10 reasons to stop this DHA[1] claim

Mead Johnson advert claiming that DHA-fortified formulas aid eye development. After investigations and legal actions the eye claims are now rarely used in the USA.

On 6th Dec 2010 the **EU Standing Committee on Food Chain and Animal Health** (SCoFCAH) [2] approved the following health claim for use on follow-on formulas [3] and baby foods: ***'DHA has a structural and functional role in the retina and DHA intake contributes to the visual development of infants up to 12 months of age.'***
A Resolution objecting to this claim was passed at the **Committee on the Environment, Public Health and Food Safety** and the majority of MEPs voted to stop the claim at the full Plenary of the European Parliament on April 6th. [4] However this was not an 'absolute majority' of all MEPs - so the Commission can still authorise the claim.

1 The claim conflicts with leading scientific opinion and is highly promotional. There is no consistent peer-reviewed independent evidence of a causal relationship between DHA-fortified formulas and better visual acuity in term babies. The 2007 Cochrane Library concluded: *"This review found that feeding term infants with milk formula enriched with LCPUFA had no proven benefit regarding vision, cognition or physical growth."* [5]

2 The European Food Safety Authority (EFSA), which evaluates the evidence for health claims, is not required to look at independently-funded research. [7] The EFSA opinions state that it could not have reached its conclusion *"without considering the studies claimed by the applicant as proprietary."* [6]

3 EFSA further clarified its opinions in a letter to the European Commission six months later, stating that there is no sound evidence to support the claim for follow-on formulas or baby foods:*"The evidence, however, does not establish that starting DHA supplementation at 4-6 months in infants who had received a control (DHA-free) formula in the first months of life would have an effect on the visual development of those children... There are no data from specific randomised control trials supporting a benefit of DHA supplementation starting at 6 months of life in infants fed a DHA-free formula in the first 6 months of life...."* [8]

4 The synthesised DHA added to formulas is in a different biological environment to breastmilk, which is a species-specific, living substance. Formula contains no co-enzymes or co-factors to enable the fats to work optimally. The US FDA stated to Martek (the DHA manufacturer): *"The bioactive fatty acids ARA and DHA when consumed in mature human milk are part of a complex matrix that includes, for example, linoleic acid, alpha-linolenic acid, and other polyunsaturated fatty acids ...important physiologic considerations relative to the matrix are not accounted for by the simple addition of LCPUFAs to infant formula."* EFSA said that "*none of the studies presented has shown a benefit of either DHA alone or DHA plus ARA on visual development as compared to the breast fed control group."* [6]

5 In 2007 the UK Scientific Advisory Committee on Nutrition said: "*We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupportable. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding."*[9]
The EU should remove inferior formulas from the market.

6 EFSA is not required to assess the 'risk' of ingredients or claims. Member States and the Commission do this in private meetings. A 2010 10-year follow-up of babies fed of DHA formulas found that the girls were heavier and had higher blood pressure.[10] The 98 reports made to the US Food and Drug Administration (FDA) indicate that a subset of babies cannot tolerate synthetic DHA enriched formulas. FDA approval for DHA was given on condition companies carry out post-market surveillance - which does not seem to have been done.[11]

7 Since 1989 the procedures governing regulations on baby foods have been undemocratic and lacking in transparency. They badly need updating. Member States have asked that all ingredients are indepently evaluated and pre-authorised but the Commission has refused to allow this. [12] At the December meeting several Member States voted no, abstained or said they did not have enough expert advice. *"Three delegations expressed the view that allowing the use of health claims on foods intended for infants and young children, and more specifically on follow-on formulae, could make such products more attractive for mothers and thus could interfere with the promotion of breast feeding and questioned their authorisation."* [2]

8 The Health and Nutrition Claims Regulations [13] **aim to help the public make healthier decisions, not to mislead.** All parents want the best for their children and need truly independent evidenced-based information - not claims that highlight ingredients and mask the risks of the whole product.

