the management of inborn errors of metabolism, renal and liver disease and a variety of gastroenterology disorders.

Warning statement for infants with galactosemia:

- suggested wording is appropriate, but the formula categories suggested for such a warning are not;
- should be used to identify formula based on the residual galactose content;
- suggest 5 mg/100 mL as an initial "safe" upper limit, until further information becomes available;
- warning should be placed on all lactose free and reduced lactose formulae, and all soy-based formulae, if they exceed the maximum permitted level of galactose;
- a method of analysis for galactose should be specified.

Maximum level of lactose:

- should be the same for cows' milk and goats' milk 'low lactose' formulae;
- two different levels are unnecessary and confusing.

Definition of lactose free and low lactose hms:

- the 'lactose free' definition suffices for all situations except where an infant has galactosemia;
- there is no need for a 'low lactose' category as well.

Prohibition on medium chain triglycerides:

- support this prohibition for infant formula, follow-on infant formula and pre-term formula, but not for proximate-modified formula with fat modification;
- infants with a variety of clinical conditions benefit from the increased absorption rate of these fatty acids;
- provision for sufficient essential fatty acid to be included in these products is crucial.

Maxima for vitamins and minerals:

- some MCT predominant proximate-modified formulae need higher than normal levels of fat-soluble vitamins to meet the needs of infants with eg. liver disease and cystic fibrosis.

Sources of fat:

- the following should be prohibited:
- coconut oil, a rich source of saturated fatty acids;
- peanut oil, because of the high allergenicity of peanuts.

Prohibition on gluten:

- supported;
- conditions pertaining to the “no detectable gluten” claim should be stated in Standard R7, eg. recommended analytical method* and labelling regulations;
- the source of starches should be listed;
- (*note: there are concerns about the prescribed method of analysis and its reliability in detecting trace amounts of gluten).

Sources of carbohydrate:

- wheat-based starches, precooked starch and gelatinised starch or other thickeners should not be permitted;
- only starches from maize, or similar non-gluten source, should be permitted.

Definitions of partially and extensively hydrolysed protein:

- the permitted molecular weight (MW) of the protein fractions should be clarified with an expert paediatrician-allergist, such as Dr David Hill, RCH Melbourne;
- the maximum MW of 5000 Dalton for extensively modified protein is high compared with the max. MW of protein fractions in the current extensively hydrolysed formula:
- Nutramigen and Pregestimil: - average 450; max. 2500; 0.1% in range 2000-3000 Daltons;
- Alfare: - range ≤150-3000, with 0.1% >6000 Daltons;
- Neocate (based on amino acids): - average 150; range 90-250 Daltons

Hypoallergenic claim:

- should not be used.

Concern over soy formulae:

- there is no published scientific basis for the recent media concern about phytoestrogens in soy-based formula;
 - indiscriminate use of soy should be avoided;
 - should be used only for:
 - infants intolerant to components in cows' and goats' milk based formulae, such as milk protein (provided that soy is tolerated), or lactose; and
 - those families who choose to avoid cows' milk for religious or social reasons.
- note: infants with cows' milk intolerance may be intolerant to soy also.

Declaration of sources of ingredients:

- the sources of all carbohydrates and fats should be stated for all formulae;
- all formulae should be required to state the source of protein, except those made from individual amino acids.

Amino acid profile:

- methionine and cystine should be listed separately rather than together in the "Reference Amino Acid Composition of Human Milk", because:
- there is a specific need for cystine (a semi-essential amino acid) in the newborn due to the relative immaturity of the cystathionase enzyme required for conversion of methionine to cystine;
- most formulae will provide sufficient of each individual amino acid judged by protein score, however cows' milk is lower than human milk in cystine, arginine, tryptophan and taurine, and supplements may be needed in some formulae;
- methionine is needed in soy-based formulae;
- provision of all non-essential amino acids is also important due to the immaturity of liver synthesis compared to growth rate in infancy - especially important in amino acid based proximate modified formulae;
- tyrosine becomes an essential amino acid in phenylketonuria, and additional amounts are needed in low phenylalanine formula, compared to what is needed for normal infants. In this situation, phenylalanine and tyrosine should be listed separately.

Feeding guide:

- on the label, the concept of demand feeding at correct dilution should be included;
- tables 1 and 2 have an unnecessary number of age groups and could be amalgamated into a single chart;
- total volume daily and number of feeds should be included;
- separation of the feed preparation from the recommended volumes would save duplication and make the chart clearer;
- instructions for making single feeds is preferred (sample tables provided in appendix);
- correct dilution as a %solution (weight to total volume) and correct weight of powder in a level scoop should be included on the label;
- it is strongly recommended that the preparation guide be standardised;

- the UK has a standard dilution of 1 level scoop of powder to 30 mL water -

Australia should do likewise because:

- this is convenient;
 - avoids excessive increments in volume when extra formula is needed; and
 - it is the commonest dilution of the current powder formula on the market;
- liquid concentrates should also be standardised to 50 mL concentrate to 50 mL water;
- manufacturers would need a lead-in time to change scoops and labels;
 - for pre-term formula, instructions for two dilutions need to be given - 65 kcal/100 mL and 80 kcal/100 mL - a suggested table format is included in the appendix.

Measuring scoop - requirement for:

- design is important, to avoid use of excess powder;
- deeper is more accurate than a shallow one.

Requirements relating to use of product:

- standardisation of instructions is recommended regarding:
- filling and levelling the scoops with the edge of a knife; and
- the amount of water to which a level scoop should be added.

22. Nestle

Lack of harmonisation:

- the proposed Standard is even more different to existing international standards than the current Standard R7, both in terms of product denominations and composition;
- this makes harmonisation with the food regulations of other countries clearly impossible.

Need for regulations to cover special formulae:

- as a consequence of deleting clause 2(b), any specialised product cannot be made without a change to the Standard;
- manufacturers sometimes supply specific products for one infant with a particular need and 2(b) assists with this.

Prohibition on medium chain triglycerides:

- this prohibition will remove a Nestle product for pre-term infants from the market.

Maxima for vitamins and minerals:

- the imposition of maximum limits, especially for water soluble vitamins, is counter to any other international standard;
- the natural variation of some of the vitamins and minerals (eg. due to seasonal variation in the levels in milk, the type of feed, the herd, the health of the cow, the breed of the cow) make it difficult to meet some of the proposed requirements the variations in the levels of nutrients in the raw materials and

the levels set for the nutrients in the products will necessitate a massive control program for testing the raw materials and finished product.

Regulatory impact:

- the proposal represents a major potential trade barrier and the Authority may be called on by the WTO to justify the proposed changes on health and safety grounds;
- if the draft revised Standard were introduced in its present form:
- all products would need to undergo reformulation;
- new raw materials would need to be sourced;
- trials would need to be conducted and stability programs set in place;
- major control programs would need to be adopted and there would have to be capital expenditure for extra equipment;
- the proposed changes will add 50% of the current total costs of manufacture on to the products and the cost would be passed on to the consumer.

Title of Standard R7:

- recommend that the Standard be named Infant Formula - this is the name use by all national and international regulations;
- the title "Human Milk Substitutes" is not suitable for the following reasons:
- has the potential to allow or disallow certain components, based on the content of human milk, regardless of whether scientific evidence has proven the need for them to be added to infant formula;
- implies that the food is the sole source of nutrition and that nutritional needs are not also met by other foods, as with the follow-on category;
- is not in the spirit of the WHO Code, as it may imply that the products within the Standard are of the same quality as human milk.

Definition of carbohydrate-modified:

- this term should not be used to describe proximate-modified formula because:
- where it is used elsewhere in the Code, it refers to the replacement of sugars by other ingredients, such as artificial sweeteners, therefore there is not consistency of terminology;
- this definition is more precisely "lactose modified" or "lactose hydrolysed", and as this is covered in another section, the definition is not needed.

Definitions of partially and extensively hydrolysed protein:

- not satisfactory because:
 - the molecular weight of the hydrolysed protein fragment is not necessarily linked to allergenicity;
- note:
- there is no international definition for this type of product;
 - there is no specific immunochemical or physico-chemical parameter which would allow a satisfactory classification;
 - the trend is to follow the definition proposed by ESPGAN. This refers to a reduction in antigen content compared to conventional formula of at least 100

fold.

Definition of fat-modified:

- this is not necessary because the term is not used in the proposed Standard;
- since there are other ways of modifying fat content than by adding MCT oil, it would be more appropriate to use specific terminology in each case

Definition of follow-on infant formula:

- different from Codex definition: "food for use in the weaning diet for infants from the 6th month on and for young children", i.e for the period from 5 months to 3 years;
- because the diet will diversify as the infant ages, this formula will not be the principle source of nutrition at all times through the first year of life.

Definition of glucose polymers:

- there is no international definition of these compounds;
- the definition does not reflect generally understood nomenclature.

Definition of human milk substitute:

- this should be replaced by "infant formula".

Definition of modified cow's milk protein:

- recommend that the term be replaced by 'adapted cow's milk protein' because:
- this is the term used in Europe; and
- the proposed definition could be confused with the 'protein-modified' definition.

Definition of protein-modified:

- this is not consistent with "modified cows milk protein";
- better to use the specific wording, hydrolysed proteins or L-amino acids.

Definition of proximate-modified:

- confusing terminology and would not be understood by a large number of people;
- this category is described internationally as "medical foods";
- the two conditions listed are not the only conditions that require special formulae;
- confining this category to these two conditions is very restrictive and means that it does not cover all products in the market place.

Problems with subclause 2(1) - refs. to a human milk substitute:

- this is better defined within the definitions.

Problems with subclause 2(2):

- it is not clear what this clause is for.

