ATTACHMENT 7

PROPOSAL P93 – REVIEW OF INFANT FORMULA

SUMMARY OF SUBMISSIONS TO PRELIMINARY INQUIRY (MAY 1999)

List of Submitters

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

Abbott Australasia Pty Ltd
Abbott Laboratories (NZ) Ltd
Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)
Attwood, Elaine
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria)
Bowman, Diane
Bristol-Myers Squibb Australia Pty Ltd
Compston, Fiona
Consulchem Pty Ltd
Consumer Food Network of the Consumers Federation of Australia
Dairy Goat Co-operative (NZ) Ltd
Daniels, Dr Lynne, Flinders Medical Centre, Centre for Perinatal Medicine
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition
Dunstone, Mark and Smith, Julie
Embassy of the United States of America, Office of the Agricultural Counselor
Food Technology Association of Western Australia Inc.
Food Technology Association of Victoria Inc
Freyer, A G
Gastric Reflux Association for Support of Parents/Babies
Gibson, Robert A, Director, Child Nutrition Research Centre and Makrides, Maria, Research Dietitian and NHMRC Fellow
Glare, Barbara
Guy, Camille
Home Economics Institute of Australia Inc
InforMed Systems Ltd
Institute of Environmental Science and Research Ltd, New Zealand
International Baby Food Action Network (IBFAN)
International Formula Council (IFC)
James, R F
James, Valerie
Kamerman, Marg
Killalea, Dr Sheila and Mc Neil, Dr John, Department of Epidemiology and Preventive Medicine, Monash University
Kingett Mitchell and Associates Ltd
La Leche League NZ for Breastfeeding Supports and Information
La Roche, Patricia
Ministry of Agriculture, Fisheries and Food (MAFF), UK
Marsh, Raeura

McIntyre, Gail
McVeagh, Patricia, Consultant Paediatrician
Minchin, Maureen, IBCLC
National Council of Women of New Zealand
Nestlé Australia Ltd
New Zealand Dairy Board
New Zealand Ministry of Health
Nursing Mothers' Association of Australia
NZ Dairy Marketing and Customer Services
NZ Infant Formula Marketers' Association
Royal Australasian College of Physicians - Division of Paediatrics
Royal New Zealand Plunket Society Inc
Safetywize Consultants
Simmer, Karen, Neonatologist and Associate Professor
Soy Information Network
Toth, Peter
Toth, Susan
Tudehope, Dr David, Director Division of Neonatology, Mater Hospital
Parnell, W, University of Otago, Human Nutrition Department
Victorian Food Safety Council Food Standards Sub-Committee
Western Australian Food Advisory Committee
Wyeth Australia Pty Ltd

General Comments

Submitter	Comments
NZ Infant Formula Marketers' Association	- recognises that breast-feeding during the first four to six months of life is the best way to ensure good health and development of babies - where the mother does not breast-feed, or when breast-milk alone is insufficient to meet all the baby's nutritional needs, access to safe alternative foods is essential - health authorities and infant food manufacturers have responsibility to provide balanced, factual and objective information about benefits of breast-feeding and proper use of infant formula and appropriate weaning foods when needed - states infant formula cannot replicate all the qualities of breast-milk - states it is important to note that many substitutes for breast milk are totally unsuitable and often dangerous (e.g. raw milk, gruels made from rice, cassava etc.) - committed to the development and implementation of appropriate infant nutrition policies based on the principles and aims of the WHO Code of Marketing of Breast-Milk Substitutes - proposal lacks balance: there is no commentary on the contra-indications of breast-feeding, after an infant reaches 6 months of age, and the benefits of complementary feeding ignored - findings concentrate on well-meaning desire for breast-feeding to be maintained during the first 12 months; totally silent on needs of 40% mothers who are not breastfeeding after 6 months - concerned about the negative impact the proposed standard may have on some members of the NZ health sector, which would impact on the NZ Ministry of Health's ability to effectively monitor the NZ Interpretation of the WHO Code
Marg Kamerman	- believes the dangers of feeding babies with artificial milk are not publicised enough - parents are not given enough information to make an informed choice regarding whether to breast-feed or not - suggests infant formula be available via prescription only - suggests WHO Code on the Marketing of Breast Milk Substitutes written into standard on infant formula - suggests women who choose not to breast-feed tend to have less education, and do not seek relevant information before making a choice - believes multi-national companies selling infant formula have huge influence and "can apply pressure and bend the rules"
Karen Simmer, Neonatologist and Associate Professor	- overall, thinks report is sound - issues a plea for ANZFA not to weaken standards further in response to pressure from industry
InforMed Systems Ltd	- concerned that standard is extremely prescriptive, significantly more so than current Codex draft revision - serious danger that standard will become outdated and require amendment
International Formula Council	- pleased to note several proposed changes to earlier drafts, which were overly restrictive and not supported by the scientific literature, were not adopted

Dairy Goat Co-Operative (NZ) Ltd	- goat milk follow-on formula will need to be significantly reformulated to comply -accept the rationale for the majority of the formulation modifications - seek a lead-in time of two years instead of the proposed 12 months to allow for product reformulation, trial production(s), and stability trials.
Consumer Food Network of the Consumers Federation of Australia	- standard needs to be considered in the light of overwhelming evidence that formula feeding of infants poses a serious risk to the health of both the infants and their mothers - infants who are formula fed are at significantly greater risk that infants who are breast fed of suffering many health conditions including infectious diseases, hypernatremic dehydration, neonatal hypocalcaemic tetany and cardiopulmonary disturbances in the neonatal period, sudden infant death syndrome, allergies and chronic diseases in later life. - estimated in USA for every 1000 babies, 4 die because they are fed artificial formula (references provided) - it is likely that similar death rates from the use formula occur in Australia, which means that hundreds of babies could be dying each year as a result of formula feeding - mothers who artificially feed rather than breast-feed their infants are at increased risk of contracting pre-menopausal breast cancer, osteoporosis, cervical cancer and ovarian cancer - proposal gives approval to a number of potentially unsafe ingredients in infant formula - proposal weakens current labelling provisions - would continue to allow unethical promotion of infant formula - does not provide sufficient warning to mothers of the deleterious effects of formula feeding on the health of both infants and mothers - concerned to read in proposal that ingredients have been added to infant formula "without rigorous, objective safety assessments, which are required for other food ingredients" - urges that no untested ingredients be permitted in infant formula - where uncertainty, or varying views, on safety of an ingredient, that it not be allowed to be included in infant formula - rigorous requirements for assessing the purity of ingredients be included in the standard
Elaine Attwood	- supports Consumer Food Network submission
Victorian Food Safety Council Food Standards Sub-Committee	- supports option 2. - there are no specific provision for MRLs for pesticide residues in infant formula - only source of assurance is from Total Dietary Surveys which are limited in the range of samples analysed - the potential for endocrine disruption from pesticide residues should be assessed before a decision about pesticide MRLs in infant formula is finalised

Nestlé Australia Ltd	- has always stated that breast-feeding is the best form of nutrition for babies, however it also believes (like the WHO) that there is a place for infant formula as the best alternative for those babies who cannot be breast-fed - supports AFGC submission - supports review, particularly where it accounts for updating the standard with respect to harmonising internationally and current scientific knowledge - extremely concerned that some current infant formula products could become illegal products under the proposed standard - states ANZFA has chosen not to harmonise with international regulations in some areas and have not properly justified this against the objectives in section 10 of the ANZFA Act - this will have a major cost impact on Nestlé due to the necessity for monitoring the raw materials in use, more extensive testing of products, increased inventory to allow for the appropriate testing regime, and also the cost of clinical trials - main areas of concern: * any formula that is manufactured to comply with an international regulation would be illegal within Australia or New Zealand * products that are manufactured as speciality products in an overseas manufacturing facility for global distribution would not comply with this draft standard * specific regulation of pre-term formula will create difficulties for current products. * some proposed labelling statements are not consistent with other legislation
Patricia McVeagh, Consultant Paediatrician	- as there is no medical indication for goat's milk, safe limits should not be adapted to accommodate goat milk based infant formula
Barbara Glare	- concerned that draft standard represents a weakening of the standards, and it is vital that they be strengthened
Food Technology Association of Western Australia Inc	- prefers option 2: to regulate using the proposed revised standard and codes of practice
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria)	- widely accepted infant feeding practices have, over several generations, resulted in a common perception that artificial formula is standard or normal - strongly recommend that any statement of standards for infant formula made by ANZFA be consistent with the current standards which are recognised both in Australia and globally (WHO CoP, the Maternal and Infant Care Services Standard)
Fiona Compston	- opposes draft standard, as it appears to be a weakening of the old standard, which reflects industry objections to earlier proposals - breast milk is known to help reduce the risk of a range of cancers in both child and mother, it helps reduce gastro and ear infections in children, it helps foster a more self confident child, it is more environmentally friendly - breast milk can ultimately save the community millions of dollars in health costs each year - there are no requirements presently to warn consumers of the adverse health consequences of feeding babies formula - provided figures from the US illustrating the costs associated with formula feeding
Food Technology Association of Victoria Inc	- agree with regulatory option 2

