Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

30th March 2012

This submission is made on behalf of the Infant Nutrition Council (INC), representing the collective views of its members. The INC represents the significant majority of companies marketing and manufacturing infant formula in Australia and New Zealand.

Members

- Bayer Ltd.
- Fonterra Co-operative Group Ltd
- H J Heinz Company Ltd
- Nestlé Australia Ltd and Nestlé NZ Ltd
- Nutricia Pty Ltd
- Pfizer Nutrition

Associate Members

- Biolife New Zealand Pty Ltd
- Dairy Goat Cooperative (NZ) Ltd
- Murray Goulburn Co-operative Co Ltd
- Sutton Group (NZ)
- Synlait Milk Ltd (NZ)
- Westland NZ Pty Ltd

The INC welcomes the opportunity to comment on the consultation paper for Proposal P293; Nutrition, Health & Related Claims.

The INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not breastfed the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole nutrition at less than 6 months old and it is therefore important when their carers have not consulted a health professional, that they have good evidenced based nutrition and ingredient information on the labels of infant formula product.

Submitter name: Infant Nutrition Council	
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
Part 2 – Claims framework and general principles **3 Nutrition content claims or health claims not to be made about certain foods (c) an infant formula products**	The INC fully supports the promotion of and strategies to increase the rate of breast feeding. However in recognition that there are circumstances when an infant is not or cannot be breastfed or is partially breastfed, where commercial infant formulas are used, consideration must be given to supporting ongoing innovation in the development of infant formula nutritional and functional profiles. To exclude the ability to state nutritional contents of infant formula will discourage innovation in these products and subsequently restrict the potential for improved health outcomes for infants where breast milk is not available or only partially available. INC supports evidence based regulation. However in this instance, there does not seem to be sufficient evidence to support the restriction of nutrition content claims on any product regulated under Standard 2.9.1. Products regulated under standard 2.9.1 are developed to meet the specific needs of infants. The development process of these products involves significant research and innovation at substantial expense. If there is no ability to communicate to the consumer the outcome of the research and innovation in terms of benefit to the consumer to enable informed choice, ongoing innovation and research will be difficult to justify on a cost benefit analysis basis. The resultant outcome will potentially be a restriction in improved health outcomes for the consumer. Although we understand that FSANZ cannot consider the issue of the ability to communicate product innovation to improve health/performance outcomes for products regulated under standard 2.9.1 in relation to P293, there is an opportunity for FSANZ to consider this issue when they undertake the review of Standard 2.9.1, and believe it is critical for FSANZ to do so.

16. New health claims deemed to be high level health claims	The intention of clause 16 is unclear and clarification is required as to whether the clause is intended to reflect the process under which new claims would be considered, or if it relates to the level of evidence industry is required to submit when FSANZ considers a new claim. INC notes that a high level health claim variation is defined in the Food Standards Act. Although we understand that the Act has provisions for confidentiality to ensure market advantage for applicants, it does not make it sufficiently clear as to what the process would be in relation to time, costs and who/how the claims would be considered. There is not enough information available for industry to make a considered submission on the question of the process of new claims consideration. Should the clause be related to levels of substantiation required to make a new claim, the requirement provides no differentiation between the substantiation for current general level health claims and new claims. The level of convincing should not be required for consideration of new general level health claims by FSANZ. Requirement for a level of convincing might have had it merits in providing a solution to the issues surrounding enforcement and the need for a definitive line, however since FSANZ will be considering all new claims a level of convincing should not be required. The level of convincing is an onerous and near to impossible level of substantiation to meet, and unnecessary when the degree of promise made by a claim is low. We encourage FSANZ to approach the substantiation of claims in the manner that was initially provided in the policy guideline on heath claims and relative to the degree of promise. The level of substantiation required should therefore be commensurate with the degree of promise – in other words the degree of promise for general level claims is low and therefore the level of substantiation or convincing should be in alignment with this.