Energy value for carbohydrate:

- this is out of step with what the Code specifies for other products with a high sugar content, eg. confectionery;
- should the energy calculation be treated differently for modified starches?
- recommend that the energy value for carbohydrate be consistent with international practices and the rest of the Food Standards Code, at 17 kJ/g.

Prohibition on gluten:

- should be linked to Standard R1, clause 3(b)(i), as this will then prescribe a method of analysis for gluten.

Maximum level of aluminium:

- recommend that the aluminium level be uniform for all types of formula, and that this level only apply to infant formula that is the sole source of nutrition; rationale:
- if the issue is one of public health and safety, then the same risk is evident in both soy-based and milk-based products;
- if the issue is not one of safety, references to aluminium should be deleted;
- a communication from the US FDA (1995) states "typical exposure to dietary aluminium is not of public health significance".

Maximum level of fluoride:

- limits for milk-based and soy-based formulae should be the same, because the risk for ingestion of fluoride is equivalent;
- since water is the major source of fluoride, a possible solution is to find an alternative vector for fluoridation.

Use of minimum levels in NIT:

- request that average not minimum values be required in the NIT, because:
- nutrition labelling elsewhere in the Code refers to average values, and consistency should be maintained;
- average values are the most significant for the consumer and health professional;
- it is the manufacturer's responsibility to ensure that the product composition is within the required limits throughout the shelf-life;
- mineral content will not change over the shelf life;
- manufacturers may be considered irresponsible if they label the minimum level of minerals rather than the average;
- declaring a minimum amount of nutrient may have dramatic consequences in terms of nutritional information, as the average will not be known;
- declaring minimum values will not allow any comparison with standard Expert recommendations.

Definition of protein substitute:

- 'protein substitute' is not needed as a definition - specific wording should be used within the standard itself ie 'protein hydrolysate' or 'L-amino acid'.

Required statements:

- in 14(1)(a), "ATTENTION" should be replaced by "IMPORTANT NOTICE", because this is the wording used by in the WHO International Code of Marketing of Breast-Milk Substitutes;
- the statement required by para 34 (1)(a), "suitable only for pre-term infants under specialist medical supervision" is not necessary because:
- the product will only be administered through medical authorities;
- the product designation must state that it is a pre-term infant formula.

Statement containing advice to introduce other foods:

- 14(1)(D) should be amended to state 4 months instead of 6 months; rationale:
- ESPGAN recommends the introduction of weaning foods between 3 and 6 months, and never after 6 months.

Print size:

- consistency in the determination of print size is required;
- this should not be based on the weight of the product - elsewhere in the Code it is based on the total area of the package, and in the case of the net weight statement, on the maximum dimension of the package.

Entries in NIT:

- units for vitamin E should be mg;
- would prefer the European format where the order is: fat, protein, carbohydrates.

Sources of protein:

- International Standards, eg. Codex, allow for other protein sources than those listed in the draft revised Standard.

Prohibited representations:

- a consequence of subclause 18(f) is that it would not permit infant formula to be labelled "infant formula with iron";
- this is not harmonised with the Codex Standard which states that a product containing not less than 1 mg iron/100 Calories shall be labelled "Infant Formula with Iron";
- recommend that this international position be retained.

Microbiological requirements:

- the method used for liquid concentrate or ready-to-feed formula must be specified properly;
- "Standard Plate Count" is not appropriate for these types of products;
- there are specific Australian standards for examining commercially sterile products in hermetically sealed containers. These examine both aerobic and anaerobic microorganisms, the latter being quite important with this type of processing and packaging.

Energy value range:

- EU Directive recommends a range of 250-315 kJ/100 mL for infant formula;
- this is broader than the proposed range for infant formula: 270 -300 kJ/100 mL;
- the maximum energy level for pre-term formula is 3556 kJ/L, which is at odds with other energy values because it has 4 significant figures instead of 3;
- the range for proximate-modified formulae should ensure that all situations are covered. Proposed range, 2700-3000 kJ/L does not cover Alfare (2730-3010 kJ/L).

Range for carbohydrate:

- there is no range for carbohydrate in the current R7;
- because there are limits placed on protein, fat and minerals, the carbohydrate value is self-limiting, especially when energy is also set - what's left over must be carbohydrate.

Use of term "lipid":

- references to lipid should be changed to fat because:
- the term "lipid" is not generally understood by the consumer;
- lipids comprise triglycerides, phospholipids and sterols;
- fats are mixtures of triglycerides;
- consistency of terminology is required, the term "fat" is used in some parts of the Standard and "lipid" in others;
- if something other than triglycerides is required where lipid is mentioned, then this should be defined.

Minimum level of lipid:

- it is noted that the minimum level for lipid (1.1 g/100 kJ) differs from that required by Codex (0.8 g/100 kJ) or the existing EC Directive (0.8 g/100 kJ) and draft EC Directive (1.05 g/100 kJ)

note:

proposed draft revised Codex Standard has a minimum value for fat of 1.05 g/100 kJ.

Sources of protein:

- there should be a wider choice for the source of protein than there is in the proposed Standard;
- the current R7 and Codex permit formula to be manufactured from other animals and/or other edible constituents of animals or plants, and this provision should be maintained.

Amino acid profile:

- is 5.5 g/100 g protein for valine in Schedule 1 an error?
- the EC reference value for valine in human milk is 4.5 g/100 g protein.

Ratio of linoleic to alpha linolenic acid:

- proposed range for ratio, 4:1 to 10:1 is too narrow;
- this range is not documented by scientific evidence;
- no Nestle product currently complies with this recommendation;
- based on the oils used in other manufacturers' products, it is doubtful if any product would comply with this requirement; - ESPGAN and the EC recommend a ratio of 5:1 to 15:1.

Fat profile and ratios:

- will make it very difficult for all manufacturers to produce products that meet the Standard;
- the proposed fatty acid profile does not reflect any international Standard;
- it is doubtful that cows' milk formula will meet the requirements set for saturated fat at all times of the year;
- there appears to be no substantiated scientific evidence used in establishing the levels imposed on the fatty acid components in infant formula;
- the range for fat in follow-on formula is tighter than that required by Codex and the EC.

Minimum level of alpha linolenic acid:

- the proposed minimum of 2% cannot be met by using traditional vegetable oils such as soy bean oil or corn oil;
- this will require the use of canola oil, necessitating major reformulations to products;
- this minimum is far greater than the average value for human milk fat, 0.95%;
- the levels in breast milk range from 0.45 to 1.85%;
- EC Directive (1996) requires an α -linolenic acid content of not less than 12 mg/100 kJ (1.1% of the fat);
- the consultant's report for proximate-modified formula recommends a different level to that finally proposed in the Standard, but there is no reference to this in the full assessment report.

Requirement for 80% carbohydrate to be lactose:

- 23(1) does not allow for soy-based products;
- there should be an amendment to exclude such formulae from this requirement.

Ratio of zinc:copper:

- this requirement is not in keeping with international standards;
- the EC Directive has no reference to a Zn/Cu ratio.

Permissions for additives:

- request that lactic acid producing cultures be permitted, in line with international practice;
- permission is needed for use as probiotics and as pH adjusting materials;
- also request separate permission to add mixed tocopherols concentrate and L-ascorbyl palmitate as antioxidants, to a level of 1 mg/100 mL;

rationale:

- Codex permits this;
- the more unstable, unsaturated fats and oils, such as LC PUFA, need anti oxidants and the level permitted for nutritional reasons is not suitable for antioxidant activity;
- if vitamin E were added at the lower level, this would be equivalent to approximately 0.3 mg/100 mL, insufficient for both nutritional and antioxidant activity;
- the antioxidant activity required by ascorbyl palmitate is a significant proportion of the nutritional requirement for vitamin C.

Levels of selenium:

- unclear why the minimum for selenium is higher in proximate-modified formulae (0.53 ug/100 kJ) than in standard formula (0.42 ug/100 kJ);
- manufacturers would not be able to comply with the proposed range for follow-on formula, 0.79 -0.89 ug/100 kJ, as the experimental error for the analysis of selenium is far greater than the actual range;
- there is no clear evidence for selenium to be added at these levels;
- Australian Formulae contain approximately 0.15 ug Se/100 kJ, and no evidence of deficiency is documented;
- the selenium from the recommended intake of follow-on formula and the ingested selenium from other foods would be in excess of the 15 ug/day for infants 7-12 months;
- recommendation:
set the minimum level for Se at 0.15 ug/100 kJ.

Permitted forms of selenium:

- sodium selenate should be a permitted form of selenium because it has better stability than sodium selenite.

Levels of zinc:

- it is not necessary to set a maximum level for zinc in follow-on formula because:
- zinc has a very low toxicity;
- Codex and the EC do not set a maximum limit for zinc.

Range for protein:

- for pre-term infants < 1 kg, the experimental error for the analysis of protein is far greater than the actual range (0.72-0.76 g/100 kJ);
- this makes the amount of protein in a product extremely uncertain if it falls within the range indicated;
- a large number of batches may be rejected because they will not fall within the nominated range.

Prohibition on medium chain triglycerides:

- subclause 31(c) does not allow the addition of MCT oil in pre-term formula;
- recommend that MCT oil be permitted to a maximum of 40% of fat;

- rationale:
- MCT oil is found in a number of pre-term formulae world-wide;
- MCT oil does not need bile salts to be absorbed and is absorbed directly into the portal vein;
- low birthweight infants show immature physiological mechanisms for fat digestion and absorption due especially to insufficient bile salts;
- the use of MCT oil has been shown to improve energy absorption and retention, weight gain, calcium absorption and nitrogen retention in the pre-term infant;
- excluding MCT oil from pre-term formula will severely affect the nutritional efficiency of these products;
- the ESPGAN Committee on Nutrition of the Pre-term Infant acknowledges the benefits of using MCT oil and recommends that no more than 40% of fat as MCT oil be used;
- the Committee on Nutrition of the French Paediatric Association made the same recommendation;
- the consultant's report on proximate -modified formula states that the use of MCT oil is advantageous where fat malabsorption is indicated; but
- the Expert Panel report on MCT oil states that there is little advantage for fat absorption with MCT oil in pre-term formula;
- this report does not appear to acknowledge the lesser ability of pre-term infants to absorb fat.