International Baby Food Action Network (IBFAN)	- it is premature to finalise a standard on infant formula at this time because Codex is currently revising their standard on infant formula, and Codex is also drafting Working Principles of Risk Analysis
Embassy of the United States of America, Office of the Agricultural Counselor	- requests that the proposal be held in draft form for another round of comment, which would allow for more detailed and constructive comment - have not reviewed the risk assessment or other relevant data and information underpinning this proposal - the proposed standard has various inconsistencies with standards in other counties, that would likely result in unnecessary trade difficulties
Home Economics Institute of Australia Inc.	- expressed concern at the proposed inclusion of a very broad range of unfamiliar ingredients - urge that a precautionary approach be adopted and that substances that have no confirmed benefit not be permitted until further more specific information is provided by industry
Abbott Australasia Pty Ltd	- appreciates the amendments made to the standard to bring the document in line with international standards, namely Codex and European TSMP regulations - however, still many areas in which the proposed standard remains too restrictive - proposed standard would not enable Abbott to introduce any of its current infant formulas which are available overseas - it would remove from the market those current Abbott products which are imported fully finished into Aust and sold in very small volumes
National Council of Women New Zealand	- believes in using prescriptive regulations. However, advise that care must be taken not to hinder any future development of infant formulas.
Bristol Myers Squibb Australia Pty Ltd	-strongly disagree with many points arising from the draft. -products would need to be removed from the market and reformulation would be required if the standard were adopted. -the draft is more prescriptive and lengthy- some of the requirements are not required elsewhere in the world. -implies that the present standard does not result in products that provide adequate nutrition for growth and development of the infant. - a food standard should include prescriptive conditions only where these are shown to be necessary, such as to ensure appropriate nutrient levels. - the inclusion of sections for pre-term formula, infant formula for metabolic and immunological conditions, aluminium, fluoride and infant formula based upon protein substitutes do not reflect the Codex or EC standards for infant formula. - to require reformulation of a product - evidence must be supported e.g. that infants are actually suffering harm at present or are in a position of real harm. - the standard for infant formula is not the appropriate place to include specifications for any particular ingredient. It purity specifications are required, they should be included in the food additives standards and be cross referenced.

Nursing Mothers' Association of Australia	- the safety, or otherwise, of formula ingredients, both proposed and current, needs to be established. - regulatory impact analysis needs to consider the effect of increased breastfeeding rates. - if regulatory standards cannot provide sufficient protection then changes to the regulatory system should be made in order that they do so. - international standards should not be used as justification for any practices in the composition, products, distribution or sale of formula that can adversely affect the health and safety of Australian infants. - submission contains conference papers from the Nursing Mothers' Association Australia's Conference (October 23-25 1997).
Mark Dunstone and Julie Smith	- the objectives set out in the issues paper for the proposed standard are not the same as those required by the legislation. The statutory objectives relating to promotion of trade and commerce do NOT provide any latitude to ANZFA to pursue the objective of "not unnecessarily hindering innovation in the infant formula industry". - promotion trade and commerce do not, even by implication, include innovation. As infants consume a fixed quantity of milk, innovation will not increase trade or commerce, and therefore innovation would not promote trade or commerce. - innovation amounts to uncontrolled experimentation on infants without informed consent. It may risk infant health. The proposed Standard is contrary to legislation because the proposed standard's requirements on "novel ingredients", "innovation" and "soy" milk place a higher priority on industry interests than on minimising adverse public health and safety risks. - the statement on page 4 - "The Preliminary Inquiry concludes that a food standard for infant formulas which protects the health and safety of infants who are routinely fed substitutes for human milk is necessary"- does not aim to discourage the routine (or even ad-hoc) feeding of infants with artificial formula. - there is evidence that infants fed artificial formula or animal milk suffer increased risks of mortality and morbidity, including in developed countries such as Australia. These adverse outcomes are from improper use of formula (i.e. mixing, using unclean water) but also when formula is used as directed.
Royal New Zealand Plunket Society Inc	- supports a revision to ensure health and safety of formula fed infants and to overcome barriers to trade. -are concerned with the prescriptive approach proposed. State that the proposed approach would hinder the addition, revision or deletion of individual ingredients necessary to reflect current scientific knowledge. - suggest an approach where manufacturers must conform with a NZ Standard which is consistent with Codex requirements e.g. in terms of permitted quantities, ingredients, safety, special needs etc. -believe self-regulation by industry is important. -compliance with the standard should be mandatory because of the importance of infant formula as a principal source of nourishment.

Parnell, W, Department of Human Nutrition, University of Otago	-it is never possible to harmonise with several international standards which are themselves inconsistent. Suggests that ANZFA follow Codex (or USA or European standards). - does not believe that the prescriptive standards will reduce costs to government. --questioned whether any infant formula manufacturers, in a highly competitive environment, are marketing an unsatisfactory product, i.e. a product with an inappropriate nutrient profile or a product not microbiologically safe or with undesirable contaminant levels?
Maureen Minchin. IBCLC	-expressed a number of serious concerns in relation to the consultation process undertaken by ANZFA (see submission). - this Proposal is to protect infant health. Therefore it needs to be far more stringent scientifically. -the current proposal cannot ensure the health and safety is protected and that carers have adequate information about infant formula to enable them to make informed choices in feeding their infant. - believe that infants that are not breastfed are at greater risk from a wider range of diseases and disorders, in infancy and adulthood. -states that ANZFA has produced a standard that; * creates a basic assumption of "safe until proven unsafe" as the basis for ingredients. The more conservative approach would be to require proof of safety, and so ensure that industry funds dedicated long-term studies that limit the risk of harm, from whole populations worldwide to study participants; * creates no additional costs for greater quality control or as saving to protect infant health(not even $1300 to reduce aluminium risks) for an industry which spends billions on advertising a product with an enormous profit margin; * allows every formula currently on the market to be left there until it is re-formulated at industry's convenience. * allows any formula made anywhere in the world by the major companies to be imported into Australia under threat of WHO sanctions, by "accommodating all known market levels". * allows industry to keep publishing misleading information on labels rather than including the detailed information that would assist in educating about infant formula risk, and put s responsibility for such education on to health professionals despite the evidence that almost all health workers are never adequately educated about such risks; * sets in place no provision for regular assays of product or other monitoring of industry's compliance with the new standard. - suggests a number of changes to strengthen the standard (see suggested changes under separate issues in summary of submissions).
Wyeth Australia Pty Ltd	- do not believe that ANZFA's objectives have been adhered to in the development of the standard because: * stipulating nutritional composition is overly prescriptive; * a risk based assessment is not used to determine the prescribed composition of infant formula; * many levels of nutrients are not harmonised with international standards' * information is confusing and not easily disseminated to carers. - any change to the standard needs to be risk based. - suggest urgent discussions with industry are required. - the current draft of the standard may contravene the WTO requirements to allow products that are safe.

La Leche League NZ for Breastfeeding Supports and Information	- urges including the strongest possible protection for breastfeeding when considering a standard for infant formula
MAFF UK	- EU Directive sets a maximum limit of 0.01 mg/kg for individual pesticides in infant formula and follow-on formula, and prohibits the use of more toxic pesticides in the agricultural products intended for their manufacture

Issue: Composition of Infant Formulae

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

Issue: Use of Novel Ingredients In Infant Formula

Submitter	Comments
Nestle Australia Ltd	- does not agree with proposal - suggests ANZFA also needs to accept a history of use overseas - if Aust/NZ is retained, then ANZFA needs to ensure that there is a minimal approval time for a novel ingredient, which should be a maximum of 3 months; expect ANZFA to accept data sourced from overseas as part of an application
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria) and Fiona Compston	- proposed acceptance of untested 'novel' ingredients, including LCPUFAs, is too lax - any artificial formula sold with 'novel ingredients' should carry large warning messages that the ingredient is experimental, and the appropriate consent arrangements be put in place for its use, consistent with other medical clinical trials in humans
Mark Dunstone and Julie Smith	- experimentation and innovation should not be allowed by the Standard - unlike older children and adults, babies are not normally exposed to other foods - allowing the inclusion of "novel ingredients" on the basis of a history of safe consumption of similar food by adults or older children is unsatisfactory - such experiments should be conducted under appropriate, designed, approved and supervised clinical trials with the informed consent of the parties involved
Bristol Myers Squibb Australia Pty Ltd	- if a substance is classed as a food then it is suitable for use in a food. If this food is widely used elsewhere in the world, in the same or similar applications, there needs to be a strong argument put forward why it cannot be used in Australia - as we are signatories to world trade agreements and trade in a global marketplace, Australia cannot arbitrarily impose isolationist restrictions.