Submitter Name	Infant Nutrition Council
Question	Comment
2. What evidence can you provide that shows consumers are purchasing foods of lower nutritional quality because they are being misled by fat-free or % fat-free claims? **FSANZ is primarily interested in the substitution of foods of higher nutritional quality with foods of lower nutritional quality which have fat-free claims. Substitution within a general food group (e.g. choosing a different confectionery product) is of lesser importance.** ***(Note: Please provide documented or validated evidence where possible)***	FSANZ is investigating additional criteria based on the principle of informed choice by consumers and to ensure they are not being misled by fat-free claims. "FSANZ is primarily interested in the substitution of foods of higher nutritional quality with foods of lower nutritional quality which have fat-free claims. Substitution within a general food group (e.g. choosing a different confectionery product) is of lesser importance." In this context INC takes the opportunity to point out that the need for consumers to have provisions to make informed choices is not limited to claims on the fat content of a food, but that the same principle applies in relation to making the most appropriate infant formula choice. We believe that food standards should be based on science and question the evidence or proof of harm to infants from the inclusion of a content or substantiated health claim on pack. Further, we request that you consider the commentary by Professor Berthold Koletzko in the Annals of Nutrition and Metabolism where he discussed the issue of health claims and made the following comment "*Preventing communication of scientifically assured benefits of optimised products bears the risk that it may slow or even stop the significant quality improvements of foods for infants that has occurred over the last decades in numerous single steps, and which has led to large benefits for child health*" (attached) Ideally a parent or carer should contact a health care professional before commencing infant formula feeding, however this will not always be the case. In addition, increasingly, infant formula representatives providing scientific and factual information on products are facing access restrictions to healthcare professionals[1]. Nutrition and ingredient information on labels provide an important source of information for consumers when a health professional is not consulted. Although we understand that FSANZ will not consider this issue in relation to P293, there is an opportunity for FSANZ to consider permissions for nutrition and health claims when they undertake the review of Standard 2.9.1. The prohibition of claims on infant formula products, when Standard 1.2.7 is gazetted, will have an impact on a number of trade related issues.

	The first issue concerns the difficulty in meeting the stock in trade provisions especially for low volume imported products. Marketers are required by the distributers and supermarkets to have 6 months of stock available. The lead-time required for the ordering and transit of these low volume specialty products is approximately 6 months. INC would appreciate that the stock in trade period was extended to 3 years. Despite the potential of an extended stock in trade period, it is likely that low volume imported specialty products will become unavailable to ANZ consumers, as the economics of getting them re-labelled to remove any claim from the pack will be cost prohibitive. The second trade issue pertains to the export of infant formula products every year out of Australia and New Zealand. Many of these products are finished products and labelled to go into market. The requirement for export certification will be complicated by the potential need for consideration of exemptions for labelling claims. This may have the unintended consequence of a technical barrier to trade.

[1] INC is currently undertaking a research project related to infant formula company communications with health care professionals. The results of this project are expected to be released in the later part of 2012.

Commentary

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Health Claims: Let Science Prevail

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On March 16, 2011, a slight majority of members of the European Parliament's Committee on Environment, Public Health and Food Safety adopted a resolution aiming at the refusal of authorising a health claim on infant foods (30 votes in favour, 28 against, 1 abstention) [1]. This resolution opposes the adoption of the health claim 'Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age', which had been recommended for adoption by both the European Commission and the Standing Committee on Food of the European Member States. Following this committee vote, the European Parliament's plenary will now have to take a decision in the near future as to whether it supports or rejects the adoption of this health claim.

How did this amazing controversy evolve? The European regulation on health claims for foods stipulates that these should be truthful and based on generally accepted scientific evidence of the relationship between diet and health [2]. Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims, and it should be based on the totality of available scientific data [2]. The European Food Safety Authority (EFSA) has been charged to perform this scientific evaluation, with the help of qualified scientists. In the current case, EFSA has reviewed the available evidence. It concluded that a cause and effect relationship is established between the intake of infant and follow-on formulae supplemented with docosahexaenoic acid (DHA) at levels at or above 0.3% of total fatty acids and visual function at 12 months in formula-fed infants, and also in breastfed infants receiving such formulae after weaning [3]. EFSA concluded that the wording 'DHA contributes to the visual development of infants' reflects the scientific evidence but should be restricted to formulae that contain at least 0.3% of the total fatty acids as DHA.

While this seemed like a straightforward case based on adequate scientific data, an activist group in the United Kingdom embarked on active lobbying against the adoption of this health claim, apparently driven by the conviction that no infant food should bear health claims. The activist group convinced some members of the European Parliament to support its cause and to propose the cited resolution, which has adopted a number of pseudoscientific arguments of the activists, unfortunately without critical evaluation of their validity.

The adopted resolution reports that scientific evidence shows a benefit of DHA in breast milk for the visual development of infants, whereas such effects of DHA in formula had not been demonstrated. To support this conclusion, one single systematic review is cited which states that there would be no conclusive evidence for benefits of adding the ω-3 fatty acid DHA to infant formulae, although the authors acknowledged that some studies found benefits on visual function [4]. However, in contrast to the EFSA analysis, these authors did not consider the amount of DHA added to formula as a predictor of outcome.

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EFSA based its conclusions on this question not on a single, selected publication, but reviewed the totality of available data with the required scientific accuracy. EFSA evaluated 43 relevant scientific publications, including 13 publications on randomised clinical trials [3]. The evaluation performed by EFSA is thorough and meets high scientific standards. It is very surprising and disturbing that the members of the European Parliament find such a profound scientific evaluation by an independent body less convincing than the arguments of a loud-mouthed lobbying group.

