ATTACHMENT 6

PROPOSAL P93 – REVIEW OF INFANT FORMULA

SUMMARY OF ISSUES RAISED IN A SUBMISSION FROM THE INFANT FORMULA MANUFACTURERS' ASSOCIATION OF AUSTRALIA (IFMAA) AND THE NEW ZEALAND INFANT FORMULA MARKETERS' ASSOCIATION (NZIFMA) FOLLOWING INQUIRY (NOV 1999).

Issue	Details
The definition of follow-on formula	Industry disagreed with the use of the term "breast milk substitute" within the definition for a follow-on formula. It was believed that this term misrepresented the intended purpose of follow-on formula, and that such products should be considered as a significant part of an infant's diet but not as a "substitute".
The units of measure for expressing amino acid composition	Industry requested that the proposed units of g/100g of protein be reverted to mg/100kJ as previously contained in Standard R7 of Volume 1. This position was taken on the basis that the majority of infant formula products would fail to comply with amino acid units expressed as g/100g of protein, and that the resulting levels were more restrictive than international requirements (draft Codex and European Union infant formula standards).
The proposed minimum level of cysteine (2.45g/100g protein)	Industry disagreed with the level of cysteine proposed for the draft standard. Industry's position was that protein levels in infant formula were higher than human milk, and this ensured the adequate provision of cysteine. Adding cysteine to infant formula as a means of meeting the proposed level was not considered feasible by Industry, who indicated that this would increase the sulphur content of the product, would significantly increase the cost of infant formula, and make the products foul tasting. When Industry raised this issue with ANZFA, it was requested that no distinct value for cysteine be provided in Standard 2.9.1 (see the issue of separate cysteine values). It should however be noted that Industry also requested the entire amino acid profile for infant formula be changed to the profile specified by the European Commission (EC) Directive (91/321/EEC) on infant formula (see below). This would therefore require a minimum cysteine content of 1.3g/100g of protein, a value that ANZFA referred to when minimum cysteine levels were discussed with Industry.
Provision of separate minimum values for cysteine and methionine	Industry disputed the requirement for an independent value of cysteine based on the position that a significant level of cysteine is only necessary for premature infants. It was proposed that amino acid requirements for non-premature infant formula have cysteine values summed with those for methionine.

Issue	Details
The minimum values of amino acids	Industry disagreed with the proposed amino acid profile specified in the Table to Clause 6. Industry raised particular concerns over the requirements for cysteine (see above), histidine, phenylalanine, tryptophan and tyrosine. Industry stated that the products on the market would not comply with these minimum levels, and that infant formula already had a history of promoting normal infant growth and development. They proposed that the amino acid requirements specified in the European Commission Directive for infant formula (91/321/EEC) be used in Standard 2.9.1.
The maximum level for locust bean gum permitted for addition to infant formula	Industry requested that locust bean gum be allowed in levels up to 1.0g/100mL of infant formula as opposed to the maximum level of 0.1g/100mL as stated in the draft standard. This increase was to accommodate the use in thickened infant formula (promoted as anti-reflux formula). The supporting argument cited the European Union Scientific Committee on Food's recommendation for a maximum level of 1.0g/100mL as a justification for the increase from 0.1g/100mL.
Required warning on infant formula labels	Industry disagreed with the mandatory warning *'…Inappropriate use or preparation [of infant formula] can make your baby very ill'*. Industry requested that "inappropriate" be replaced with "incorrect" and that the term "very ill" should be removed as it was an ambiguous and alarmist statement.
Required statement on infant formula labels	Industry requested that the required labelling statement indicating infants over the age of 6 months should receive foods in addition to the infant formula product is unnecessary as it reiterates common knowledge and crowds available space on labels.
Print and package size	The November 1999 draft of Standard 2.9.1 required that infant formula products with a net weight greater than 450g were to print statements on their labels in a minimum type of 3mm. Industry argued that this should be increased to 1kg as this type size was deemed too large for the common 900g and 454g cans that were available on the market.
Declaration of nutrition information - values per 100g	Industry requested that the requirement for a "per 100g" column of the nutrition information panel be removed. This request was made on the basis that such information crowded a label, would confuse general consumers, and was only necessary for health professional use, which is met by other means.
Permission for an "added iron" claim.	Industry requested that the permission of an "added iron" claim be allowed on the label of infant formula as a public health measure (addressing infant iron deficiency).