Wyeth Australia Pty Ltd	- novel nutrients are often identified initially as components of breast milk and then investigated for clinical benefit through clinical appraisal for addition to infant formula. The safety of such nutrients should not be unfairly constrained by the safety standards that apply for novel food additives - novel nutrients are added for nutritional benefit, therefore, a 100 or even 10 fold no-observed effect level (NOEL) cannot be applied to nutrients in assessing novel safety - safety assessments of novel nutrients must be made at human milk levels (with average for manufacturing)
Winsome Parnell, Department of Human Nutrition, University of Otago	- would not discount retaining a variation of Option 1 i.e. retaining a general recommendation such as Regulation 242 in the New Zealand Food Regulations 1984, with any necessary generic prohibitions such as on novel ingredients, not safety tested.

Issue: Lactic Acid Cultures

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

Issue: Addition of Nucleotides to Infant Formula

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

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

Issue: Cadmium and Lead

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

Issue: Lactose Free

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

Issue: Protein

Submitter	Comments
Nestlé Australia Ltd	- protein level set at 0.45 mg/100 kJ. Codex level is 0.43 mg/100 kJ - Codex level should be adopted to ensure a harmonised approach - declaration of source of protein appears to be overly prescriptive, particularly when manufacturers include the ingredients in the ingredient statement (discusses in detail, cow's milk vs. other sources, Fair Trading laws, Proposal P156 Naming of Foods, etc.) - objects to placing maximum levels for some nutrients even where the nutrient is not added (natural components of milk-based products contain choline and carnitine) - seasonal variation would render some Nestlé products illegal at certain times each year (graphs included to support claim), including products containing whey powder - it is impossible to formulate within these levels (detail on process included)
Infant Formula Council	- concerned that caline content in the reference amino acid composition of human milk is much higher than the reference cited by the EU (4.5g/100 g of protein) - suggest that 4.5g/100 g protein is more accurate
Dairy Goat Co-operative (NZ) Ltd	- goats milk infant formula and follow-on formula will be required to be supplemented with at least two amino acids (tryptophan and cystine) - levels stated are not consistent with EU directive in that the concentrations of methionine and cystine can not be added together in the proposal. Adoption of EC directive protein quality requirements would mean there would be no requirement to add cystine to these products - strongly opposed to amino acid fortification of goat milk infant formula and follow-on products - no evidence to suggest that protein quality of these products is inadequate - concerned about additional risks that can be associated with amino acid fortification (enclosed information on L-tryptophan) - suggests that protein quality requirements be included in the final standard, but that products that use unmodified cow or goat milk protein be excluded from meeting these requirements - if amino acid fortification is required, a minimum lead-in time of two years is sought (three being preferable), as sources need to be found, suitable modes of addition developed, impact on product flavour and stability investigated (in this context, shelf-life of these products is currently three years)

Maureen Minchin IBCLC	- Questioned whether ANZFA was aware of the research that indicates that the standard but excessive protein content of infant formula and its unphysiological amino acid patterns is linked with brain deficits. - indicated that there is evidence that autism is related to casein intolerance. - expressed concern about parents giving their infants (under 6 months of age) follow on formula (which is often cheaper), particularly when the protein level is almost double that meant for this age group. Questions whether anyone will monitor RSLs of infant formula independently or whether industry will do this. - ANZFA needs an intensive education campaign addressing the changes to the infant formula standard and particularly pre-term formula. - believes that ANZFA has legal duty of care to state on the can: "This product contains a level of protein that can be dangerous to infant bowel, kidney and brain. Medical monitoring of infants using this product is essential".

Issue: Levels of Total Fat in Infant Formula

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

Issue: Addition of Long Chain Polyunsaturated Fatty Acids to Infant Formula

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

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

Bristol-Myers Squibb Australia Pty Ltd	- acknowledge the addition of VLCPUFAs is contentious. BM indicate that it is the actual levels of two fatty acids, docosahexaenoic acid (DHA, 22:6 n-3) and arachidonic acid (AA 20:4 n-6) and the ratios of one to another - research indicates that dietary and geographical factors influence the levels and ratios of DHA to AA in human milk. Codex has not set a ratio level. It would be premature to set a fixed ratio on present evidence as they can be difficult to change at a later date - recommends that ANZFA include levels and ratios but that these are not prescribed in the standard.
Robert Gibson Director , Child Research Centre Maria Makrides Research Dietitian & NHMRC Fellow	- indicated there is no scientific basis for having one aspect of option 3 as the preferred option - indicated that the ratio of n-6:n-3 LCPUFAs in the breast milk of Australian and American mothers is currently about 2:1 but this is entirely a phenomenon of the current diet in these two countries. Examples given of how the ratio varies in different countries according to the diet of the mothers. - recommend that the Authority have the maximum levels of LCPUFA in formulas as shown in Option 3 (n-6 LCPUFA - max 2%; 20: 4n-6 - max 1%; n-3 LCPUFA - max 1%) but NO ratio IMPLIED for n-6:n-3 - oils containing n-3 LCPUFA should have a ratio of DHA to eicosapentaenoic acid (EPA) of at least 2 so that high EPA oils such as Maxepa are not used in infant formula - If the committee had reservations about this it could add the expression: "If n-3 LCPUFA are added to infant formula, n-6 PUFA should be added in such a way as to prevent a decline in the arachidonic acid (AA) status of the infant (as measured by plasma total fatty acid) below that of infant fed unsupplemented formula". In that way, manufacturers have the option of adding either AA itself or a precursor of AA in order to maintain plasma AA levels in the infant. - table to clause 30 is accepted without qualification - the suggestion that fats in formula for pre-term infants must comply with the fats in formula for term infants is not based on scientific evidence. There is little known about the fat requirement for term infants. EG the accretion rate of DHA of an infant in utero is such that the fats in the formula should contain at least 1% DHA and not the 0.25% in current pre-term formula. Therefore, it is incongruous to be basing the fat composition of formula for pre-term infants on the fats that are in breast milk of mothers who gave birth to term infants. It is clear that this model was totally inadequate for dietary protein, calcium, iron and many other nutrients for pre-term infants, and there just isn't the data available to be making these recommendations for the fats for pre-term infant.
Maureen Minchin IBCLC	- option 3 is the only option consistent with ANZFA's primary duty for care of infant health - ANZFA needs to work with APMAIF to restrict industry claims being made to suggest that LCPUFAs alone account for better cognitive development. There is no evidence to date of better cognitive development in term bottle-fed infants.

Issue: Use of Medium Chain Triglycerides in Infant Formula

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

Robert A Gibson Director, Child Nutrition Research Centre Maria Makrides Research Dietitian and NHMRC Fellow	- recommended that MCTs be permitted to be added to all formulas - up to 20%. Could see no scientific reason for preventing their use. commented that there are about 15% MCT in breast milk fats (albeit of more complex structure than coconut oil). - acknowledged initial concerns that if MCTs were too high then infants may become EFA deficient, that evidence about the absorption of MCT was poor and that high levels of MCT meant that the fat composition deviated too much from breast milk.
Maureen Minchin IBCLC	-sees no reason to permit high levels of MCT if there is any health risk and because companies are making and selling these products. -if there were to be any danger of restricted supply of formula the requirement could have a lead in time of 3 years for industry to reformulate. - all novel food ingredients - those not natural constituents of the milk-based ingredients of formula should be proven to be safe and efficacious prior to addition. - permitting nucleotides while prohibiting MCTs would be discriminatory.
Bristol Myers Squibb Australia Pty Ltd	- do not agree that the use of MCFA should be prohibited. BM is not aware of any manufacturers lowering the content of MCT in their infant formulae and have no plans to do this themselves. The proposal to change existing products of longstanding is highly questionable. - prohibition of MCFA in infant formula is totally inappropriate as they are found in human milk (4-12%) depending on which fatty acid groups are included, animal and vegetable fats. The fatty acid profile of human milk will vary - however the aim of infant formula manufacturers is always to match a "typical" profile of human milk fat as closely as possible. The amount of MCFA added will only be added to match the typical profile. MCFA are expensive therefore their addition in formula is self limiting. - the fact that MCFA are not normally present in large quantities in human milk is essentially irrelevant as an argument. Bovine albumin and B-lactoglobulin are not present in human milk - the nitrogen is present in the form of human milk proteins and significant quantities of non-protein nitrogen. - up until now cows milk protein has been accepted as a relatively safe, inexpensive and convenient form of protein to use in an infant formula. MCTs can be viewed in a similar light when regarding the special needs of infants where there are concerns with fat malabsorption. MCTs have been used for 30 years in several Mead Johnson formulations. Several studies confirm the efficacy and safety of the use of MCTs in the standard. - provided details of MCT content of their formulas and units sold in Australia and New Zealand
Nursing Mothers' Association of Australia	- health and safety of infants needs to be the primary consideration at all times. The argument that pre-term infants may be disadvantaged by disallowing MCTs needs to be clarified to ensure that it is infant health which is the main consideration here, and not the industry market share.
Abbott Australasia Pty Ltd	- proposed prohibition of MCT is inappropriate, particularly for pre-term formulas - improvement of lipid absorption with MCTs in the pre-term infant has been documented in the scientific literature - provided details of MCT content of their formulas and units sold in Australia and New Zealand