Sources of carbohydrate:

- glucose syrup and dried glucose syrup should be permitted in pre-term formulae.

Minor amendments:

- subclauses 33(a) and 42(1)(a) should be amended from "in relation to each vitamin or mineral" to "in relation to each vitamin or mineral or electrolyte".

Rationale for composition of pre-term formula:

- no rationale has been provided for the composition criteria for pre-term formulae;
 - they do not cover the range of variations that may be found in a range of formulae;
 - the Standard should take into account all of the recommendations on nutritional needs of pre-term infants made by the following Expert Committees:
 - AAP Committee on Nutrition;
 - ESPGAN Committee on Nutrition of the Pre-term Infant;
 - a group sponsored by the International Union of Nutrition Sciences;
- feeding of infants below 1000 g is highly specialised and tends to be adapted daily by hospital neonatologists to the individual needs of each infant. An ideal composition for these formulae cannot be defined.

Maximum level of lactose:

- there should be only one maximum level of lactose in the “low lactose” category;
- the lactose limit should be related to the disease state, not the raw materials used to manufacture the product.

Lactose free/low lactose claims:

- it is recommended that formula with less than 1% lactose be able to make the claim “lactose free”;
- rationale:
 - the “no detectable” limit is unrealistic and the possibility that new methods will be able to detect lower levels of lactose than at present will make the situation unclear;
 - the full assessment report states that formula with less than 1% lactose is suitable for non-galactosemic lactose-intolerant infants.

Warning statement for infants with galactosemia:

- this statement should be linked to the galactose content, not the lactose.

Ratio of alpha tocopherol equivalents to PUFA:

- in sub clause 42(3), should the ratio be 0.9 instead of 0.5?

Maximum level of manganese:

- it is unclear why the maximum level for manganese is lower in proximate-modified formula (7.2 umg/100 kJ) than it is in standard formula (13 ug/100 kJ).

Permission to add chromium and molybdenum:

- this permission should not have been granted until the chromium and molybdenum salts had undergone toxicological evaluation.

Amino acid profile:

- in Schedule 1, the heading of column 1 of the table should be L-amino acid;
- in the note at the bottom of the table, “cysteine” should be amended to “cystine”;
- it is noted that the EC reference value for valine is 4.5 g/100 g, not 5.5.

Permitted forms:

- permitted forms of vitamins and minerals should include those that are allowed by Codex and the EC Directive.

Maximum level of thiamin (B1):

- the natural range of variation in the raw material is of concern.

Maximum level of vitamin B12:

- the accuracy of the determination for vitamin B12 and the limits imposed in Schedules 3 and 4 will be a problem.

Range for folate:

- in schedule 4 there is particular concern over the range imposed for folate and the accuracy of the determination.

Range for pantothenic acid:

- in Schedule 4 there is particular concern over the natural range of variation in raw materials and the range imposed and the accuracy of determination.

Feeding guide:

- should be a guide only;
- the format of the age groupings should be determined by the manufacturer;
- many manufacturers have international products that are used throughout the world;
- Nestle recommends the feeding guides used by our company internationally (examples provided).

Declaration of sources of ingredients:

- there should be a requirement for a statement of protein source for proximate-modified formulae.

23. Tang, Shelley

Microbiological requirements:

- TGA has carried out microbiological survey of infant milk powders and other dietary substitutes in the Pharmaceutical Benefits List;
- testing of products has revealed problems in sensitivity of the test method for coliforms specified in AS 1766, the reference method specified in Standard R7;
- since microbiological criteria are to be carried forward to the proposed new Standard, the TGA submits a paper on the findings of the project, as comment on Proposal P93;

results:

- coliforms were detected when using the TGAL method, but not the Food Standards Procedure. Clearly the methods of AS 1766 are not capable of detecting all coliforms which may be present in a product.

24. South Australian Health (SA Health)

Maximum level of aluminium:

- given that the proposed values will not result in exceedances of the PTWI, the values proposed for aluminium in infant formula are acceptable;
- consideration should be given to appropriate labelling to address the concerns raised by Dr Simmer in the full assessment report regarding potential risks to preterm, very young and renally impaired infants.

Maximum level of fluoride:

- the fluoride level of 2 mg/L proposed for soy-based infant formulae may lead to fluoride consumption exceeding the threshold range for dental fluorosis;
- it is understood that this value has been chosen to accommodate products that are currently available in the marketplace;
- data provided in the full assessment report indicates however, that a value of 0.5 mg/L, which is considered more appropriate, will not exclude all soy-based formulae;
- it is considered that labelling of these products with advice against reconstituting with fluoridated water is not practical as the alternative would be to use mineral/spring water which is permitted to contain up to 1.5 mg/L fluoride;
- consumers should be informed of the risks of dental fluorosis and be advised to consult a doctor before making a choice;
- should a fluoride value greater than 0.5 mg/L be set for soy-based formulae, then those products which contain more than 0.5mg/L fluoride should be required to carry a statement informing the consumer of the risk of dental fluorosis and advising them to seek medical advice;
- this would enable consultation with a professional who could provide dietary advice, as well as information on dental fluorosis and ways to reduce fluoride intake eg. using a domestic water purifying device

Hypoallergenic claim:

- no provision should be made for a claim of “hypoallergenic” due to the lack of criterion to be used as a basis for this claim; a claim of this type could be misleading, given the great variety of allergies or sensitivities experienced by various individuals;
- there is also no precedence for this type of claim in the Food Standards Code.

Minor amendments:

- a drafting error has been identified : The paragraph referred to as (zf) should in fact be (zh) and should be inserted after subclause (1) (zg)

25. Mead Johnson Australia (MJA)

Size of Standard R7:

- agree with the use of a prescriptive standard for infant formula, but not with the expansion of the Standard to its proposed length (from 10 to 45 pages);
- rationale:
the revision of the Food Standards Code is aiming for simplicity and brevity - this Standard has been developed in the opposite direction.

Regulatory impact:

- no infant formula marketed in Australia complies with all provisions;
- we are not aware of any formula that complies with the fatty acid requirements or the selenium requirements, for instance;
- many formulas may also require other reformulations in order to comply with

the draft standard. To set minima and maxima for linoleic acid, alpha linolenic acid, the ration of these two to each other and a narrow, permitted range of levels of selenium, is a substantial challenge to manufacturers of infant formula. Added to this are new maxima for many micronutrients and very small ranges for the permitted levels of some micronutrients;

- the reformulation of an infant formula is a major project for any manufacturer, involving trial production, product stability testing and clinical trials;
- some sections of the draft revised Standard reflect a somewhat academic approach, and appear to ignore the production difficulties for manufacturers to comply with narrow nutrient ranges on a regular production basis.

Definition of human milk substitute:

- the term in wide popular use is 'infant formula';
- it seems unnecessary to change the title of the Standard;
- a broader definition of infant formula would be more appropriate and easier to manage;
- MJA prefers the term 'infant formula' rather than 'human milk substitute'.

Concern over soy formulae:

- aware of concerns shown towards the use of soy protein isolate based infant formula;
- have investigated the scientific reasonings behind the concerns and do not agree with the conclusions drawn;
- most of the concerns appear to stem from reports generated in NZ, and refer to the isoflavones (and their physiological activity in infants) in soy protein isolated based infant formula;
- we do not believe that soy-based infant formula poses any risk to infants, other than those with allergy to soy protein or other metabolic disorders connected to soy protein;
- for a more detailed discussion on the action of phytoestrogens, including isoflavones we refer you to Dr Graham Kelly of Norvet Pty Ltd, 140 Wicks Road, North Ryde 2113. Dr Kelly has specialised in studying the activity of phytoestrogens in human food and animal feeds.

Definition of carbohydrate-modified:

- do not believe the definition is necessary, as this appears to refer specifically to low lactose or lactose free infant formulas and is used nowhere else in the Standard.

Definitions of partially and extensively hydrolysed protein:

- a more realistic definition of 'extensively hydrolysed protein' would limit the protein fragments to "less than 1% with a molecular weight greater than 5000 daltons" and needs to be tied to a method of analysis;
- the European Society of Paediatric Allergy and Clinical Immunology (ESPACI) definition does not use molecular size and relates the hydrolysis to the "lack of allergic reactions shown by most sensitised children";

- the ESPACI position paper also defines hypoallergenic as “with reduced allergenicity to induce allergic reactions or allergic sensitisation”

Definition of fat-modified:

- 'fat-modified' specifically refers only to the inclusion of added medium chain triglycerides;
- this is an unnecessary definition, and is used nowhere else in the Standard.

Definition of follow-on infant formula:

- a more appropriate definition is 'means an infant formula that is nutritionally complete and represented as being suitable as a substantial source of food for healthy infants over six months of age'.

Definition of glucose polymers:

- glucose polymers is not an internationally defined term as such and is only mentioned for pre-term human milk substitutes;
- the inclusion of glucose polymers in the definition and as a separate permitted ingredient appears to be unnecessary and impossible to regulate.

Definition of infant formula:

- infant formula needs to be defined as suitable as the 'sole' source of food, rather than 'principal' source up to six months of age.