Issue	Details
Prohibited representations; Anti-reflux formula	Industry requested that the prohibition on claims relating to particular conditions, diseases or disorders should be restricted to a prohibition on disease states only. The supporting argument stated that consumers would benefit from knowing the health condition for which an infant formula product was promoted. This request was made in relation to thickened formula providing a benefit to reflux conditions.
Fat Content - Alpha Linolenic Acid (ALA) requirements	Industry proposed to reduce the required level of ALA from 1.75% of total fat to 12mg/100kJ (using proposed units of expression – see below). Industry's supporting argument was that reduction to 12mg/100kJ of ALA was safe as supported by the Lucas[1] study and Makrides[2] report.
Fat Content – ratio of n-3 to n-6 long chain fatty acids	Industry requested that the ratio specified for n-3 to n-6 long chain polyunsaturated fatty acids (LCPUFA) be removed from the standard. The supporting argument was that research had indicated that infants required docosahexanoic acid (DHA), a n-3 LCPUFA, for effective growth and development, but it was Industry's view that the same could not be said for arachidonic acid (ARA), a n-6 LCPUFA. No other international infant formula standards specified such a ratio, and therefore Industry did not consider that its inclusion was justified.
Fat Content - units of expression	Industry proposed to have ALA expressed as mg/100kJ instead of being expressed as a proportion of total fat. The basis for this argument was that the draft Codex Alimentarius Standard contained values expressed in this format.
Maximum phosphorus composition requirements	Industry requested that the maximum permitted phosphorus content be increased from 25mg/100kJ to 40mg/100kJ. This increase was requested due to the increase in protein limits of 0.43g/100kJ to 1.3g/100kJ for follow-on formula. Industry indicated that the typical phosphorus content of cow's milk was 28mg/100g protein, and therefore any follow-on formula based on cow's milk with a protein level above 0.9g/100kJ would fail to comply with a 25mg/100kJ restriction.
Minimum iron composition requirements	Industry requested that the minimum requirements for iron content be lowered from 0.2mg/100kJ to 0.12mg/100kJ. The supporting argument for this position was that the draft Codex Alimentarius Standard on Infant Formula had proposed a minimum iron content of 0.12mg/100kJ.

[1] Lucas A, Stafford M, Morley R et al. *Efficacy and safety of long chain polyunsaturated fatty acids supplementation of infant formula milk: a randomised trial.* The Lancet 1999; 345: p1948-54.
[2] Makrides M, Bryan D, Paine B, Gibson R (2000) *Review of amino acid profiles, zinc to copper ration and essential fatty acid composition of infant formulas.* A Report to the Infant Formula Manufacturers' Association of Australia.

Issue	Details
Zinc to copper ratio	Industry proposed that the upper limit on the ratio of zinc to copper for infant formula be raised from 12:1 to 20:1. Industry stated that studies have indicated a ratio up to 25:1 as being safe; Codex Alimentarius, European and United States infant formula standards do not specify a zinc to copper ratio; the 12:1 ratio was based on an extreme dietary modelling process; and that significant reformulation of infant formula would need to occur to meet a ratio of 12:1.
Special Purpose Infant Formula	Industry indicated that the majority of infant formula for pre-term and rare medical conditions did not comply with the proposed regulation of these products. A request was therefore made to ANZFA to consider an exemption of such products from composition, labelling and health claim requirements due to their specialised use and method of purchase.
Chromium and molybdenum provisions	Industry noted that chromium and molybdenum were permitted for addition to special purpose infant formula, but not for standard formula. It was therefore requested that Standard 2.9.1 provide a provision for standard infant formula that permitted the voluntary addition of these minerals as listed for special purpose formula (up to 0.35 g/100kJ for chromium and up to 0.36 g/100kJ for molybdenum).
General Microbiological Requirements	Industry indicated that the proposed Standard Plate Count (SPC) for *Bacillus Cereus* was more restrictive than that stated in Standard R7 of Volume 1. Therefore Industry proposed that the requirements stated in the draft Standard should revert back to such levels.
Innovation Clause	Industry tabled a request for a new clause to be added to the standard to the effect that nutritive substances may be added to infant formula to the levels found in human milk. Industry claim the usual ANZFA application process to vary a standard is unacceptable because this would then be assessed in the public domain and this removes any exclusivity rights to the company that has made a significant resource investment.