Issue: Trans Fatty Acids

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

Issue: Fatty Acids: Alpha-linolenic Acid

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

Issue: Linoleic Acid to Alpha-linolenic Fatty Acid Ratio

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

Issue: Valine

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

Issue: General Comments

Submitter	Comments
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- monitoring required to ensure that good manufacturing practice occurs - see no problem in having the same level of vitamins and minerals in special formula as in formulas for healthy infants - special need cases would be monitored on an individual basis
Karen Simmer, Neonatologist and Associate Professor	- the removal of maximum levels for many nutrients is not acceptable
NZ Dairy Marketing and Customer Services	- recommended guideline for maximum level of vitamins and minerals in infant formula products is commended

International Formula Council	- commend evaluation of maxima for individual nutrients, and recommending levels for vitamins and minerals on basis of significant risk to infants, while establishing advisory guideline maximum levels for other nutrients
Dairy Goat Co-Operative (NZ) Ltd	- goat milk infant formula will require some minor modifications to levels of some vitamin and mineral additions - this could lead to an increased price to the consumer
Victorian Food Safety Council Food Standards Sub-Committee	- supports approach, however subsequent to the preliminary inquiry report, the EC has adopted a standard for infant formulas for special medical purposes that sets levels for 13 vitamins and 15 minerals - it would be of value to first examine the arguments for setting levels for all vitamins and minerals in the EC directive (1999/21 of 25.03.99)
Nestlé Australia Ltd	- agrees there is a need to impose maximum limits on vitamins and minerals where there is a health and safety issue involved - guideline levels should not become pseudo legislation - where the minimum and maximum levels are different to the EU requirements, then formula that is manufactured in Europe would hardly ever comply to the requirements of the combined Aust NZ standard (uses example of copper) - findings of LSRO report based on some of the maximum levels on the 90th percentile found in infant formula in the USA; there has been no health and safety reason for imposing the maximum limits on some of these vitamins and minerals
Patricia McVeagh, Consultant Paediatrician	- the LSRO report developed for the Center for Food Safety and Applied Nutrition, Food and Drug Administration (reference included) addresses many of the issues raised
Maureen Minchin IBCLC	- if ANZFA goes with average ingredients rather than ranges of expected maxima and minima, it must be clearly stated that these are NOT actual averages calculated by batch assay, but expected averages for this brand when made to the company's specified recipe. - ranges are less misleading and useless for clinical purposes. - nutrition information panels take up space which could be better used to give clear instructions and warning s in many languages. - recommend that nutrition information panels be abandoned. Community health workers on the ANZFA teleconference agreed here - opposed to only having advisory guidelines. - maximum levels should be set for every ingredient where this is currently possible and made mandatory for all infant formula. - as the EC Directive on Dietary Foods for Special Medical Purposes , heavily influenced by industry, specifics a narrower range of vitamin and mineral levels, these minima and maxima are clearly achievable - compliance should be monitored by an independent agency. If advisory maxima are allowed for any ingredient, widespread publication of the mandatory monitoring results should advise consumers about products which breach the advisory maxima

Bristol Myers Squibb Australia Pty Ltd	- agree with the present nutrition information panel requirements, however questions the use of the nutrition information panel for the parent who uses the information. If every formula has relatively narrow compositional guidelines to meet at present, is this panel used for comparison with other brands? The panel appears to be presented to reassure the parent that the nutrients are in the product. - it seems unnecessary to add a column of nutrients per 100g of powder per 100 ml of concentrated liquid. The change would impose an enormous cost upon industry, affecting every single product on the market.
W Parnell, Department of Human Nutrition, University of Otago	- comments that the statement "recommended mandatory maximum levels be set for those vitamins and minerals which are considered...." for the reason of "eliminating unnecessary costs for industry" is wide off the mark of commercial reality - comments that no food industry uses resource unnecessarily
Nursing Mothers' Association of Australia	- the long term safety of vitamins and minerals needs to be established before allowing them to be added to formula.
Wyeth Australia Pty Ltd	- maximum levels should be determined by risk assessment and harmonisation with international standards - inference of unlimited nutrient contents for infant formula without R7 regulation is unrealistic and misleading, as all infant formula manufacturers are committed and legally bound to producing safe products both at common law and under various State and Federal Legislation - it is not appropriate to state that human milk has a self-limiting level for all vitamins and minerals. The composition of human milk varies considerably, dependent on maternal diet, stage of and even during a feed. The setting of maximum levels should therefore, be based on risk assessment. Advisory maximum levels which are recommended for nutrients whose risk is insignificant should not be included in guidelines. Although guidelines do not have force of law, compliance is expected to be monitored. The question arises of who will monitor compliance, monetary constraints within government agencies and even industry make the process seem unlikely and it adds unnecessary complexity and prescription to the Standard. (see references)

Issue: Selenium

Submitter	Comments
Karen Simmer, Neonatologist and Associate Professor	- suggests available data does not support proposed maximum and minimum selenium values - RDI for selenium (Aust) is 10µg/day, equivalent to amount a breastfeed baby receives. Lower levels may meet nutritional needs of infants - cites Adelaide: breast milk selenium 13±4µg/l (mean±SD) and formula selenium varies from 3-10µg/l.

International Formula Council	- recommends a higher max of at least 1.1 mcg/100 kJ, if selenium is added to infant formula - establishing a selenium maximum based on added selenium would enable continued use of manufacturers' existing premix systems, which has been shown by experience to be safe and reliable. It is critical to add selenium in an accurate, safe and reliable way because the range between adequate selenium and potentially selenium toxicity is relatively narrow. The most accurate, safe and reliable way to add selenium to infant formula is via a premix
InforMed Systems	- selenate: studies available on the bioavailability of selenate (reference given); papers suggests selenate may be better absorbed than either selenite or selenomethionine - it may be preferable to set a lower level for selenate on the basis of that study, but not to prohibit its use
NZ Dairy Marketing and Customer Services	fortification of some current formula will be required, which will incur additional monitoring costs
Dr Lynne Daniels, Flinders Medical Centre, Centre for Perinatal Medicine	- submits that infant formula should permit supplementation with either selenate or selenite to the levels proposed [note: detailed submission on selenium, including 30 references]
Nestlé Australia Ltd	- sodium selenate is a permitted form within New Zealand Food Regulations and the EU Directive for infant formula. If sodium selenate is not permitted, formulas manufactured in NZ and Europe would become illegal products - sodium selenate is a more stable salt and is less sensitive to reduction to the inactive selenium by ascorbic acid (references included) - limits proposed for selenium are rather narrow based on the analytical methods available and the varying level of selenium found in raw materials
Abbott Australasia Pty Ltd	- limit to the amount of added selenium in infant formulas is still too low - due to variations of selenium in soil, and therefore raw materials, a higher maximum level is needed - selenium in human milk varies, depending on geographic region and maternal selenium intake - proposed level of 1.19 mcg/100 kJ, which is in line with LSRO recommended maximum of 5.0 mcg/100 kcal - level is consistent with the levels found in human milk from women consuming foods from selenium adequate areas, and their infants have no problems with this level - proposes inclusion of sodium selenate as a permitted form, in line with EU Directive
Abbott Laboratories (NZ) Ltd	- agree that it is appropriate to limit the amount of added selenium in infant formulas. -state the new limit still remains too low given the natural variation in selenium content in soils and therefore the raw materials used in the manufacture of infant formulas. -propose a maximum level for selenium of 1.1 ug/100 KJ because it is consistent with the level found in human milk from women consuming foods from selenium adequate areas. The level is also in line with the LSRO (Life Sciences Research Office) recommended maximum of 1.19 ug/100 KJ. -propose the addition of sodium selenate as an allowed selenium fortifier in accordance with EC Directive 91/321/EEC Annex III.