Definition of medium chain triglycerides:

- the definition of medium chain triglycerides refers to how they are made, not what they actually are;
- medium chain triglycerides are the glyceride form of the medium chain fatty acids of 6, 8, 10 and 12 carbon chain lengths.

Definition of modified cow's milk protein:

- unnecessary to define this;
the protein must comply with the 'amino acid score' and the protein source must be stated;
- casein predominant and whey predominant formulas are both marketed in Australia. There appears to be no need to distinguish between the two by definition or as the permitted form;
- a minimum amino acid score should apply to all proteins, as a safety issue, regardless of source.

Definition of proximate-modified:

- this appears to be a category designed to regulate certain more specialised infant formulas that are at present permitted under clause (2)(b) of the present Standard R7;
- this definition is not broad enough to encompass the variation which is presently permitted;
- using the broader, Codex ranges for protein and fat levels, so-called proximate-modified would fit into a general nutritional standard. The Codex labelling provision 9.1.5 allows for special nutritional requirements to be labelled accordingly;
- the particular emulsifiers and stabilisers required for formulas based on hydrolysed protein can be included in a clause under "Other permitted additions" in the infant formula standard;
- using the broader, Codex nutrient level requirements, so-called 'proximate - modified' infant formula could be expected to comply with the general standard. This, of course, also assumes that a clause such as the existing (2)(b)

in the present standard is incorporated into the revised standard. This would allow the inclusion of particular ingredients, such as added MCT.

Energy value for carbohydrate:

- carbohydrate should be given an energy value of 17kJ per gram, for the sake of consistency with the rest of the Food Standards Code;
- the permitted forms of carbohydrate, including maltodextrin, dried glucose syrup and starch, would all be more appropriately given the energy value of 17kJ per gram; Standard R2 could be used as a reference for energy values in this Standard.

Prohibition on gluten:

- the prohibition on gluten should more appropriately state: "An infant formula must be gluten free, when examined by the method prescribed by subclause 3(h) of standard R1".

Maximum level of aluminium:

- the limit on aluminium in infant formula is understandable, given the considerable exposure of this issue in the popular press;
- the level of aluminium in infant formula for healthy, full term infants, however, has not been scientifically demonstrated to be a health concern;
- the upper limit value needs to be connected to an established test method;
- would regard a level of 1.0 mg /L as an acceptable limit, which should apply to all infant formula;
- as a safety issue, the limit should not vary between sources of protein merely because some may be naturally lower than others.

Maximum level of fluoride:

- the limit for fluoride is presumably a safety issue;
- if this is the case, then one limit should apply to all infant formulas;
- this limit also needs to be connected to an analytical method;
- suggest that an upper limit of 2.0 mg /litre be used for all infant formulas, using the Taves method of separation and ion selective electrode detection.

Use of minimum levels in NIT:

- the NIT should reflect the average values of nutrients, rather than minimum values;
- it is unclear whether the levels of micronutrients in the schedule are minimum claim levels or minimum actual levels.

Minimum level of lipid:

- recommend harmonisation with Codex with regard to fat levels: 0.80g - 1.50g per 100kJ.

Maximum level of protein:

- recommend harmonisation with Codex with regard to protein levels: 0.43g - 0.96g per 100 kJ.

Prohibition on medium chain triglycerides:

- medium chain fatty acids are present in human milk and also in vegetable oils commonly used in infant formula;
- it is inconsistent to prohibit the fats in infant formula from containing medium chain triglycerides and, practically speaking, almost impossible to achieve;
- suggest that a limit is set that can be achieved by all manufacturers;
- a starting point may be maximum limit of 10% of total fatty acids, as fatty acids of 6-12 carbon chain lengths are permitted in infant formula.

Fat profile and ratios:

- the fatty acid profile may represent an ideal profile but would require reformulation of every infant formula on the market in Australia;
- this would be understandable if it was believed that the current formulations presented a grave risk to infants;
- this is clearly not so, and the revised fatty acid profile must be considered only as a desirable improvement to the present requirements.

Requirement for 80% carbohydrate to be lactose:

- (23)(1) should read: 'the preferred source of carbohydrate is lactose';
- the minimum level of 80% lactose, as given in the draft, precludes the marketing of soy protein based formulas which contain no lactose;
- the former clause (2)(b) of the original standard R7 allowed for the variation of no lactose, provided it was claimed on the package (Reintroduction of this clause would simplify the standard).

Ratio of zinc:copper:

- certain formulas would have difficulty meeting the zinc to copper ratio;
- a formula not based on soy protein could comply with the minimum level of copper and maximum level of zinc and have a ratio of 25.7:1. For a soy protein based formula the equivalent ratio would be 20.5:1;
- suggest that a more realistic maximum is 20:1.

Permissions for additives:

- there is no provision for the addition of antioxidants;
- commonly used antioxidants are ascorbyl palmitate and mixed tocopherols, both of which are permitted as forms of Vitamin C and Vitamin E, respectively. This simplifies the testing of product as on total level applies to a combined antioxidant and nutrient level;
- to omit permission of the addition of antioxidants is to not recognise the need for the protection of oils in the production system and this is unrealistic;
- both ascorbyl palmitate and mixed tocopherols concentrate should be permitted as antioxidants as well as nutrients;
- the maximum levels as nutrients need not be altered.

Requirements relating to use of product:

- the requirement to include words and pictures for the use of infant formula would require showing an infant drinking from a bottle;
- this is clearly not intended and 26(c) should be withdrawn; the present Standard R7 only requires directions for preparation.

Definition of follow-on infant formula:

- the statement for follow-on formula 28(a) should read: 'Suitable only for infants 6 months of age or older'.

Levels of selenium:

- the tolerance limits for selenium in follow on formula are too narrow and unlikely to be achieved in a production setting on a regular basis;
- recommend that the tolerance limits for infant formula be used for follow on formula.

Definition of pre-term human milk substitute:

- MJA does not believe that it is necessary or appropriate to standardise pre-term infant formula in Standard R7;
- these formulas are only used in hospitals in Australia;
- they are very specialised and are therefore beyond the scope of the products in Standard R7;
- pre-term formulas would be more appropriately standardised under proposed Standard R10 - Foods for Special Medical Purposes;
- more consultation with industry is required to arrive at an appropriate standard for pre-term infant formulas.

Lactose free/low lactose claims:

- the lactose content of lactose free and low lactose infant formulas must be connected to a test method. The limits of detection of this test method must also be stated.

Requirement for 80% carbohydrate to be lactose:

- the requirement in 23(1) for "at least 80% lactose" must also not apply for lactose free and low lactose products.

Warning statement for infants with galactosemia:

- galactosemia is a metabolic condition associated with the presence of galactose, not lactose as such;
- there is evidence to suggest that common infant foods, other than formula, may contribute as much or more galactose than a lactose free infant formula;
- the warning statement may well be appropriate if a nil galactose diet is required. This warning would also apply to reduced lactose formula and may be relevant for other infant foods;
- the clinical significance of the level of galactose in a lactose free infant formula is open to question;
- there is no set 'safe' intake of galactose at present, although on study indicates

that up to 200mg galactose per day has little effect on an adult galactosemic patient.

Sources of carbohydrate:

- corn syrup solids is a term used widely overseas but is not defined in Australia;
- the appropriate term, as defined under Standard K1, would be 'dried glucose syrup' or 'maltodextrin';
- corn syrup solids is not an appropriate term to use in Standard R7.

Warning statement for proximate-modified:

- the warning statement in 44(a), "THIS PRODUCT HAS BEEN SPECIFICALLY FORMULATED FOR INFANTS WITH SPECIAL DIETARY NEEDS AND SHOULD BE USED UNDER MEDICAL SUPERVISION" is unnecessary;
- if a 'proximate-modified' infant formula complies with the nutrient compositional standard, then it poses no risk to an infant, as such;
- because the products that this category is intended to standardise use specialised processing techniques and ingredients, the product cost is much higher than the widely used cow's milk based infant formulas;
- cost and availability of these products prevents the inappropriate selection of these products by consumers.

Schedule for vitamins and minerals:

- MJA agree with the expanded schedule of permitted forms of vitamins and minerals. This allows for maximum flexibility in formulations for a manufacturer and shows a high level of harmonisation with other infant formula standards, such as Codex and EC guidelines.

Problems with subclause 2(1) - refs. to a human milk substitute:

- concerning point 2 (1), suggest: 'A reference to infant formula refers to infant formula as consumed in a liquid form. This form may be as a ready- to-use liquid, a diluted concentrate or reconstituted powder'.

Ratio of linoleic to alpha linolenic acid:

- the ESPGAN recommendations of a linoleic acid to alpha-linolenic ratio of 5-15 appear to be more appropriate;
- this is a published value from an association of medical professionals and reflects a consensus view from different individuals.

Use of term "lipid":

- believe that 'fat' is a more appropriate term than 'lipid'.

Maxima for vitamins and minerals:

- by setting maximum values for all micronutrients, the Standard becomes much more difficult to comply with;
- vitamins are routinely added at levels greater than shown on the label. This is known as 'overage' and allows for some decrease in potency over the shelf life

of the powder. In setting maxima, it should be acknowledged that human milk nutrient values vary considerably.

Need for regulations to cover special formulae:

- clause (2)(b) allows for the marketing of low lactose and lactose free formulae, being exempt from clause (3)(a)(iv), and used for lactose intolerant infants;
- because Standard R7 is so prescriptive, the risk of any deficiency or excessive intake of a particular nutrient is minimised or eliminated;
- it seems quite logical that if a single nutrient is modified or substituted, this presents no additional risk to the infant, provided the rest of the Standard is complied with;
- the requirement that this modification addresses a well-recognised dietary or physiological problem, requires justification for the modification itself, and the need to explain the manner of modification;
- retaining this clause would entail no risk to the infant, simplify an unnecessarily expanded draft Standard, and allow future modifications within the Standard;
- there are commercial considerations for the retention of this clause when a company may wish to launch a formula with a modified ingredient;
- if the Standard needs to be varied to accept this modification, there is a cost and time component involved with the application to vary the Standard;
- the confidential aspect of this new product is compromised by the publication of the application, and any commercial advantage is lost;
- if there is no risk to the infant with the new formula and perhaps only a benefit, the requirement of an application to vary the Standard appears to be unproductive.