9 Private legal actions and investigations by the US FDA, the Federal Trade Commission and Health Canada of the Mead Johnson claims, described them as *'repeated flagrant violation of the US industry self-regulation adjudications'* and as *"unsubstantiated, unacceptable, misleading and unauthorized."*[11]

10 EU **authorisation of this claim will damage infant health globally**, especially in developing countries where breastfeeding can be a matter of life or death. The claim will appear on formula exports and policy makers, assuming the EU follows the highest standards, will 'cut and paste' the authorisation into national laws.[14]

[9] *"We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupportable. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding."*
UK Scientific Advisory Committee on Nutrition (SACN) 2007

[9] *"The Royal College of Paediatrics and Child Health supports breast feeding as the optimal way to feed an infant. Its totally inappropriate for infant formulas or follow on formulas to carry health or nutrition claims, which inevitably imply a health advantage over breastfeeding. Claims are especially problematic (or misleading) when independent and well respected bodies such as the Cochrane Library have found no evidence to support them. Since infants are a vulnerable group the safety of the ingredients is paramount, so additives should only be used if they have been demonstrated by an independent review of scientific data to be safe and essential. Then they should be added to ALL formulas - not promoted with a claim."* Dr. Colin Michie, Chair of Nutrition, Royal College of Paediatrics and Child Health, 2010

"Even if Formulaid (DHA/AHA) had no benefit we think that it would be widely incorporated into most formulas as a marketing tool and to allow companies to promote their formula as 'closest to human milk'."
Hambrecht & Quist Spot Report on the Martek Bio-sciences Corporation in 1996 - when synthetic DHA was first developed commercially.

[9] Member States are called on to *"end to all forms of inappropriate promotion of foods for infants and young children and to ensure that nutrition and health claims shall not be permitted except where specifically provided for in relevant Codex Alimentarius standards or national legislation."* WHA 2010 Resolution on Infant and Young Child Nutrition (63.23)

References:

1 DHA (docosahexanenoic acid) is a long-chain-polyunsaturated fatty acid found in mammalian milk. Long chain polyunsaturated fatty acids (LCPUFA) are important in the normal development of infants, and whilst human milk contains small concentrations of DHA, formula milk generally only includes precursor fatty acids which can only be synthesized into DHA in limited amounts. DHA is a major fatty acid in the phospholipids of the photoreceptor cells of the retina in the eye.

2 The SCoFCAH committee meets in private. The summary record of the December 6th meeting is published, but does not state the positions of national delegations. See: http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/sum_06122010_en.pdf

3 Follow-on formulas are breastmilk substitutes for older babies and according the *WHO/UNICEF International Code of Marketing of Breast-milk Substitutes* and subsequent WHA Resolutions, should not be promoted. Follow-on formulas are not necessary - babies not breastfed can be fed infant formula after 6 months and for as long as necessary. Follow-on formulas were invented by the baby food industry to get round the *International Code* and their promotion invariably transfers to infant formulas sharing the same brand. The EU *Infant Formula and Follow-on Formulae Directive* (141/2006/EC) has only minimal restrictions on the promotion of infant formulas and no restrictions on follow-on formula promotion. Infant formulas can carry six nutrition claims and one disease risk reduction claim. Claims for follow-on formulas must be authorised.

4 *Motion for a Resolution by Glenis Willmott, Daciana Sarbu, Nessa Childers and Karin Kadenbach on the draft Commission regulation on the authorisation and refusal of authorisation of certain health claims made on foods and referring to children's development and health*, Environment, Public Health and Food Safety Comm. 24.2.2011 www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/re/858/858750/858750en.pdf

5 *Simmer K, Patole S, Rao SC. Longchain polyunsaturated fatty acid supplementation in infants born at term. Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD000376. DOI: 10.1002/14651858.CD000376.pub2* www2.cochrane.org/reviews/en/ab000376.html
Infant Formula Supplementation With Long-chain Polyunsaturated Fatty Acids Has No Effect on Bayley Developmental Scores at 18 Months of Age. Beyerlein et al, J Pediatr Gast Nutr. 2010 Jan;50(1):79-84 *"LCPUFA supplementation of infant formula does not have a clinically meaningful effect on the neurodevelopment as assessed by Bayley scores at 18 months...except possibly for very low-birth weight babies."* www.ncbi.nlm.nih.gov/pubmed/19881391