Issue: Manganese

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

Issue: Aluminium

Submitter	Comments
International Formula Council	- endorse decision to raise proposed aluminium max for non-soy formula to 0.5 mg/L
NZ Dairy Marketing and Customer Services	- additional monitoring costs will be incurred
Maureen Minchin IBCLC	- the lower level should be universal, not the higher - $1300 per annum is not too much to pay for assays that ascertain industry compliance with aluminium and cadmium levels
Nestlé Australia Ltd	- prescription of an aluminium level is consistent with international regulations - if there is no issue with the level of aluminium proposed for soy-based products, then there should be one limit only - in keeping with WTO obligations, it would be more suitable to retain the aluminium levels in a guideline
Bristol Myers Squibb Australia Pty Ltd	- suggest there is no international agreement on limits for aluminium. There has been no demonstrated danger to public health and safety with present levels of aluminium under the present standard - any level imposed, must be regarded as a public health and safety issue and supported with clinical evidence that present levels are actually harmful. If this is the case, then one level of aluminium must be applied to all formulae. To do otherwise is inconsistent. The level set also needs to be achievable. ANZFA needs to consult with industry to set this level.

Issue: Fluoride

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

Dr Sheila Killalea, Dr John McNeil, Department of Epidemiology and Preventive Medicine Monash University	- there is increased evidence to suggest that prolonged intake of infant formula may contribute to dental fluorosis, which is increasing in prevalence in Australia and many other countries (references included) - fluoride intake from infant formula reconstituted with low-fluoride or optimally-fluoridated water may exceed the recommended intake in infancy, in some cases, more than two-fold (included information on estimates of intakes in fluoridated and non-fluoridated areas for children up to one year of age) - reduction of dry formula fluoride level to negligible amounts would reduce fluoride intake from this source by up to 30% - acknowledges that many factors may contribute to the increase in dental fluorosis, and that a multifaceted approach to the reduction of inappropriate ingestion of fluoride is needed. Nevertheless, feels there is sufficient evidence to warrant a limitation of the fluoride content of infant formula at this time (references included) - suggests two ways of limiting excessive fluoride intake from infant formula: * regulate the fluoride content of water used at the manufacturing site, which some manufacturers already monitor
Dr Sheila Killalea, Dr John McNeil, Department of Epidemiology and Preventive Medicine Monash University (cont)	* infant formula be reconstituted with low-fluoride water in a natural or artificially fluoridated area; would add to cost of infant formula if distilled or mineral water has to be purchased; likely to result in variable compliance; less effective method of lating rise in prevalence of dental fluorosis in Australian children
New Zealand Ministry of Health	- received expert advice on this issue - the upper limits for fluoride are, although on the high side, acceptable - advisory statement required under clause 24 should refer to “a dentist”; although preference would be to delete reference to a medical practitioner or other health professional, as there is some confusion amongst health professionals on this issue
Nestlé Australia Ltd	- do not agree that there is a need to include advisory statements on products regarding fluoride and dental fluorosis - no international equivalent legislation and would constitute a technical barrier to trade
National Council of Women of New Zealand	- suggest a regulated required maximum level should be determined
Bristol Myers Squibb Australia Pty Ltd	- fluoride is not mentioned in either the Codex or EC standards - if fluoride intake by infants is truly a public health and safety issue, the fluoridation of the water supply around Australia needs to be reviewed - concerns have been expressed previously regarding the safety of fluoridation of water supplies; in this case, a level of intake of 1 mg fluoride per litre of formula from the powder or concentrate was regarded as the proper limit of safety, assuming the water itself contained 1 mg fluoride per litre - this translates to approximately 36 ug fluoride per 100 kJ for a routine formula, compared to the 17 ug/100 kJ in the draft; this level is unnecessarily low

Issue: Tocopherols

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

Issue: Zinc to Copper Ratio

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

Issue: Permitted Form of Nutrients

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

Issue: Iodine

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

Issue: Chromium and Molybdenum

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

Issue: Carnitine and Choline

Submitter	Comments
Dairy Goat Co-Operative (NZ) Ltd	- carnitine composition of goat milk needs to be considered in relation to protein quality requirements included and the recommended maximums set for carnitine
Nestlé Australia Ltd	- the way this clause is written will require infant products where the optional nutritive substances are not added to comply with the maximum levels specified for each of the nutrients - range proposed for carnitine too narrow - this does not take into account the natural variation of these nutrients that can occur with the ingredients of the products - permission should also be included for lecithin: lecithin also naturally contains a proportion of choline - these permissions do not harmonise with any international legislation and would be considered as technical barriers to trade. EU Directive allows addition of choline and choline citrate as well as choline chloride and choline bitartrate - EU Directive allows addition of the hydrochloride of L-carnitine - these forms need to be permitted for choline and carnitine
Abbott Australasia Pty Ltd and Bristol Myers Squibb Australia Pty Ltd	- proposed level for carnitine is still too low - carnitine is naturally present in cows milk, typically at concentrations as high as 1 mg/100 kJ - therefore the restriction to 0.8 mg/100 kJ is unrealistic - propose a level of NMT 1 mg/100 kJ

Issue: Choline

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

Issue: Vitamin B6

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

Issue: Riboflavin

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

Issue: Follow-on Formula

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

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

Issue: Special Purpose Formulas

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

Issue: Pre-Term Formula

Submitter	Comments
Nestlé Australia Ltd	- does not agree with the regulation of a pre-term formula, as the area is changing rapidly, especially where micronutrients are concerned - no other country regulates this products - products exclusively used for sick infants under strict medical supervision in hospitals only. Risk of improper use is therefore at a minimum - pre-term formulas are only available in hospitals for babies under specialist medical supervision; therefore unnecessary to include a statement on the label to this effect as it is the only way that the products can be made available to infants - pre-term formulas should be based more on weight than age - scientifically, it is now being recognised that this segment needs to be split into two parts:- one for infants less than 1.5 kg and one for infants greater than 1.5 kg (attachment included on Nestlé publication: Nutrition of the very low birth weight infant) - number of pre-term infants is approx. 3% total births, so from a commercial point of view amount of pre-term formula used is very small and companies generally make one formulation which is used globally
Nestlé Australia Ltd (cont)	- when segment is divided into two, quantities in each segment will be even smaller and companies will not make special pre-term formulas to suit different regulations in each country - therefore these regulations run the risk of these products of not being available to Australia and NZ infants and the regulations will be out-of-date very quickly - Nestlé's pre-term formula contains less vitamin D than specified within draft standard; level in product corresponds to ESPGAN, which recommends a max of 3 µg/100 kcal (0.7 µg/100 kJ) - ESPGAN also recommends a minimum folic acid content of 60 µg/ 100 kcal (14.3 µg/100 kJ) in pre-term formulas; product meets these requirements and contains the minimum amount - pantothenic acid content of product complies with ESPGAN recommendation of 0.45 mg/100 kcal (0.11 mg/kJ) which is lower than the levels specified in the draft. This would mean that the pre-term formula would not comply with the standard
Dr David Tudehope, Director Division of Neonatology, Mater Hospital	- pre-term formulas comprise approximately 3-5% of the total market of infant formulas - because of the relatively small market, there is not a wide range of pre-term infant formulas available - most infant formulas take 7 – 8 years of formula development - it is not reasonable to expect Australia to play a significant role in development of pre-term formulas - pre-term formulas are prescribed by a relatively small number of paediatricians specialising in neonatology - individual hospitals make decisions regarding availability or purchase of pre-term formulas based on scientific evidence - nutritional committees are established to make these difficult decisions - the regulation of pre-term formulas would result in an unnecessary delay in introduction of recently developed formulas - any decision regarding regulation of pre-term infant formula needs a great deal of consideration with extensive input from neonatologists, nutritionists and probably the pharmaceutical industry

Issue: Infant Formula Products for Special Dietary Uses Based on Protein Substitutes

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

Issue: Anti Reflux/Thickened Formula

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

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

Issue: Drafting

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

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

InforMed Systems Ltd (cont)	- specifications for nucleotides: needlessly detailed. Codex has no such requirements. Should require that a constituent be "proved to be suitable for infant feeding" as in Codex draft - the section on thickened formula is needlessly complex; these products should be categorised as special purpose formulas and restricted accordingly; it is not the function of food standards to define what is or is not clinically appropriate; it is not the function of food standard to support breastfeeding - should be left to WHO Code - section 4a - specifications. Borage oil has been widely used as a source of gamma-linoleic acid, should not be confused with whole borage plant; no justification for excluding its use in infant formula - it is not the function of the standard to be active in the implementation of WHO Code provision, except for labelling provisions; adequate mechanisms in place in Aust and NZ to care for such issues; the extensive reference to the Code in the standard should be deleted
NZ Dairy Marketing and Customer Services	Clause 8 - inositol:- analytical variation may create difficulties in determining levels of this nutrient Clause 8 - choline:- small amount of choline (0.3 mg/100 kJ) contributed by lecithin used as a processing/ functionality aid (emulsification) should not be considered as an addition of choline in terms of the need to comply with the max noted in table to clause 8 Clause 8 - carnitine:- natural levels typically found in milk and whey-based infant formula range from 0.6 - 1.0 mg/100 kJ; total carnitine levels three times the required max (0.42 mg/100 kJ) can be found in non-fortified whey-based infant formulas Clause 28 osmolality/potential renal solute load:- Clause 29 (1) - amino acid score:- agrees with the proposed introduction of the amino acid score; additional costs will be incurred with compliance, monitoring, and testing; some products will require reformulation and therefore be subject to additional supplementation and relabelling costs Clause 29 (2) - added amino acid maximum:- wording that "L-amino acids may be added solely for the purpose of achieving the minimum amino acid score specified in subclause (1)" is quite restrictive; would prefer the permission to add L-amino acid up to a max of X (e.g. 1.1) times the level noted from the specific amino acid listed in column 2 of the Table to Clause 6, which conforms with Codex requirements and also places controls on added ingredient levels Clause 31 (3) - calcium to phosphorus ratio:- the current Codex guidelines for follow-on formula is 1.0; consideration should be given to allowing this lower min for follow-on formulas