Permission to add nucleotides:

- agree with giving this permission, provided that international patents do not prevent any company from adding nucleotides if it chooses to.

26. Roche

Definition of fat-modified:

- this definition may be omitted, as MCTs are prohibited.

Definition of medium chain triglycerides:

- should be retained because it is useful, even though the use of MCTs is prohibited.

Energy value for carbohydrate:

- propose that the Codex specification be adopted, namely 17 kJ per 1 g carbohydrate.

Maximum level of aluminium:

- should be the same for all formulae, whether soy-based or otherwise.

Maximum level of fluoride:

- should be the same for all formulae, whether soy-based or otherwise.

Required statements:

- para 14(1)(e) should be amended to:
“... FURTHER VITAMINS OR MINERALS SHOULD BE GIVEN ONLY ON MEDICAL ADVICE”, replacing “... NO FURTHER VITAMIN OR MINERAL SUPPLEMENTS ARE NECESSARY”;
- SOME INFANTS MAY BENEFIT FROM THE INTAKE OF ADDITIONAL VITAMINS, AND IT IS THEIR MEDICAL ADVISOR WHO SHOULD DECIDE ON THE RECOMMENDATION.

Entries in NIT:

- suggest the following order for vitamins:
- oil soluble vitamins (A,D,E,K)
- water soluble vitamins (C, thiamine, riboflavin, B6, B12, biotin, folate, niacin, pantothenic acid);
- suggest that the units for vitamin E be mg, not µg (for consistency with Schedules 3 and 4);
- suggest that the meaning would be clarified if clause 15 was amended as follows: “... and the minimum amount of nutrients per 100 mL of the product ready-to-use, in the following form-”.

Lack of harmonisation:

- the draft revised Standard R7 differs from Codex and other major international standards on several points;
- it is to be assumed that in future the Codex Standard will be the reference standard for international trade, in which case further harmonisation may become necessary.

Definition of principal source:

- this term should be defined as it is used several times.

Use of term "lipid":

- suggests that the maximum be changed from 3.4 to 3.2 g in TABLE TO PARAGRAPH (20)(c) and from 3.4 to 3.1 g in TABLE TO PARAGRAPH (29)(1)(c);
- rationale:
- the total energy for the minimum amount for protein and lipid and the maximum amount for carbohydrate exceeds 100 kJ.

Fat profile and ratios:

- suggest that the LCPUFA listed in the TABLE TO PARAGRAPH 22(d) be required constituents of human milk substitutes, i.e. that there be minimum as well as maximum values specified;
 - (refers to recommendations made in FAO Food and Nutrition Paper 57 “Fats and Oils in Human Nutrition - Report of a Joint Expert Consultation”)
- suggest also that TABLE TO PARAGRAPH 31(d) and TABLE TO PARAGRAPH 40(c) be amended so that the minimum values for linoleic, α-linolenic, arachidonic and its associated LC n-6 fatty acids and DHA referred to

in the above paper be incorporated in column 2 of the TABLES;

- note that the minimum value for cis-monounsaturated fatty acids has been omitted from the TABLE TO PARAGRAPH 40(c), when compared with other similar tables.

Sources of carbohydrate:

- suggest that corn syrup, as well as corn syrup solids, be permitted in infant formula (para 23(2)(d));
- note that glucose is permitted as a source of carbohydrate in pre term formula, but not in other human milk substitutes.

Permissions for additives:

- note that the list (clause 25) is substantially shorter than that provided for by Codex;
- note that sodium and potassium citrates have not been included;
- suggest that further alignment with Codex be contemplated.

Minor amendments:

- all references to "d-a-tocopherol" should be amended to read "a-tocopherol", to be consistent with the new Standard A9, i.e. paras 24(3), 33(3), 42(3) and columns 3 and 4 of Schedule 3 (entry for vitamin E).

Ratio of linoleic to alpha linolenic acid:

- note a discrepancy between the ratio quoted (15:1) in para 31(b), and that achievable in TABLE TO PARAGRAPH 31(d) , where the maximum ratio possible is 10:1.

Ratio of alpha tocopherol equivalents to PUFA:

- in para 42(3) should be 0.9 mg, not 0.5, in line with paras 24(3) and 33(3); also in Schedule 3, columns 3 and 4 (entry for vitamin E).

Amino acid profile:

- note the discrepancy between the reference to "methionine and cystine" in the table (Schedule 1) and that in the footnote, which reads "methionine and cysteine".

Maxima for vitamins and minerals:

- Codex, the EU and the US FDA do not specify maximum quantities for vitamins, except A and D, whereas the draft revised Standard R7 proposes maxima for all 13 vitamins;
- note that no reasons have been given for imposing maxima on all vitamins;
- suggest reasonable harmonisation with Codex.

Age suitability statement:

- for follow-on infant formula 28(a) the labelling requirement "SUITABLE ONLY FOR INFANTS OVER 6 MONTHS" is not harmonised with Codex or the EU which have "from the 6th month" and "aged over 4 months" respectively;
- suggest alignment with Codex.

Ratio of maximum to minimum values for vitamins:

- this varies considerably from vitamin to vitamin, eg.:

thiamine 2.2:1

niacin 11.8:1

vitamin C 3.2:1;

- note:

no reasons have been given for the seemingly arbitrary set of ranges between vitamins.

Minimum level of folate:

- in draft revised Standard R7 is 1.7 ug, compared with 1.0 ug in Codex.

Minimum level of vitamin A:

- in draft revised Standard R7 is 17 ug, compared with 18 ug in Codex.

Minimum level of vitamin C:

- in draft revised Standard R7 is 1.7 mg, compared with 1.9 mg in Codex.

Reference to conversion factors for vitamins A and E:

- with regards beta carotene and vitamin E, suggest that a footnote be included either to detail the various conversion factors of various carotenoid and vitamin E forms to retinol and a-tocopherol equivalents respectively;
- OR to mention that such conversion tables are detailed in Standard A9.

27. Scientific Hospital Supplies

Lack of harmonisation with the EU standard:

- there are a number of variations between the Australian and the EU Stds for a number of nutrients (see Appendix 1 of submission);
- SHS requests that there is harmonisation between the Australian draft Std and the EU/UK Std.

Minor amendments:

- recommend that the following be added to the end of 36(2)'...or lactose enzyme may be added to hydrolyse the lactose in the milk during manufacture';
- NB. Now called lactase beta galactosidase and permitted in A16 as a processing aid - Clause 5(c) of R1 has been deleted.

Lactose free/low lactose claims:

- essential that the term 'detectable' should relate to a specific scientific method of analysis;
- if there is no method of analysis to determine 'not detected', then a 'less than' standards should be used eg 'must not contain more than 0,025g of lactose per 100 kJ when determined by HPLC';
- would like to have a nil standard and a specified analytical technique, but in

its absence would advocate a specified technique and a less than 0.025g/kJ level to call the product lactose free.

Regulatory impact:

- as the new Standard becomes more restrictive, specially formulated products imported into Australia from UK/Europe will have to be modified;
- reformulation will be extremely costly, especially where the market is very small.

Need for regulations to cover special formulae:

- most of the SHS products are covered under Clause 2(b) of the current R7 Infant Formula Standard, allowing for infant formula to be specifically formulated to satisfy particularly well recognised dietary requirements resulting from a specific physical or physiological condition, disease or disorder;
- with the omission of this clause from the new draft Std, we will urgently require an extension to the new Standard for these types of feeds, or the establishment of a medical foods std.

Required statements:

- due to cost, hospitals only buy small quantities of product, therefore SHS International maximum package size is 500g;
- this is insufficient to provide a label that is big enough to include the amount of information and warning statements required by Aust Stds;
- there is also concern that so many statements on a label will result in consumers ignoring the information.

Maxima for vitamins and minerals:

- use of maximum levels of some vitamins and minerals is a problem since neither the EU nor US Stds define upper levels, and this will be a barrier to harmonisation with these Stds;
- in some metabolic and malabsorptive conditions, higher levels of some vits and mins are required to overcome losses due to malabsorption;
- some specialised formulas will therefore have levels above the maximum, and these will not be permitted under the new Std.

Entries in NIT:

- there is a problem in requiring in the nutritional table that nutrients should be expressed in the described units eg vit B6 in ug not mg;
- all countries should standardise these unit requirements and this should be done at manufacturers discretion.

Warning statement, general:

- should be a general requirement for various warning statements, as in EU directive, with exact wording at discretion of manufacturer;
- prescriptive nature of statements may have space constraints;
- if each country develops its own specific statements, can be a barrier to trade

in highly specialised products, leading to higher costs and delays in supply of products in emergency situations.

Required statements:

- concerned over statement relating to the superiority of breastfeeding;
- this is inappropriate on a label for proximate-modified formula, since the option of breastfeeding is sometimes not available to mothers of infants with metabolic disorders and may undermine advice given by physicians as well as cause confusion amongst parents and carers;
- if told to ignore such statements, parents and carers may also ignore other information on the label.

Hypoallergenic claim:

- suggest that ANZFA adopt the EU definition (see appendix 2 of submission), and prohibit the use of hypoallergenic, except where products meet this;
- should also restrict use of claims as in 44(2)(a)(ii) that the product be used for treating allergies where products do not meet the definition of 'hypoallergenic'.