6 The potential for bias is present in all research and compounded by publication bias where trials with negative outcomes are less likely to be published. Misleading findings are reduced if research is commissioned and funded by a disinterested party rather than one active in the market and where academic rigour can be demonstrated in the research process. There is a need for independent publicly financed studies to evaluate the safety and efficacy of ingredients used in formulas.

7EFSA published three opinions on DHA and ARA in January and March 2009: www.efsa.europa.eu/en/efsajournal/doc/941.pdf www.efsa.europa.eu/en/efsajournal/doc/1003.pdf www.efsa.europa.eu/en/efsajournal/doc/1004.pdf

8 Letter from EFSA to the European Commission 3.9.2009: http://ec.europa.eu/food/efsa/comments/efsa_reply_q_2008_211.pdf

9 See SACN and RCPCH Quotes in Box above. Also the view of the UK Baby Feeding Law Group represents 23 health professional and lay organisations including the Royal College of Paediatrics and Child Health and the Royal College of Midwives www.babyfeedinglawgroup.org.uk/index.html

10 *The 10-year follow-up of a randomised trial of longchain polyunsaturated fatty acid supplementation in preterm infants: effects on growth and blood pressure. Arch Dis Child 2010;95:588–595. 588 doi:10.1136/adc.2009.167270* with responses http://adc.bmj.com/content/95/8/588/reply#archdischild_el_8934

11 98 reports obtained after a Freedom of Information request US FDA. *Replacing mother - Imitating Breast Milk in the Laboratory.* www.cornucopia.org
FDA Q&A: www.fda.gov/Food/FoodSafety/Product-SpecificInformation/InfantFormula/ConsumerInformationAboutInfantFormula/ucm108079.htm
FDA letter regarding the lack of post-market surveillance: http://info.babymilkaction.org/sites/info.babymilkaction.org/files/FDA Post market.pdf
Obama administration bans two additives used in organic baby food www.washingtonpost.com/wp-dyn/content/article/2010/04/27/AR2010042704500.html
Mead Johnson and Martek stop using DHA claims in the USA and Canada http://info.babymilkaction.org/news/policyblog/USA

12 In 1986 MEPs voted overwhelmingly in favour of the *International Code of Marketing of Breast-milk Substitutes* as a Directive for Europe. In 1989 the rules where changed and a Framework Directive (*Council Directive on Foodstuffs Intended for Particular Nutritional Uses* (89/398/EEC) called PARNUTs was adopted. This transferred the power to initiate and finalize legislation on baby foods and specialised foods to the European Commission, with no need to consult Parliament. PARNUTS is on the agenda of the *Employment, Social Policy, Health and Consumer Affairs Committee* on 6-7th June 2011, where it is hoped that it will be scrapped or made transparent, accountable and democratic.
http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm http://register.consilium.europa.eu/pdf/en/10/st16/st16030.en10.pdf

13 *European Nutrition and Health Claims Regulations* (1924/2006) make provision for *"implementing measures to ensure that any claim made on foods' labelling, presentation or marketing in the European Union is clear, accurate and based on evidence accepted by the whole scientific community. Consequently foods bearing claims that could mislead consumers will be eliminated from the market."* Since 2008 EFSA has been preparing scientific opinions on 4185 industry dossiers for claims - extracted from 44,000 supplied by Member States. http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

14 *Breaking the Rules - Stretching the Rules 2010.* This independent monitoring report from over 46 countries shows how the baby food industry uses claims that mislead parents to increase sales of breastmilk substitutes and baby foods. www.ibfan.org/icdc/ http://info.babymilkaction.org/node/387