NZ Dairy Marketing and Customer Services (cont)	**Schedule 1** - potassium iodide is missing from list of potassium containing salts - calcium pantothenate is not included under calcium salts - choline chloride is not included under chloride containing salts - magnesium hydroxide is not included under magnesium containing salts **Standard 1.3.4 - Nucleotides** - specifications need to be carefully checked prior to their inclusion; chemical nomenclature on p26 appear to be incorrect; awaiting further information from suppliers to pass on to ANZFA
Dairy Goat Co-Operative (NZ) Ltd	Table to clause 8 - the innate carnitine level in infant formula and follow-on products using unmodified goat milk protein frequently exceeds the max permitted amount - the innate carnitine level in whey-based cow milk formulations also frequently exceeds this max - recommends max be deleted or set higher
Nestlé Australia Ltd	- the way clause 20 is drafted actually does not allow for a nominal weight of 1 kg. Recommends clause 20(2) be redrafted to state that a package having a net weight of 1 kg of less then the size of type must be not less than 1.5 mm - clause 21(2)(b)(ii) needs to state 'the average amount of' rather than 'the amount of' for consistency - not necessary to include the average amount of product on a per 100g basis; this information is not used and is therefore not necessary - relevant information is per the made up product - proposed nutrition labelling standard and current labelling provisions require products that are to be reconstituted with water to only be labelled as the reconstituted amount, not as the dehydrated or concentrated amount - labelling requirements should be consistent - clause 22 (1) should state that a date mark must be included rather than a best before date - ANZFA should not pre-empt use of a best before date as our requirement for these products is that they should carry a use by date rather than a best before date - differences between best before and use by date will be picked up in the revised date marking standard. Reference to requirement for a best before date here will not allow Nestlé to sell their products with a use by date, without creating confusion. Draft date marking standard will permit products to be sold past its best before date but not past its use by date

Wyeth Australia Pty Ltd	-there is not maximum applied to the level of choline in infant formula either in Codex or the EC. Unless it can be demonstrated that this is PH issue, the maximum should be omitted. -Nutrient addition is self limiting - only those levels that are necessary are added. -Choline can be present as a carryover nutrient from the cows milk ingredient. It is possible that actual levels may be higher than the proposed maximum. -"Food additives" 11 (3) - more appropriate wording would be "Liquid infant formula product may contain not more than 0.03g carrageenan per 100 ml". - Point 12 should read: " Other than by direct addition, a food additive or nutrient may be present ". This takes into account nutrients like choline. -specifying a method for measuring lactose is necessary as varying methods are inconsistent. As with levels of cholesterol and fat under the present code of practice, limits of detection and clinical significance need to be considered. Division 4, clause 18 should read: "A package, other than a single serve sachet or a package containing single serve sachets, containing infant formula product". -disagree with the use of "very" in Division 4, clause 19(a), (b) and (c) as it is emotive and unnecessary. Division 4, clause 22 (i) - the standard needs to be flexible enough to allow for "use by" and "best before" date marks. Division 4, clause 25 (3)(b)- this requirement presumably relates to the needs for infants with galactosaemia. For those infants with problems digesting lactose (lactose deficiency, disaccharide intolerance etc) the level of galactose is irrelevant. -believe it is unnecessary to list the presumed galactose content on the label and will contribute to confusion. Issues relating to galactosaemia are best addressed by specialises in the area of genetic and metabolic disorders. They are not issues that are considered at the retail level, as a consumer buys an infant formula. Division 4, clause 26(f) - this prevents a manufacturer from making any reference to a new formulation as distinct from a previous formulation. This restricts trade and consumer information. Food companies invest time and money supporting research into diet and nutrition and believe it is legitimate to inform consumers in this manner.
Wyeth Australia Pty Ltd (cont)	Division 4, clause 30(e) - The fatty acids are properly spelt "eicosapentaenoic acid" and "docosahexaenoic acid". Division 4, clause 31 - Codex or the EC prescribe maxima for vitamins other than Vitamins A and D. There is no maximum for Manganese or Iodine and no minimum for Selenium. The proposed levels are inconsistent with international standards and should be withdrawn. - Division 2 - Infant formula for metabolic and immunological conditions.

	-these formula are designed for when breast feeding is contra indicated and therefore should be used under medical guidance. -many of these products are listed, with their indications, in the Pharmaceutical Benefits Scheme, as the Federal Government contributes funding for their use. They are significantly more expensive to manufacture and to formulate. There are several points to make: Codex does not have this standard. EU includes this product as "Foods for Special Medical Purposes". It is not appropriate to control these products under a general standard. metabolic disorders are different from immunological conditions. Metabolic disorders will require the omission of a particular nutrient (e.g. PKU). in immunological conditions the form of nitrogen is designed to prevent the immunological or allergic reaction. The notation "not suitable for general use" is not correct". The nutritionally complete products are not designed for general use, however, their suitability is not an issue. recommend that infant formula that are not nutritionally complete and are designed to meet nutritional requirements in special medical cases be included in the standard for Foods for Special Medical Purposes. For nutritionally complete infant formula where, for instance, the protein has been hydrolysed or amino acids used as the source of nitrogen, we recommend that the standard be broad enough in its descriptions and allowances to allow these products to conform without alteration.
Bristol Myers Squibb Australia Pty Ltd	<u>Definitions</u> - recommend a definition of "follow-on formula" to be similar to Codex. definition for "infant formula product" is too prescriptive and should follow Code. Clause 6 - Calculations of amino acid score: the proposed increases of amino acid levels are scientifically unsubstantiated and will result in reformulation of many of BM products. Unjustified because there have been no health risks with these products. -submission contains a table where shows that if the current R7 amino acid values are converted to g per 100g protein, values do not produce the proposed amino acid score of 0.8 in all cases. Also, the current R7 standard and Codex express individual amino acid requirements on a calorie basis. Clause 9 - Limit on Nucleotide 5'-monophosphate maximum total nucleotide level should be set at 1.76 mg/100 kJ (the sum of the maximum nucleotide permitted) and not 1.2 mg/100 kJ. Clause 7 - restrictions and prohibitions. (1) the clause is prescriptive and limiting and restricts innovation. Recommend the relevant Codex Clause 3.2.1. -inappropriate for ANZFA to include a clause for infant formula to contain no undetectable gluten without including a method for analysis or minimum levels of detection (see submission for explanation). The phrase "must not contain any detectable gluten" should be replaced by "must be gluten free" as defined by Section 32.991.19 of the Second Supplement to the AOAC, 15th edition (1990).

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

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

Issue: General Definitions

Submitter	Comments
New Zealand Ministry of Health	- believes that definition of infant formula needs to be described not only as being suitable as the *principal* but also the *sole* source of nutrition for infants in the first four to six months of life (except in follow-on formula, where *sole* is not appropriate) - believes definition for follow-on formula should reflect that this formula is the principal liquid element in the diet of infants; however can agree with proposed definition - suggests an editorial note to explain reasoning behind this definition - could be helpful to cross-reference to the advisory statement required in clause 19(3)
Nestlé Australia Ltd	- alternative name for follow-on formula is follow-up formula; this should be included - starter formula is also used to describe the products that are suitable for infants under 6 months of age; this term needs to be considered
Abbott Australasia Pty Ltd	- endorse the term 'Infant Formula Standard' - however, would like to suggest the use of specific terms, such as hydrolysates or amino acids instead of the proposed term "protein substitutes" - believe the definition "fat-modified" is still inappropriate due to the fact that there are other means of modifying the lipid component than through the use of MCTs

Issue: Definition of Pre-Term Formula

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

Issue: Definition of an Infant

Submitter	Comments
Maureen Minchin, IBCLC	A definition for infant should be included in the standard. She suggests the following definition. "An infant is a person under 12 months of age."