Energy value for carbohydrate:

- for the sake of harmonisation, recommend that 17 kJ/g be used to calculate the energy content of infant formula in line with both EU directive and other Aust Stds such as R2.

Calculation of protein:

- no provision has been made for the calculation of protein content of formulae based on amino acids. Suggest adding '(c) For amino acids: Protein content = amino acid content x appropriate factor'. SHS uses factor 0.833 but this is dependent on the quantities of individual amino acids added.

Use of minimum levels in NIT:

- concerned about min levels for macronutrients in the tables; fat, protein, minerals and water in a formula powder must add up to 100%, so it is not possible to use averages of one nutrient without reducing another;
- to meet min requirements, manufacturers would have to declare a macronutrient level significantly less than average, to account for variations in manufacture adding up to less than 100%;
- suggest that the level be the average amount of each macronutrient present in the food, rather than an amount that is only a minimum and may not actually relate to that present in the food.

Use of minimum levels in NIT:

- support the use of minimums for vitamins and average amounts for trace elements and electrolytes;
- rationale:
 - for vitamins overage is used, and the amount is so small that it is not displacing other nutrients;
 - trace elements and electrolytes do not degrade on storage, therefore the amount present at manufacture will be the same as at the end of the shelf life;
 - average amount gives the health workers and consumers a better indication of the amount present.

Ratio of zinc:copper:

- current Std requires a min level for Cu and Zn of 14 ug and 120 ug per 100kJ respectively, giving a ratio of 8.75;
- many of our imported products have a ratio just over 10;
- suggest increasing the ration to 12, so that these products can still be imported.

Concern over 'suitable from birth' statement:

- recommend that where a product is labelled as 'for use under medical supervision only', the statement 'suitable from birth' not be required, in order to reduce the amount of warnings and information given on the label (see comments on labelling).

Energy value range:

- EU directive permits energy levels between 2500kJ/L and 3150 kJ/L;
- some imported feeds for malabsorption have energy levels towards the maximum end of the range and would not meet the Aust Std of between 2700 to 3000 kJ/L;
- request harmonisation with the EU.

Amino acid profile:

- the draft Std does not list permitted non-essential amino acids which are required in the amino acid based infant formulas if the profile is to be based on breast milk.

Permission to add MCTs to proximate-modified formulae:

- the Standard for routine formulas specifically excludes addition of MCT oil;
- believe that since the intention is to allow MCT oil to be added to fat modified proximate formulas, the Standard should specifically mention this, to overcome confusion in interpretation.

Sources of protein:

- amino acids should be added to the list of protein sources suitable for use in a proximate-modified formula.

Definition of proximate-modified:

- suggest that more descriptive terms should be allowed to be used to replace the terms in the Std, eg. 'fat modified' should be able to be replaced by 'based on MCT fat' if required; suggest that the descriptions be permitted to be combined eg 'infant formula based on amino acids, glucose polymer and MCT fats'.

Feeding guide:

- current feeding guide has a column headed 'cooled boiled water in ml';
- recommend using the column heading in the current Std 'previously boiled water in ml', since some specialised formulas are very difficult to dissolve in cold water, especially if consumer interprets cooled as refrigerated;

- water temperature can be dealt with in directions (eg. Boil fresh water for 5 mins, cool so that it feels warm to wrist and pour desired amount into sterilised feeding bottle), allowing manufacturers to advise on best method of preparation.

Additional ingredients:

- note that the draft Std permits chromium sulphate and sodium molybdate;
- would like consideration to be given to allowing magnesium acetate, L-lysine and L-glutamate, also the addition of diacetyl tartaric and fatty acid esters of glycerol (E472e) as an emulsifier for amino acid based formula;
- supporting data was provided.

Criteria for setting nutrient levels:

- levels of nutrients reported in breast milk are used as reference and carefully considered, but it is not always appropriate to base levels of nutrients in infant formulas on those in breast milk, due to such factors as superior bioavailability of nutrients in breast milk;
- it is common practice to take established and accepted recommended daily amounts into account and we base these on those published in USA by National Research Council, in EU by Scientific Committee for Foods, in Aust by NHMRC and in UK by Committee on Medical Aspects of Food Policy.

Maximum level of chromium:

- recommend lowering the minimum level of chromium to 0.5ug/100kJ, so that formulae more closely meets intakes recommended in UK and USA;
- chromium is required for normal glucose metabolism, deficiency results in impaired glucose tolerance;
- UK and USA do not have a recommended daily allowance for infants, but USA does set estimates for safe and adequate dietary intakes for infants 0-12mths and 6-12mths;
- SHS recommends that only a minimum level be set;
- Table supplied of comparison of UK and US recommendations on chromium and draft std.

Maxima for vitamins and minerals:

- the approach taken by the EU and USA in setting maximums for very few nutrients should be adopted;
- this means that maximum levels are set only for those nutrients that are known to be harmful if consumed in excess quantities eg. vits A and D, iron, sodium, potassium and chloride;
- although no maxima for all other nutrients would be set, general provisions for the manufacture of safe food would apply, and oblige manufacturers to ensure that the levels that are considered appropriate would not be harmful to health.

Maximum level of manganese:

- recommends a minimum level only for Mn of 15ug/100kJ;
- the UK/EU and USA do not have any recommended daily allowances for infants;
- the US has set estimates for safe and adequate daily intake, but does not set any maximum;
- EU directive on infant formula does not make a rec but permits addition of Mn in same forms as Aust draft Std.;
- current maximum levels in Aust draft Std would require consumption of >2L of formula by an older infant to satisfy the requirement;
- Mn intake studies show consumption of 1100-2500 ug Mn/day by infants <1 year;
- richest sources of Mn are whole grains and cereal products, often excluded in the diets of children with severe protein allergy and malabsorption;
- specialised formulae often a sole or near sole source of nutrition;
- manganese is cited by UK and US RDI background documents as the least toxic of all elements, as absorption is low when excess is consumed;
- Neocate has 30 ug/100 kJ of Mn;
- Table of comparison of US, UK recommendations and draft Std. included.

Maximum level of molybdenum:

- request that the maximum limit be removed and only a minimum level for molybdenum of 0.36 ug/100kJ be applied; if a maximum was necessary then a level of 3 ug/100kg would be acceptable(rationale supporting the use of this maximum supplied);
- note that units in the draft Std should be in ug not mg;
- table of comparison of levels for US and UK and draft Std included;
- request that a review of the range for Mo be done so that permitted quantities reflect the US and UK recommendations for safe and adequate daily intakes;
- even at the maximum level permissible under the draft Std, intakes of Mo from formula would not meet the daily dietary intakes;
- extensive faecal losses may occur in short bowel syndrome and Crohn's Disease. Duhamel(1988) observed Mo deficiency in children with severe digestive pathologies;
- richest sources of Mo are dairy products, usually excluded from the diets of children with severe protein allergy, therefore their formula must contain sufficient Mo

Maximum level of inositol and taurine:

- request an increase in the maximum permitted level for inositol from 5.4 mg/100kJ to 7 mg/100kJ;
- the current maximum does not allow for any overage;
- EU Std allows the addition of inositol, but doesn't stipulate min or max levels;
- USA Std allow 0.4 mg/100kCals

Maximum level of fluoride:

- request that the permitted level of fluoride in lactose hydrolysed and proximate modified formula be increased to half the permitted level in soy based formula eg. 1.0 mg/L fluoride, on the basis that extra ingredients used in formulation of these formulas may contain trace amounts of fluoride

Maximum level of aluminium:

- request that the permitted level of aluminium in lactose hydrolysed and proximate modified formula be increased to half the permitted level in soy based formula eg. 0.5mg/L, on the basis that extra ingredients used in formulation of these formulas may contain trace amounts of aluminium.

Maximum level of thiamin (B1):

- request an increase to the max level from 22 ug to 30 ug/100kJ;
- many infant formulas contain 20 ug/100kJ, which is very close to the maximum permitted.

Permissions for additives:

- requests that the maximum quantity permitted for mono and diglycerides of fat forming fatty acids be in line with the EU Std (4g/L);
- cows milk protein is present in standard infant formula and confers certain emulsifying and stabilising properties;
- protein modified formulas may require the presence of additional emulsifier, since the protein sources have limited inherent emulsifying properties.

Need for regulations to cover special formulae:

- it is important in terms of the availability of specially formulated products, and low cost to customers, that Australian regulations harmonise very closely with England or that an alternative mechanism for evaluation and approval of products for sale be established.

Need for regulations to cover special formulae:

- most SHS products are covered under clause 2(b) of the current Standard;
- some of the conditions requiring these products are very rare - a number of our products are used by one patient only;
- we urgently require an extension to the new Standard for formulae "specifically formulated to satisfy particularly well recognised dietary requirements that are a result of specific physical or physiological condition, disease or disorder" (eg. formulae for clinical conditions involving inborn errors of metabolism), or the establishment of a medical foods standard;
- as the new Standard becomes more restrictive and the labels more descriptive, it becomes more difficult to be able to bring products without modification from England;
- many of the English products require a registration type process in England, and in some markets are classified as therapeutic products. Such processes can become very long and costly;
- the alternative for SHS is to have different products to meet the regulatory

requirements of each country;

- this would be extremely expensive as many products would only be made in extremely; small batches;
- if children are to be able to receive these lifesaving products quickly, and at a reasonable price, it is important that Australian regulations harmonise very closely with those of the UK, or that an alternative mechanism for evaluating and approving the products for sale be established in Australia.

Warning statement for proximate-modified:

- a better wording is: 'use only under strict medical supervision'.

