OVERARCHING COMMENTS

Pfizer Nutrition believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. We however recognise that some infants are not breastfed, for a variety of medical, practical or personal reasons. Pfizer Nutrition believes it is very important that these infants and their carer's are also supported. Often bottle-feeding parents are struggling to find adequate information on formula feeding. A small qualitative study conducted in Queensland has indicated that bottle-feeding mothers want to be taught and be given information on formula feeding, but they feel that they are not receiving it (Wirihana and Barnard, 2011). These results are consistent with the findings of a recent review of implementation of the World Health Organisation (WHO) International Code of Marketing of Breast-milk Substitutes (the WHO Code) in New Zealand, which concluded that *"...there are strong indications that mothers frequently have difficulty obtaining timely information on, and access to, infant formula when they cannot or choose not to breastfeed*" (Burgess and Quigley, 2011).

Ideally, formula-feeding parents should seek infant formula information from a health care professional before starting a formula; however we acknowledge that this will not always be the case. Further, increasingly, infant formula representatives providing scientific and factual information on products are facing access restrictions to healthcare professionals and hence, adequate and accurate formula information is less likely to be passed onto formula-feeding parents. We therefore consider that on pack information is a very important source of information for formula-feeding parents before making an informed choice.

Clause 3 of the revised draft Standard 1.2.7 states that 'a nutrition content claim or health claim must not be made about an infant formula product'. Pfizer Nutrition considers that this should be re-considered as this is not consistent with FSANZ's three primary objectives of protection of public health and safety, provision of adequate information relating to food to enable consumers to make informed choices while preventing misleading or deceptive conduct. Not having access to adequate information may result misleading formula-feeding parents about an infant formula product which can unintentionally cause damage to public health and safety.

Furthermore, as we have provided in our previous submission (Wyeth to FSANZ 15 May 2009), there is an international regulatory precedent in the European Union (EU) for the inclusion of infant formula products in claims regulation that requires pre-market approval. Article 14 of the EU regulation No 1924/2006 (20 December 2006) permits claims referring to children's development and health, including infant formula products. European Food Safety Authority (EFSA) evaluates scientific substantiation of the claim and provides ether positive or negative opinions.

Pfizer Nutrition notes that only three product groups are prohibited from making a nutrition content claim or health claim. Two of these are kava and alcohol, which are not consumed for a nutritional reason, and hence should not be considered as in any way similar to infant formula. On the other hand, for formula-fed infants less than 6 months old, the only source of nutrition is infant formula and therefore infant formula is only consumed for a nutritional reason. It is important that these infants are supported by having the latest science as the foundation when an infant formula is formulated. Innovation should

be encouraged and not discouraged. However, not being able to communicate the latest product innovation may result discouraging manufacturers from investing into research and innovation.

Pfizer Nutrition also considers that the inclusion of 115 pre-approved food-health relationships in draft Standard 1.2.7 is not adequate. This list should also include claims that are currently in use and complies with the transitional standard 1.1A.2 for all permitted nutritive substances as these are intentionally added to a food to achieve a nutritional purpose and such information should be communicated to consumers for them to make an informed choice. Pfizer Nutrition further notes that FSANZ has proposed to review only EU approved claims for inclusion. Pfizer Nutrition strongly recommends review of other authoritative source documents such as health claims approved in US and Canadian regulations as suitability of these claims will be assessed by FSANZ to ensure that they are appropriate for the Australia New Zealand food regulatory system.

SPECIFIC COMMENTS

Table 1: Revised draft Standard 1.2.7

Submitter name: Pfizer Nutrition	
1. Does the revised drafting accurately capture the regulatory intent as provided in Attachment B? Please consider the clarity of drafting, any enforceability issues and the level of 'user-friendliness'. If not, please provide specific details in the table below. Ensure that the relevant clause number, schedule number or consequential variation item number that you are commenting on is clearly identified in the left column. Lines may be added if necessary.	
Clause number	**Comment**
Editorial note – transitional period	Pfizer Nutrition notes that only two-year transitional period has been given and there is no stock-in trade period after this period. This may not be an adequate time period for products with more than two-year shelf life. Furthermore, two year-period won't give the industry adequate time to put an application and FSANZ to approve for claims that are not yet approved for inclusion within the transition period. Pfizer Nutrition suggests at least 3 year-period transitional period.

Clause 3	As addressed in the Overarching Comments section and in the Infant Nutrition Council submission, Pfizer Nutrition considers that there does not seem to be sufficient evidence to support that the restriction of nutrition content claims or health claims on any products under Standard 2.9.1 is necessary.
Clause 8	Pfizer Nutrition notes that a comparative claim is permitted but not in relation to the vitamin or mineral content of a food. Pfizer Nutrition further notes that this prohibition does not include claims comparing the old vitamin or mineral content to the new content of the same brand.
Schedule	**Comments**
1 – Lactose Free	As a testing method is not prescribed in the Code and the testing methods for lactose are improving, Pfizer Nutrition considers a level of threshold should be given as a condition to meet instead of 'the food contains no detectable lactose'. EU Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae provides "Lactose content is not greater than 2.5 mg/100kJ) (10mg/100kcal)" as the condition for "lactose free" claim.
1 and 2 – permitted claims for Infant Food standardised under Standard 2.9.2. E.g. Vitamins, minerals or protein	The fact that a nutrition content claim or health claim is permitted on infant foods standardised under Standard 2.9.2 for 6-12 month infants but these claims are prohibited on follow-on formula (intended for infants from 6 months) is inconsistent. Pfizer Nutrition supports consistency in approach throughout the draft Standard.

Table 2: Fat-free and % fat-free claims

No comment.