Issue: Definition for Lactose Free and Low Lactose

Submitter	Comments
Maureen Minchin, IBCLC	A definition for 'lactose-free' or 'low lactose' formula should highlight the temporary nature of the condition and the short-term nature of the formula use. 'Lactose –free' or 'low lactose' formula means infant formula products with reduced lactose content for short-term use by infants with medically diagnosed problems with lactose malabsorption.

Issue: Definition of Soy Protein Formula

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

Issue: Definition of Special Purpose Formula

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

Issue: Definition of Protein Substitute

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

Issue: Definition of Fat Modified

Submitter	Comments
International Formula Council	- endorses ANZFA's decision to rename the standard Infant Formula Standard and to drop the proximate modified. They had earlier expressed concern about the term "fat modified" and wish to clarify that this term has been dropped.
Abbott Australasia Pty Ltd	- they believe the definition 'fat-modified' is still inappropriate due to the fact the there are other means of modifying the lipid component than through he use of MCTs.

Issue: Warning Statements

Submitter	Comments
Consumer Food Network of the Consumers Federation of Australia	- proposals weaken current labelling provisions by downgrading prescribed statements into advisory statements - believes infant formula should be treated as potentially dangerous products, with mandatory warning statements - recommends that a mandatory warning statement, in 6 mm type, to the effect that artificial formula feeding can be dangerous to the health of the infant
Nestlé Australia Ltd	- provision to require infant formula to carry statements advising carers to seek medical advice where the fluoride content is unnecessarily high imposes restrictions that would be considered a technical barrier to trade

Barbara Glare	- very worried about warning that should appear on the can - there are a growing number of additives to infant formulas, such as LCP formulas, and thickened formulas to supposedly treat reflux - there needs to be clear warnings on the can that these are experimental - these additives are completely unproven, and yet are being accepted as 'normal' - parents should have the right to know that their children are being experimented upon, and to give their informed consent, as they would in any other trial - - believes slogan "breast is best" is totally inadequate
Fiona Compston	- requirement for a statement that "Breast milk is best" and for consumers to "seek advice from health professionals" is inadequate in informing consumers of the health risks of formula - current labelling does not warn consumers that even one formula feed is likely to affect ongoing breastfeeding of the baby, and could produce a reaction in the child - "Breast is best" also suggests artificial formula is standard or normal
Australian College of Midwives Inc (Victoria) and Baby Friendly Hospital Initiative (Victoria)	- requirement for "Breast is best" and for consumers to "seek advice from health professionals" is inadequate in informing consumers of the health risks of formula
Maureen Minchin, IBCLC	- the standard allows industry to keep publishing useless and misleading information on labels. It would be preferable to include detailed information that would assist in educating about infant formula risk and put responsibility for such education on to health professionals despite the evidence that almost all health workers are never adequately educated about such risks. States that appropriate mandatory hazard warnings should be included on the label. Suggests the following statements. 'WARNING Artificial feeding can make your baby ill. It also costs a lot of money and can result in more days off work for the baby's parents. If you are having breast-feeding problems, most can be solved, so seek expert help before using this product. Breast IS best.' 'WARNING Follow the instructions below. Infant formula can harm your baby if you do not. Always read the instructions on every can of formula you use, as they may be different. Never use more or less powder or water or a different measuring scoop and use only shrink proof bottles with reliable markings. DO not overheat infant formula, as you can destroy important ingredients. Do not heat infant formula in a microwave.'
The Dietitians of the New Children's Hospital	- recommend the statement 'breast feeding for at least six months is superior to the use of infant formula'. Supply of breast milk is reduced by the introduction of infant formula. The duration of breast-feeding is the problem in developed countries rather than the initiation rates.

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

Issue: Soy and Phytoestrogens

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

International Formula Council	- Extremely disappointed regarding overly restrictive position on soy-based infant formulas. Concerns about the safety of soy formulas due to their phytoestrogen content are scientifically unfounded. For over 60 years, these products have been fed to millions of infants and studied in controlled clinical research, no adverse effects related to phytoestrogens in soy protein isolate formulas have been identified. - US FDA determined that soy-based infant formula are safe - refers to Dr Karen Kline report on isoflavones, soy-based infant formulas and relevance to endocrine function. - refers to studies by Luisa Businco and Dr Ken Setchell. - provided information on a study in infants fed a soy-based formula compared to a reference group of infants fed human milk. - IFC and US National Institutes of Health are sponsoring a study "Follow-up study of subjects fed soy-based formulas during infancy", which is currently underway - strongly urges that, as a minimum, ANZFA not implement or encourage the implementation of strategies to deter use of soy-based infant formulas pending the completion of this study, which is anticipated this year - recommend that standard clarify that, in addition to soy protein isolate, other forms of soy protein (e.g. soy flour, soy extract) should be permitted
Victorian Food Safety Council - Food Standards Sub-committee	- until safety of soy-based products is resolved, recommends that use of this formula be appropriately labelled to discourage use save on the advice of a health professional
New Zealand Ministry of Health	- pleased that ANZFA is considering strategies to deter the use of soy-based infant formula - thinks clause 19(3)(b) could be altered to "*Soy infant formula should not be used except on the advice of a health professional*" - queries whether water quality guidelines are sufficient to protect infants fed soy infant formula, given that nitrates are present in soy protein - given the presence of phytates in soy formula, has ANZFA considered if there is a need to increase the levels of certain minerals (e.g. calcium, iron)? - questioned whether there is a need to specify a level or a denaturation process for trypsin inhibitors - questioned whether ANZFA has considered if the level of iodine is high enough in soy formula, given possible phytoestrogen effects - concerned with the 1.0 mg/L limit proposed for aluminium in soy infant formula. The toxicological assessment does not provide a robust argument demonstrating the safety of 1.0 mg/L limit. Some references suggest infants may be at risk of aluminium toxicity at levels above 300 micrograms per litre (reference included)
Peter Toth	- concerned about infant soy formulae (included letter to editor of one parent, stating that there are many more worried parents)
Susan Toth	- information tells her that there is no safe level of soy for infants (or adults) - infants feed on soy formulas receive the estrogenic equivalent of at least five birth control pills a day - provides information on the adverse effects of phytoestrogens - the FDA did not give a GRAS approval for the use of soy protein

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

Abbott Australasia Pty Ltd	- concerns about 'alleged hazards associated with the consumption by infants of soy-based formula' containing phytoestrogens are not well-founded and are contradicted by scientific data - additionally, there is insufficient data to support a warning statement on soy-based formulas. For over 60 years, soy based infant formulas have been fed to millions of infants and studied in controlled clinical research; no adverse effects related to phytoestrogens have been identified - soy-based infant formulas are a safe and important feeding option for many infants - scientific data have demonstrated that infants fed soy-based infant formulas grow normally; US FDA determined that soy-based infant formulas are safe - standard should clarify that other forms of soy protein (e.g. Soy flour and soy extract) also could be utilised in the production of soy-based infant formulas
Maureen Minchin IBCLC	- it is not clear why ANZFA has focussed solely on soy formula, when bovine milk not only contains phyto-oestrogens but can contain higher levels of the more active compounds. - making less hypo-allergenic infant formula available should be a priority , not simply continuing the use of products whose impact on reproductive and physical health are at least questionable - research into the impact of phyto-oestrogens in infancy on later gender differentiation might make any decision to ignore these questions now seem less than responsible in future. The NZ public statement will have little impact on parental behaviour when a desperately unhappy infant improves (as many still do, even if about 40% will also become soy allergenic) when taken off bovine formula and tried on soy - Soy protein isolate - is soy protein isolate the only possible form of soy that might be used in infant formula? It may cause problems to limit the definition this way otherwise.
Mark Dunstone and Julie Smith	- given the absence of clinical trials showing soy-based artificial formula is not harmful, and the evidence that it may be, soy-based artificial formulas should not be allowed.
Nursing Mothers' Association of Australia	- where the safety of the product cannot be established the public have the right to know that this is the situation. This will allow them to make a more informed decision about infant feeding - withholding information about the potential risk from the phytoestrogen content of some soy-based formula prohibits informed choice. It is not enough to say breastfeeding is best - it is important to remember that formula can be the sole form of nutrition for an infant whose digestive system that is designed for breast milk and whose immune system relies on the protective properties of breast milk. An infant fed on soy-based formula is a very different situation from an adult having an occasional meal of soy beans

