

16th April 2009

Lars Korsholm  
Administrator  
European Commission  
DG SANCO  
200 rue de la Loi  
Brussels B11049

**BFLG**  
Baby Feeding Law Group  
Strengthening UK baby food laws

Dear Lars Korsholm

**Mead Johnson claim on visual development associated with DHA and ARA supplementation Scientific Opinion. EFSA Journal (2009) 941, 1-14. Question No EFSA-Q-2008-688**

Further to my telephone call I am writing to express the concern of IBFAN and also of the Baby Feeding Law Group, regarding the opinion of the EFSA expert committee to approve the claim, "*DHA contributes to the visual development of infants,*" for infant and follow-on formula for a target population of "*formula-fed infants born at term from birth up to 12 months and breastfed infants after weaning up to 12 months.*"

In the box below we outline why we consider this approval is unjustified and why the claim should not be permitted - even if qualified with a warning. Aside from the specific comments regarding the scientific evidence, breastmilk substitutes (including follow-on milks, which are breastmilk substitutes for the older baby) will never have a health advantage over breastfeeding (which is not packaged and promoted). It follows that health or nutrition claims for these products can never be justified and their use will mislead the public, masking the risks and undermining breastfeeding, so conflicting with national and European health policies.[2] These problems are exacerbated when these products are exported to countries where the risks of artificial feeding are even greater.

We are pleased that EFSA has taken a fairly tough line with many other applications, for example claims about DHA and AHA and brain development (EFSA-Q-2008-212, EFSA-Q-2008-329) and galacto-oligosaccharides and intestinal ailments (EFSA-Q-2008-270). We hope that these decisions will be accepted by the Commission and Member States and that the misleading claims will be removed by the companies wherever they occur.

If an ingredient has been unequivocally demonstrated to be essential and beneficial by an independent review of data (which must contain as large as possible proportion of independently-funded research) it should be a mandatory ingredient in all breastmilk substitutes, not flagged up with a claim for commercial advantage.[3] While opposed in principle to all claims on foods for infant and young children, the BFLG recommends that if any are permitted they are placed at the back of the package next to the nutrition panel in non-promotional text.

Claims on commercial complementary foods compete unfairly with fresh, home prepared family foods, continued breastfeeding and sound complementary feeding practices. For this reason the Codex Guidelines on Health and Nutrition Claims[4] recommended in Paragraph 1.4 "Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

I would be grateful if you could forward this letter to Member States for consideration at the Standing Committee meeting where this matter will be discussed.

With best wishes



Patti Rundall, OBE,  
on behalf of The Baby Feeding Law Group  
cc Juliane Kleiner, EFSA

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**Member organisations:** Association of Breastfeeding Mothers - Association for Improvements in the Maternity Services - Association of Radical Midwives - Baby Milk Action - Best Beginnings - Breastfeeding Community - Breastfeeding Network - Caroline Walker Trust - Community Practitioners and Health Visitors' Association - Food Commission - Lactation Consultants of Great Britain - La Leche League (GB) - Little Angels - Midwives Information and Resource Service - National Childbirth Trust - Royal College of Midwives - Royal College of Nursing - Royal College of Paediatrics and Child Health - The Baby Café - UK Association for Milk Banking - Unicef UK Baby Friendly Initiative - UNISON - Women's Environmental Network.

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Scientific Opinion EFSA Journal (2009) 941, 1-14). Question No EFSA-Q-2008-688**