The resolution also raises concerns on the safety of adding the ω-3 fatty acid DHA to infant formulae, borrowing analogous statements of the said activist group. This is anomalous since independent from any potential health claims, any formula for infants is only suitable for marketing in Europe if it is safe for infant feeding [5]. European legislation supported by the European Parliament accepted the optional addition of DHA and other long-chain polyunsaturated fatty acids to infant and follow-on formulae as a safe measure [5], based on a thorough scientific assessment of its suitability and safety by the Scientific Committee on Food [6].

The resolution raises worries on safety by referring to a follow-up study in a subgroup of 10-year-old children who had previously participated in an infant feeding study [7]. However, the citation of findings from this study is incomplete and misleading. An unbiased evaluation of this study leads to the conclusion that it does not at all demonstrate untoward effects of DHA addition to infant formulae. The authors revisited a small subgroup of 45% of the initial study population at the age of 10 years. The considerable attrition with a high potential for selection bias obviously limits the conclusions that can be drawn with respect to long-term effects of early feeding. Moreover, the study did not find any group differences for growth in the total study population, and among boys. The small group of 25 examined girls, who as infants had received an infant formula with DHA, was significantly taller at the age of 10 years (by about 4 cm) than the group of girls who had received a control formula without DHA. The taller group of girls also had a proportionally higher body weight, whereas the body mass index was not different. As one would expect, also the mean blood pressure was slightly higher in the girls with a larger body size, which reflects the fundamental laws of physics: larger people have a higher blood pressure. Of importance, these evaluations represent a secondary subgroup data analysis deviating from the original study hypothesis. Therefore, these analyses do not have the power to demonstrate a causal relationship to the type of feeding provided in infancy. If one would wish to construct such a relation, one would actually have to conclude that DHA supply of infant formulae had a beneficial effect on length growth and not untoward effects.

Furthermore, the adopted resolution does not reveal that a systematic review and meta-analysis of a large number of controlled trials showed no effects of DHA enrichment of infant formulae on child growth [8]. Also, it does not refer to a follow-up study in children that had previously received infant formula with or without DHA [9]. Children in the DHA group did not differ in growth but showed a beneficial blood pressure-lowering effect at early school age. The rather selective presentation of data in the draft resolution is very disturbing since it does not facilitate a balanced and rational judgement by the members of parliament.

The resolution proposes that there would be no scientific agreement on the usefulness of providing the ω-3 fatty acid DHA with food products for infants. This suggestion is in stark contrast to numerous national and international recommendations that uniformly recommend a DHA supply to infants and are supported i.e. by the World Health Organisation, the Food and Agriculture Organisation of the United Nations, the World Association of Perinatal Medicine, the Child Health Foundation, the Diabetic Pregnancy Study Group, the Early Nutrition Academy, the European Association of Perinatal Medicine, the European Society for Clinical Nutrition and Metabolism, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition, the International Federation of Placenta Associations, the International Society for the Study of Fatty Acids and Lipids, and the French Food Safety Authority AFFSA.

Perhaps one might question whether there should be any health claims made for infant food products, since breastfeeding is clearly considered the optimal form of infant feeding which therefore must be strongly protected, promoted and supported [10]. However, not all infants are fully breastfed during the first half year of life and partially breastfed thereafter. For these infants, safe infant formulae of the highest possible quality are required, and health care professionals and families should be able to receive appropriate information on their characteristics [11]. European legislation supports that relevant science-based product properties can be declared for formulae for infants to allow for a selection of appropriate products by physicians, other health care professionals and families, given they are based on a properly scrutinised

scientific basis (e.g. properties such as lactose free, hypoallergenic) [5]. In the European Union, EFSA has been charged with examining the scientific basis of potential further product claims, which EFSA performs with high scientific thoroughness applying very strict standards. Clearly, any decisions on the authorisation of health claims for food products for infants should be based on such a meticulous, medical-scientific evaluation and not on biased lobbying of activist groups.

Preventing communication of scientifically assured benefits of optimised products bears the risk that it may slow or even stop the significant quality improvements of foods for infants that has occurred over the last decades in numerous single steps, and which has led to large benefits for child health. In the future, manufacturers might not be willing any more to invest major resources into the development, clinical evaluation and implementation of further improvements, if there is no chance to communicate such improvements. Such a development may considerably compromise the further optimisation of infant nutrition which is so necessary for further improving child health. Therefore, it is truly important that science and not lobbying prevails in this matter.

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European Parliament vote on Health Claim for Baby Foods

Proposals to allow producers to claim that adding the fatty acid DHA to baby food 'contributes to the normal visual developments of infants up to 12 months of age' were backed by the European Parliament on April 6, 2011. The resolution opposing the plan did not achieve the majority of votes required (328 for, 323 against and 26 abstentions) and is therefore rejected.

http://www.europarl.europa.eu/en/pressroom/content/20110406IPR17110/html/DHA-in-baby-food-European-Parliament-approves-health-claim