Need for prescribed format for non-warning statements:

- draft Standard requires that proximate-modified formulas list conditions on the label for which the product has been specially formulated; applicable where there are one or two specific conditions which relate to use of the specific formula;
- this is a problem where there a number of conditions for which the product can be used, making the label list very long, and can lead to confusion by consumers who do not recognise the specific condition covered by a more general term eg. malabsorption;
- also unclear is whether the label must only mention the two conditions listed ie. malabsorption and protein allergy, or whether these are just examples;
- when there is a new condition for which a proximate modified product can be used, there may be some consumer confusion if it is not listed on the label;
- unsure as to whether we could recommend the product for a condition which would not be covered by the Australian Standard, to allow the product to be used for that condition.

28. Wyeth

Permission to add nucleotides:

- agrees with recommendation to include nucleotides;
- this is in accordance with EEC recommendations and promotes harmonisation;
- CMP, AMP, GMP, IMP and UMP are currently safely added in several infant formulas;
- although recent literature suggests that the level of IMP in human milk is lower than previously reported, Wyeth believes that inosine 5'-monophosphate should be permitted. It is the known precursor in the biosynthesis of adenosine and guanosine 5'-monophosphate and it would be expected that IMP present in formulas would be converted to GMP and AMP once absorbed into cells.

Fat profile and ratios:

- recommends that:
- arachidonic acid (AA) be permitted at levels of 0.6% and 0.7-0.8% of the fat blend for term and pre-term formulas respectively;
- docosahexaenoic acid (DHA) be permitted at levels of 0.4% and 0.6% of the fat

- blend for term and pre-term formulas respectively;
- eicosapentaenoic acid (EPA) level should not exceed 0.1%, with a DHA/EPA ratio of 3:1;
 - rationale:
 - these levels would be in line with the levels in breast milk (AA 0.4%, with an overage to account for difference in bioavailability) and are the levels that are in the process of being adopted by the EEC;
 - would be consistent with international authoritative expert recommendations;
 - elevating the maximum value for the ratio of linoleic to a-linolenic acid from 10:1 to 15:1, and reducing the a-linolenic minimum level from 2 to 1.2 % would allow for the preparation of safe and efficacious formula;
 - under the draft Standard, in order to achieve the required range for a-linolenic acid and also maintain linoleic acid in the range 8-20%, soy oil could not be used. In order to meet these requirements in all batches, some level of canola or related oil would have to be used. The US do not permit the use of canola oil in products for infants less than one year old;
 - the table of 31(d) (max. linoleic acid 20%; minimum a-linolenic acid 2%) and the text of 31(b) (maximum ratio of linoleic to a-linolenic is 15:1) are incompatible;
 - agree that the upper limit of linoleic acid should be 20%, therefore the upper limit of linolenic acid would have to be 1.3%;
 - the level of AA is too low for pre-term infants;
 - the PUFA requirements for pre-term infants may be higher than for term infants, due to reduced capability for endogenous synthesis;
 - suggest a maximum of 0.7-0.8%, which would also account for manufacturing considerations;
 - the upper limit of AA should be greater than the upper limit of DHA;
 - the upper limits, DHA 0.6% and EPA 0.2% are acceptable as is this 3:1 ratio.

Concern over soy formulae:

- there was a report from NZ in 1994 regarding birds suffering from allegedly toxic effects when fed unprocessed soya products, however there is a tremendous difference between unprocessed or partially processed soya, and soya protein isolate used in infant formulas;
- phytoestrogens are present naturally in many plants and have an oestrogenic activity, but it is 1/1000 to 1/100,00 times weaker than that of human oestrogens;
- phytoestrogens are also present in human milk;
- children in Asia have eaten soya foods for many years without adverse effects, and soya protein isolate infant formulas have been available for over 30 years and have been used safely by millions of babies worldwide;
- soya protein isolate has GRAS status in the US;
- WHO/FAO is unaware of any phytoestrogen hazard related to soy formulae;
- NZ Health has no knowledge of any reputable studies that suggest that soy formulae are detrimental to babies;

- the inclusion of a warning statement on soya-based formula:
- would be considered inappropriate (based upon the current scientific knowledge and epidemiological data showing no adverse effects of soya protein isolate used in infant formulas);
- will lead to further anxiety from the parent;
- may lead to inappropriate use of other preparations for which there may be no suitable/cost-effective alternative.

The Authority should follow the advice of the EEC, Codex, WHO and the US FDA regarding this issue.

Regulatory impact:

- some of the recommendations, such as the prohibition on MCTs and carrageenan and the limits on vitamins and minerals, could lead to product unavailability which would have major public impact;
- a number of the recommendations will mean new formulation development work, stability data generation and changes in labelling which will cost Wyeth Australia in the order of \$118,500, for artwork changes alone;
- the minimum label claim will create major difficulties with regard to removal of trade barriers because the product would still need to be manufactured specifically to meet the Australian requirements and labelling conditions.

Prohibition on medium chain triglycerides:

- this prohibition will lead to major manufacturing difficulties;
- fat blends used by Wyeth-Ayerst International (WAI) and other companies contain innate levels of MCTs;
- a chart (provided) containing the fatty acid analysis of the fat blends used by

WAI shows that the sum of the C8:0 and C10:0 vary between 1.5 and 5.8% of total fatty acids, comparable to reported human milk MCT levels;

- currently no manufacturer can supply a product which can meet this requirement, and a specialised fat blend will need to be developed;
 - this would lead to increased costs and may lead to the unavailability of products;
 - MCTs are present in human breast milk and as such it would be in the best interest of infant nutrition to permit them in human milk substitutes;
- MCTs should be permitted in pre-term formulae because:
- research to date indicates that they are of potential benefit to pre-term infants; and
 - there is a lack of sufficient data to contraindicate their inclusion;
- fatty acids with 12 or fewer C atoms are a valuable source of energy for neonates (Ref supplied), however premature infants may oxidise only 32-64% of MCT to CO₂ (Reference supplied). This finding could explain recent publications in which MCT have not improved energy balance, nitrogen retention or growth in healthy pre-term infants (Refs supplied). However as MCT do not require micellarization by bile salts for absorption, they are readily absorbed from the intestine of neonates (Ref supplied). Thus MCT may be

beneficial for Ca balance (Ref supplied), and may reduce the occurrence of hypoglycaemia by increasing glucose production in low birthweight newborns (Refs supplied);

- there is a considerable body of research literature which supports the potential benefit of MCT for pre term infants, while raising some concerns over their excessive intake. To this end the ESPGAN Committee on Nutrition recommends that MCT, if used in formulas for low birthweight infants, should not exceed 40% of total fat. (Ref supplied). Another researcher has stated that a rational upper limit for MCT content has yet to be established (Ref supplied);
- the ideal MCT level for pre-term formulae should have an optimal benefit/risk ratio and allow for adequate concentration of long chain and essential fatty acids to meet the needs of the infant.

Lack of harmonisation:

- areas of non-conformity with Codex, ESPGAN and the EEC Directive include:
- the ratio of linoleic to α -linolenic acid;
- the use of minimum label claims;
- the prohibition of carrageenan;
- the upper and lower limits set for vitamins, minerals and electrolytes.

Definition of carbohydrate-modified:

- the term is not used in the text of this Standard, therefore a definition may not be appropriate;
- the term is used in Standard A8 - Artificial Sweetening Substances;
- would be more appropriate to replace with a term such as "lactose-modified".

Definitions of partially and extensively hydrolysed protein:

- the provision is meaningless unless the sensitivity of the analytical method is specified, because the various methods vary greatly in sensitivity;
- hydrolysis techniques cannot produce a product which is absolutely free of very small amounts of higher MWt peptides;
- suggest that this definition be amended to state that less than one percent of the protein be less than 500 Daltons in MW.

Definition of fat-modified:

- the definition is unnecessary as the term does not appear to be used in the Standard.

Definition of follow-on infant formula:

- a product could be classified as an infant formula or follow-on infant formula, but it cannot be both;
- the common theme in the definition of infant formula (WHO, EC and UK) is that an infant formula can be used as the sole source of nutrition for the young infant;
- the EEC, ESPGAN and Codex definitions of follow-on/follow-up formula recognise that these are not the sole source of nutrition;
- recommend that in Standard R7:

- the term “follow-on formula” be used instead of “follow-on infant formula” ;
- the word “principle” be replaced with a phrase such as “substantial part of food” (as the diet of an infant aged six months and over is made up of various food substances besides infant formula);
- the definition should read “follow on formula means human milk substitute represented as being a substantial part of food for healthy infants aged 6 months and over”.

Definition of medium chain triglycerides:

- should be expanded to indicate that these compounds may be synthetically and naturally derived compounds.

Problems with subclause 2(1) - refs. to a human milk substitute:

- it is not clear what forms of a human milk substitute it is actually referring to;
- a better phrase would be:
- “A reference to a human milk substitute is a reference to (i) a concentrated liquid form of the human milk substitute (ii) the human milk substitute when reconstituted according to directions, and (iii) a ready-to-feed form of a human milk substitute.”

Lead-in time:

- one year is insufficient time to implement the changes because formulation development work and stability studies would need to be generated prior to placing the product on the market.

Energy value for carbohydrate:

- believe that the conversion factor of 16 kJ/g is inappropriate for carbohydrate and that the factor of 17 kJ/g should continue to be permitted;
- the factor of 16 kJ/g for carbohydrate was proposed by Southgate and Durin (1970) but is applicable to mixed diets only and therefore not appropriate for infants whose sole source of nutrition is infant formula.