1. The claim should have been rejected by EFSA on the basis 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” and that “Such amounts can be easily consumed as part of a balanced diet.”
2. Infant formulas will (rightly) not be able to carry the approved claim because it is not listed in Annex IV of EC Directive 141/2006. However, if a follow-on milk does so - even if qualifying statements are made along side the claim - parents might well believe that the product - on its own- will confer the advantage suggested and might discontinue breastfeeding on the strength of this – even though there is no evidence for this.
3. It is our understanding that the evidence provided by Mead Johnson in this case relates to infant formulas fed from birth, to breastmilk and to a study using solid food - but not to follow-on formulas fed alongside other foods. One of the studies quoted (Hoffman et al) supposedly proved an effect for supplementation of solid food alongside breastfeeding studied 51 infants. However, there is no mention of blinding either of parents or investigators and the milk intakes are not measured, but assumed. The actual contribution of breastmilk to DHA intake in either group is therefore not known but estimated.
4. EFSA based its opinion on industry sponsored research: “The Panel could have not reached this conclusion without considering the studies claimed by the applicant as proprietary” Industry sponsored research seems to claim positive results more often than research that is independent from commercial interests (BMJ 2003;326:1167-70; JAMA 2008;300:1069-71).
5. A link to declarations of conflict of interests by the members of the panel and all those consulted is missing from the report. We have contacted EFSA about this and they have agreed to make access to this information clearer in future. While transparency is extremely important, and we welcome the many steps that EFSA has taken to improve this matter over the years, it is no substitute for independence, and questions remain about some members of the panel who seem to have financial interests that could constitute an unacceptable conflict.
6. We have concerns about the efficacy and safety of the artificially-made versions of DHA and AA - and note with alarm the EFSA disclaimer: “The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of docosahexaenoic acid and arachidonic acid, a positive assessment of its safety, nor a decision on whether docosahexaenoic acid and arachidonic acid are, or are not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.”
7. We have previously referred EFSA and the Commission to the report by the Cornucopia Institute in the USA, regarding the adequacy of information to determine safety and efficacy of the clinical trials required for premarket approval of LCPs. Cornucopia and the National Alliance for Breastfeeding Advocacy (NABA) are petitioning the Food and Drug Administration for labels to warn of the possibility of an adverse reaction to DHA/ARA-supplemented formula. (see Replacing Mother, Imitating Human Breast Milk in the Laboratory (Jan 08) [www.cornucopia.org](http://www.cornucopia.org))

[1] Baby Milk Action is the UK member of the International Baby Food Action Network, a global network of over 200 citizens groups in more than 100 countries working to protect infant and young child health through strengthening independent, transparent and effective controls on the marketing of the baby feeding industry. [www.babymilkaction.org](http://www.babymilkaction.org) [www.ibfan.org](http://www.ibfan.org)

[2] All EU Member States endorse World Health Assembly Resolutions on infant and young child nutrition. These Resolutions recommend exclusive breastfeeding for the first six months of life, followed by continued breastfeeding, alongside appropriate complementary feeding for two years and beyond as the optimum way to feed infants and young children. Follow-on milks are considered “not necessary” by the World Health Assembly [2] and several Member States. Non-breastfed children should continue to have infant formula as the milk component of its diet.

[3] Baby Milk Action/IBFAN/BFLG Submissions regarding Martek claim for LCPs, Unilever Claim for Alphalinolenic Acid, Aug,Sept 2008. EFSA-Q-2008-079

The UK Baby Feeding Law Group is an adhoc group of 23 health professional and lay organizations working to bring UK and EU legislation into line with the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions. Its members are: The Association of Breastfeeding Mothers, the Association for Improvements in the Maternity Services, the Association of Radical Midwives, Baby Milk Action, the Breastfeeding Network, the Food Commission, the Caroline Walker Trust, the Community Practitioners and Health Visitors' Association, Lactation Consultants of Great Britain, La Leche League (GB), Little Angels, Midwives Information and Resource Service, the National Childbirth Trust, the Royal College of Midwives, the Royal College of Nursing, the Royal College of Paediatrics and Child Health and the Unicef UK Baby Friendly Initiative. [www.babyfeedinglawgroup.org.uk](http://www.babyfeedinglawgroup.org.uk) The Breastfeeding Manifesto Coalition is a coalition of 40 organisation calling for action in 7 areas to protect, promote and support breastfeeding. [www.breastfeedingmanifesto.org.uk/](http://www.breastfeedingmanifesto.org.uk/)

[4] Guidelines For Use Of Nutrition And Health Claims CAC/GL 23-1997, Rev. 1-2004)