Wyeth Australia Pty Ltd	- soy based formula have been used as a sole source of nutrition for infants for over forty years - there is no potential risk to normal infants fed soy formula. Soy formula does not cause thyroid dysfunction (or hypothyroidism, which may be classed as a metabolic disorder) - For vegetarian/vegan carers who cannot, or do not wish to breast feed, soy-based formula provides complete nutrition for their infants without health or safety risks. Potential strategies to reduce the level of unnecessary soy-based infant formula consumption should not be included in this Standard
Bristol Myers Squibb Australia Pty Ltd	- the use of soy protein as an alternative source of protein continues to be a safe and a valid alternative to cows milk protein - use of soy protein is a viable, safe alternative. A recent review of data (see reference in submission) on the use of soy protein based infant formula, confirms the normal growth and development of the infant - requirement for a warning statement is unwarranted and reflects activities of "anti-soy" lobby groups, more than true science
Safetywize Consultants	- expressed concern that so many manufacturers are stating that there is no evidence of adverse effects from soy protein in infant formula - enclosed document called "Soy Infant Formula: The Health Concerns - A Food Commission Briefing Paper" which provides evidence to illustrate some adverse hormonal effects of soy products which have been know for many years
Camille Guy	- animal studies show clear evidence of reduced fertility due to phytoestrogen intake. - submission discusses in some detail concerns in Japan over the country's exceedingly low birth rate, low incidence of dizygotic twinning - In the report ANZFA does not recognise that there is a great deal of recent work with a bearing on phytoestrogen risk assessment. Specific evidence is provided on Professor Clifford Irvines presentation on the Role of Soy in Preventing and Treating Chronic Disease (Brussels 1996). Other data on primate post-natal estrogen exposure is presented. - refute the Authority's claim that "there is no evidence that exposure of healthy infants to soy-based infant formula over 30 years of use has been associated with any demonstrated harm" - explained concerns relating to development of soy fed children e.g. menstrual disorders, early puberty, excessive breast development etc which were outlined in her NZ Herald article (26.8.95) Attachments (letters to and from Pat Tuohy to Camille Guy)

Kingett Mitchell and Associates Ltd	- does not agree with ANZFA's conclusion that there is no potential for adverse effects. Believes there is clear evidence of harm - supports some of ANZFA's comments relating to food contaminants (see submission - pleased that ANZFA talks about the precautionary approach but believes that this approach needs to be accompanied with precautionary action. Urges ANZFA to require the removal of phytoestrogens from soy- - main concern is that ANZFA does not address concerns that relate to thyroid, the accuracy of evidence presented and various issues of interpretation - see submission which includes discussion of the Ishizuki study and other relevant studies related to phytoestrogens
Soy Information Network	- challenges submissions stating that "that concern over the health hazards of soy formula raised in New Zealand are not well founded" Provides discussion on scientific literature, arguments presented in submissions and in public presentations. (see detail in submission)
R F James	- isoflavones should be removed from soy protein based infant formulas, pursuant to the precautionary principle of avoidance of unnecessary risk (attached several references to support their removal) - oppose the view that "no evidence of harm" appear in the Preliminary Inquiry Report - provides numerous references to scientific literature and views of other countries (see submission) - soy formulas cause mineral deficiencies due to the high and variable amounts of phytate in them which cannot be exactly balanced by mineral addition , or the widely variable trypsin levels in soy protein isolates - states that at least a precautionary approach should be advocated, particularly when there are a number of compelling retrospective dietary studies which indicate isoflavones should be removed from soy baby foods (including "follow-on" products") - calcium levels are associated with the levels of phytate which decrease the bioavailability of calcium. Has anecdotal evidence about dental deficiencies in male children who have been fed soy formulas several years previously - food standards must be consistent with international trade obligations. SGOGS Committee have not given nitrosamine and nitrate contamination of soy protein GRAS status - perhaps because the industry has concealed the nitrate content of soy protein and soy formula. The water quality issue is a red herring which diverts attention from the issue of soy protein itself. (cites references) -disagrees with certain statements made in the preliminary report and comments on other submissions to the full assessment report (see submission) -references included in submission

Issue: Microbiological Standards

Submitter	Comments
International Formula Council	- concerned that unnecessarily restrictive, particularly for coliforms - US regulations allow 10 microorganisms per gram of dry product

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

Issue: Renal Solute Load

Submitter	Comments
Department of Nutrition and Dietetics and the James Fairfax Institute of Paediatric Clinical Nutrition	- page 4 - calculation of potential renal solute load:- There is a revised formula for calculating renal solute in Fomon, Zeigler: Renal solute load and potential renal solute load in infancy *Journal of Paediatrics 134 (1): 4-11 1999*
InforMed Systems Ltd	- suggests being more restrictive than Codex would be "most unwise"; unnecessary to be included in standard
NZ Dairy Marketing and Customer Services	- accepts change to PRSL - limit proposed will necessitate reformulation of a few products currently on the Australasian market - the imposition of a max PRSL on follow-on formula due to potential high contribution from other dietary sources appear to be unfairly targeting follow-on formulas
Nestlé Australia Ltd	- renal system of infants over the age of six months is more mature than that of the 0-6 month infant - inclusion of this provision may create difficulties for manufacturers - does not comply with international legislation, therefore some imported foods may become illegal
Bristol Myers Squibb Australia Pty Ltd	- method for Potential Renal Solute Load and the proposed limits for PRSL need to be reassessed - a recent article by Fomon and Ziegler (see reference) raised the issue of available phosphorous - this method also uses total nitrogen rather than protein, thereby excluding differing conversion factors for different protein - the conversion of the nitrogen to yield the nitrogenous solutes also appears to be slightly different to the one given in the draft

Issue: Food additives - General Comments

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

Issue: Food Additives - Carrageenan

Submitter	Comments
International Formula Council	- endorses position not to prohibit use of carrageenan in liquid infant formulas
InforMed Systems Ltd	- Codex permits up to 0.1 g/100 mL in hydrolysed and amino acid based formula - proposed standard is more restrictive
Victorian Food Safety Council - Food Standards Sub-committee	- recommends that carrageenan not be permitted for use in infant formula until the conflicting international results concerning its effect on immunosuppression are resolved
New Zealand Ministry of Health	- some reservations to permit carrageenan to liquid infant formula, particularly as it is the more vulnerable infants (e.g. pre-term) who consume this product - JECFA review stated specifically that its ADI does not apply to infants under 12 weeks old - advised that scientific reports listed on p175 do not give reliable data on the potential toxicity of carrageenan in infant formula - data limited in terms of length of study, whereas intake of infant formula may go on for longer in some situations - appreciate use of liquid formula is usually limited to hospital situations, however there is potential for commercial sale - as additive is still under review internationally, request further consideration be given to its permission for use
Nestlé Australia Ltd	- drafting does not actually give permission for addition of carrageenan into liquid infant formula - 'must not contain more than' should be written as 'may contain not more than'

Issue: Food Additives - Citric Esters of Mono- and Di-Glyceride of Fatty Acids

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

Issue: WHO Code of Marketing of Breast-Milk Substitutes

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

NZ Infant Formula Marketers' Association	- NZ Ministry of Health regulates the CoP in New Zealand - committed to the development and implementation of appropriate infant nutrition policies based on the principles and aims of the WHO Code of Marketing of Breast-Milk Substitutes - concerned about the negative impact the proposed standard may have on some members of the NZ health sector, which would impact on the NZ Ministry of Health's ability to effectively monitor the NZ Interpretation of the WHO Code - proposal in conflict with WHO Code and Codex Standard for follow-on formula - believes proposed standard represents a major potential trade barrier, and ANZFA may be called on by the WTO to justify the proposed changes on health and safety grounds - follow-on formula has been excluded from the NZ Interpretation of the WHO Code (refer to Ministry of Health Publication: Infant Feeding) - ANZFA will "inevitably create unnecessary code interpretation and management problems for NZ, therefore, undermining the ability of the Ministry of Health to effectively monitor the NZ Interpretation of the WHO Code -NZ Ministry of Health recently acknowledged that many health professionals are far to literal in their interpretations of the WHO Code, communicating only negative information on bottle feeding to infant carers who are unable, or wish not, to breast-feed - currently do not advertise infant formula in NZ, in line with WHO Code - quotes Chen and Palmer, who argued that banning the advertising of infant formula and follow-on formula represents a serious violation of several sections of the NZ Bill of Rights Act 1990 - understands that only five countries (Bahrain, Botswana, Malaysia, Tanzania, Vietnam) have extended the interpretation of the WHO Code to include follow-on formula - believe APMAIF have consistently over-interpreted the intent of the WHO Code
La Leche League NZ for Breastfeeding Supports and Information	- does not consider that the NZ Infant Marketers' Association's CoP for the Marketing of Infant Formula provides the same degree of protection as the WHO Code, either in its intent or in its wording - NZIFMA CoP applies only to a few companies, and only to infant formula - unlike WHO CoP, it excludes bottles, teats, follow-on formula and any other breast milk substitutes - WHO Code states no advertising, whilst NZIFMA CoP states that "general advertising of infant formula by NZIFMA companies through mass media ... or at point of purchase should be avoided" - NZIFMA CoP contravenes Australian and NZ MoH's definition of an infant as a child under twelve months of age