Prohibition on gluten:

- a requirement that an ingredient or impurity be “not detectable” is problematic because a component that is not detectable today may become detectable tomorrow;
- the phrase “must not contain any detectable gluten” should be replaced by a statement such as “must be gluten free as defined by Section 32.991.19 of the Second Supplement (1991) to the AOAC, 15th Edition (1990).”;
- recommend that the actual method for testing be stated rather than a reference to the Standard which states the method, as it makes the Standard more complete and prevents confusion that may be caused by cross referencing;
- method validation should be provided by ANZFA, to support the application of the method to both powder and liquid infant formula, as the ELISA based method that is prescribed for the detection of gluten is one that cannot be easily performed by most laboratories.

Maximum level of aluminium:

- various methods exist that may produce differing results;
- suggest that a method of testing, which has been validated, be provided so as to ensure consistency and reproducibility of results between various manufacturers and those of the ANZFA.

Maximum level of fluoride:

- fluoride is difficult to analyse and different testing methods may produce different results;
- the TAVES or the AOAC method should be the prescribed method for testing.

Print size:

- recommend that upper and lower case lettering be permitted to be used for the warning statements, because care givers find it difficult to read the upper case lettering.

Statement on preparation of bottles:

- recommend that in place of the statement "Prepare only one bottle at a time" there should be the following: "Prepared formula should be refrigerated and used within 24 hours";
- rationale:
 - the vast majority of Australian homes have refrigerators. It is not logical to insist on the preparation of only one bottle at a time, when a day's supply can easily be prepared at a time provided that the prepared product is refrigerated;
 - the final draft of the NH&MRC Infant Nutrition Panel Guidelines for Health Workers states, "Store all made up formula in the centre back of the fridge where it is coldest, not in the door where it is warmer," and "Put formula straight back into the refrigerator as soon as it is made." The product label instructions should be consistent with the instructions given by health workers.

Use of minimum levels in NIT:

- the Authority is asked to reconsider their decision to retain the minimum label claim system for the following reasons:
 - the average label claim (ALC) more accurately depicts the actual composition of the product during its shelf life because it is determined by calculating the average of the readings taken at various intervals during the product's shelf life;
 - both the EC and Codex require that average label claims be used for infant formula;
 - Taiwan recently adopted into regulation a refined version of the ALC system. It allows for a defined degree of variance between the label claim declaration and laboratory test values (eg for vitamins A, D, E and K, 80 to 180% variance is permitted between the analysis result and the label claim);
 - as a signatory of GATT, Australia must provide a scientific justification for labelling requirements which are different from those in the Codex Standard'
 - there is a trend towards the worldwide use of average label claims on infant formula products.

Ratio of linoleic to alpha linolenic acid:

- the 10:1 ratio is very difficult to produce in all batches of infant formula;
- the EC and ESPGAN permit a range of 5:1 to 15:1;
- there appears to be no scientific data that would suggest that a ratio of 10:1 would produce a more desirable outcome in very long chain fatty acid status than 15:1;
- agree with the requirement for a range of 5:1 to 15:1 in pre-term formulae.

Requirement for 80% carbohydrate to be lactose:

- this provision does not take into account soy formulae, which are lactose free;
 - it should therefore be expanded to exclude soy formulae;
- recommend that this provision be worded as it is in the current Standard, namely that infant formula "must not contain more than 20 mg/100 kJ of carbohydrate, other than lactose";
- rationale:
 - the expression of the permitted lactose content as a percentage rather than as mg/100 kJ is confusing, as the expression of the permitted levels of all other nutrients is per 100 KJ.

Ratio of zinc:copper:

- the arbitrary ratio of 10:1 is too low; would prefer 12:1 or 15:1, which have been shown by experience to be suitable;
- in some Wyeth formulae the label claim for Zn is 5 mg/L and for Cu 470 ug/L, giving a Zn/Cu ratio of 10.6, close to but outside the proposed limit;
- it should be noted that other authoritative and regulatory guidelines do not specify ratio limits for Zn and Cu.

Ratio of alpha tocopherol equivalents to PUFA:

- support the level of 0.9 mg d-a-tocopherol equivalents per gram PUFA.

Minor amendments:

- for 33(1)(a) and 42(1)(a) the word "electrolyte" needs to be added as follows: "the added vitamin or mineral or electrolyte is in a form specified in column 2";
- in schedule 3, change "selenomethionine" to "seleno methionine";
- in Schedule 1, the amino acids should be specified as "L-amino acids".

Permitted forms of selenium:

- sodium selenate should be permitted because it is already used in some formulae.

Levels of selenium:

- minimum level, 0.42 ug/100 kJ, is too low;
- Wyeth formulas, especially soy, tend to be lower than this level;
- there is no clearly defined selenium deficiency in formula-fed infants and therefore requirements have not been established;
- strongly recommend that either no selenium requirement be placed on infant

formula, or that selenium be permitted as an optional ingredient with an upper limit only;

- if the provision were to come into effect in its present form, WAI would need to initiate a major project to add Se to our formulae, including new formulation development and stability studies.

Feeding guide:

- it is not clear if these are guides or if the format for the label must be identical to what appears in Schedule 5;

- ideally the first column would include, "Average weight, Average age".

However if only one factor is to be used, weight is preferable, as all nutrient requirements are on a per kg basis;

- in Table 5 in Schedule 5, for pre-term formula, the 200 g increments seem to be unnecessarily precise. Larger increments would be more sensible, eg. less than 1500-2000, 2000-2500 etc.

Maxima for vitamins and minerals:

- under the proposed revised R7, with its new maxima and tighter ranges, Wyeth would be required to reformulate all products specifically for Australia in order to produce a product that meets the requirements of this standard;

- recommend that if the Authority wishes to tighten nutrient ranges and include an upper limit for nutrients that the nutrient declaration be changed to an average claim.

Maximum level of vitamin D:

- there is none specified by Codex or ESPGAN (for pre-term formula).

Maximum level of phosphorus:

- there is none specified by Codex or ESPGAN (for pre-term formula).

Maximum level of magnesium:

- there is none specified by Codex or ESPGAN (for pre-term formula).

Maximum level of iron:

- there is none specified by Codex or ESPGAN (for pre-term formula).

Maximum level of manganese:

- there is none specified by Codex or ESPGAN (for pre-term formula)

Maximum level of choline:

- there is no maximum specified by Codex or ESPGAN (for pre-term formula);

- they also do not specify a minimum level which must be present before an entry in the NIT can be made.

Maximum level of inositol and taurine:

- there is no maximum for inositol specified by Codex or ESPGAN (for pre-term formula);

- they also do not specify a minimum level of inositol which must be present before an entry in the NIT can be made.

Maximum level of B vitamins:

- there is no maximum specified for any of the B vitamins by Codex or ESPGAN (for pre-term formula).

Ratio of zinc:copper:

- there is none specified by Codex or ESPGAN (for pre-term formula).

Maximum level of chlorine:

- there is none specified by Codex or ESPGAN (for pre-term formula).

Methods of analysis:

- recommend that methods are supplied to determine the levels of the nutrients;
- very different results can be obtained depending on the method used, eg. with vitamin B6 it depends on whether a chemical or microbiological method is used.

Definition of pre-term human milk substitute:

- recommend that this be widened to include low birthweight infants;
- rationale:
- our infant formula is intended for use by both LBW and pre-term infants;
- LBW is a more inclusive category, as virtually all pre-term infants are LBW, but LBW infants are either 'pre-term' or 'intrauterine growth retarded for gestational age'.

Prohibition on carrageenan:

- many low birthweight and ready-to-feed products on the Australian market use carrageenan as an emulsifier;
- this prohibition will lead to major manufacturing difficulties, as there is a significant lead-in time in formulation development, clinical validation, stability and manufacture of a carrageenan-free product;
- carrageenan is permitted by the proposed revised Codex Standard 72-1981. It is also permitted as an emulsifier in foods under Standard A6;
- the EEC has not prohibited carrageenan recommend that:
- the Food Authority consult with the US FDA and the EC before prohibiting the addition of carrageenan - that way the Australian Infant Formula Standard will be more closely harmonised with international scientific opinion;
- as carrageenan is permitted in Standard A6 of the Food Standards Code, it also be permitted in Standard R7 (this would promote harmonisation of the FSC);
- a provision similar to that in the proposed revised Codex Standard 72-1981, be included in R7, namely:
- carrageenan maximum level in 100 mL of the ready-to-drink product 0.03 g in regular, milk and soy-based liquid infant formula only. 0.1 g in hydrolysed protein and/or amino acid-based liquid infant formulae only.

Need for regulations to cover special formulae:

- under the draft Standard, not all infant formulae that are currently available under the existing clause 2(b) are covered;
- recommend that the conditions of clause 2(b) be maintained, so as to ensure the supply of specialised infant formula for infants who require it;
- it is clear that clause 2(b) covers a greater variety of physical and physiological conditions than are covered under the proximate-modified definition;
- recommend that the conditions for which a proximate-modified formula is suitable be expanded, to maintain the provision for these specialised formulae in Australia.

29. Consulchem

Microbiological requirements:

- suggest that the absence of *Clostridium perfringens* and *Listeria monocytogenes* should be part of the microbiological requirements for Infant Formula, as is the case in the current NZ Code;
- Clostridial species are robust organisms that can readily survive heat treatments;
- *Listeria monocytogenes* is an environmental organism with a wide distribution - marine and freshwater fish, vegetables, meats and a large variety of environmental niches; no longer regarded as limited to a dairy problem;
- both pathogens affect the immuno-compromised, including the very young, more readily than the population at large;
- in recent tests of 'from birth' and 'follow-on' formulae, Clostridia were found, though not the *perfringens* variety. This demonstrated that the genus can survive the stringent manufacturing regime followed for these products;
- had the pathogenic Clostridial species been present in significant numbers in the raw material, these too may have survived the processing treatment.