## Baby Feeding Law Group Members. January 2007

- 1 **The Association of Breastfeeding Mothers** (ABM) is a membership-based Charity, founded in 1979, with 400 breastfeeding counsellors providing mother-to-mother support to women. ABM takes no money from infant feeding companies.
- 2 **The Association for Improvement in the Maternity Services** (AIMS) is a pressure group, with 730 members which was founded in 1960. AIMS gives information and advice about all aspects of maternity care, including parents' rights, choices, technological interventions, normal childbirth and complaints procedures.
- 3 **The Association of Radical Midwives** (ARM) is a charity which provides a support for its 1,400 members who are midwives, student midwives and others in the UK committed to improving the maternity care provided by the NHS and who believe that all women have the right to a service tailored more closely to their needs. The ARM is funded by membership fees and takes no money from the baby feeding industry,
- 4 **Baby Milk Action** is a membership-based organization of over 2000 members which aims to save lives and to end the avoidable suffering caused by inappropriate infant feeding. It works within the European and global network, the International Baby Food Action Network, to strengthen independent, transparent and effective controls on the marketing of the baby feeding industry. IBFAN has over 200 citizens groups in more than 100 countries, including nearly all EU Member states. It takes no money from the infant feeding industry
- 5 **Best Beginnings** is a not-for-profit organization working to increase breastfeeding rates in the UK.
- 6 **The Breastfeeding Network** (BfN) is a mother-to-mother support and membership organisation with 725 members. BFN takes no money from the infant feeding industry.
- 7 **The Food Commission** is an independent national non-profit organization, campaigning for the right to safe, wholesome food. It is largely funded by public subscriptions and donations and takes no subsidy from the government or food industry. Its flagship publication, The Food Magazine, has a readership of 10,000.
- 8 **The Community Practitioners and Health Visitors Association** (CPHVA) represents its 21,000 members who are community health professionals.
- 9 **Lactation Consultants of Great Britain** (LCGB) represents over 100 Lactation consultants in Great Britain.
- 10 **La Leche League GB** is part of an international organisation that provides information and support to breastfeeding mothers, through mother-to-mother support. LLL GB has 200 breastfeeding counsellors, 749 mothering members, 1242 peer counsellor members and 97 health professional members. LLLGB does not accept funding from producers of infant formula or any other product or service which might undermine breastfeeding or devalue the importance of nurturing.
- 11 **Little Angels** is a community non-profit making organization which provides breastfeeding support.
- 12 **Midwives Information and Resource Service** (MIDIRS) is an educational charity set up in 1985 which in 2004, distributed 54,000 copies of its Midwifery Digest to midwives and other health professionals, giving an overview of key midwifery and medical research. Its Enquiry Service provides access to the MIDIRS database of over 110,000 articles, with over 500 new references added each month to this valuable resource. Currently MIDIRS processes over 750,000 enquiry requests per annum from health professionals wishing to gain access to this information. The MIDIRS Informed Choice Initiative was launched in 1996 and to date over 1.4 million leaflets have been used by health professionals and prospective parents.
- 13 **The National Childbirth Trust** (NCT) is a membership-based charity, established 49 years ago, and with currently over 64,000 members in the UK and a network of over 350 local branches. NCT provides a range of services for parents including antenatal classes, postnatal discussion groups, breastfeeding counselling which are available to members and non-members alike. The NCT takes no funding from formula companies.
- 14 **The Royal College of Midwives** (RCM) is the only trade union and professional organisation run by midwives for midwives. It is the voice of midwifery, providing excellence in professional leadership, education, influence and representation for and on behalf of midwives. The RCM has a membership of 37,000.
- 15 **The Royal College of Nursing** and the RCN Midwifery Society is the leading professional union for nursing, safeguarding the interests of patients and nursing by lobbying government and other professional bodies to ensure that the views of the profession are heard where it counts. The RCN is a member-led organisation of around 370,000 nurses and midwives and is signatory to WHO/UNICEF Baby Friendly Standards.'
- 16 **The Royal College of Paediatrics and Child Health** (RCPCH) has about 7,000 members. The College aims to advance the art and science of paediatrics, improve standards of medical care to children, and to educate and examine doctors in paediatrics. The College also provides information to the public on children's health care.
- 17 **The UNICEF UK Baby Friendly Initiative** (BFHI) is a global programme of UNICEF and the World Health Organisation which works with the health services to improve practice in the support of breastfeeding. In the UK, the UNICEF Baby Friendly Initiative is commissioned by various parts of the health service to provide advice, support, education, networking, assessment and accreditation.