

Basil Mathioudakis  
European Commission  
DG SANCO  
200 rue de la Loi  
Brussels B11049



6th May 2011

Dear Basil,

I am writing on behalf of Baby Milk Action, the International Baby Food Action Network and the Baby Feeding Law Group, regarding the following two opinions.

- 1. Scientific Opinion on the substantiation of a health claim related to alpha-linolenic acid and contribution to brain and nerve tissue development pursuant to Article 14 of Regulation (EC) No 1924/20061 On request from the Competent Authority of Germany, following an application by HiPP GmbH & Co Vertrieb KG, Question No EFSA-Q-2009-00197, adopted on 25 March 2011 and published on the 8th April.**
- 2. Scientific Opinion on the substantiation of a health claim related to thiamin and maintenance of normal neurological development and function pursuant to Article 14 of Regulation (EC) No 1924/20061 On request from the from the Competent Authority of Germany following an application by HiPP GmbH, Question No EFSA-Q-2009-00455, adopted on 28 January 2011.**

We are aware that the deadline for comments on Question No EFSA-Q-2009-00455 has passed, however since the discussion on both claims are related and unfinished, we would like to request that the following comments are passed on Member States and all those involved in the risk assessment of these claims.

**We consider the approval of both the above claims to be unjustified and request that they are not be permitted for the following reasons:**

1. Authorisation of such highly promotional claims for follow-on formulas and baby foods conflicts with leading scientific opinion, and undermines the aim of the Health and Nutrition Claims Regulations which is 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 certain ingredients in a way that will mask the risks of the whole product.
2. The ingredients are already listed as essential in the COMMISSION DIRECTIVE 2006/141/EC and COMMISSION DIRECTIVE 2006/125/EC so should be covered by the safeguard in the General Labelling Directive. Article 2 (1) which states that: *"The labelling and methods used must not: (a) be such as could mislead the purchaser to a material degree, particularly: (iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics"*
3. By highlighting just one ingredient the claim will distort parents perceptions of the nutritional value and safety of the product as a whole, which in the case of products covered by the COMMISSION DIRECTIVE 2006/125/EC allows unacceptably high levels of sugar.
4. The fact that the claim may also be carried on baby foods or drinks that meet just 15% of the required composition presents further risks and will allow even poorer quality baby foods to carry promotional claims. This could seriously undermine infant and young child health as the products will compete unfairly with foods that may be healthier: fresh, home prepared family foods, continued breastfeeding. All EU Member States have a responsibility to protect optimal child health and sound complementary feeding practices.

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5. The fact that health claims for essential ingredients are now being considered for approval demonstrates that there is an urgent

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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.

need for a revision of the legislation covering the marketing of these products. It also strengthens the argument put forward by WHO, UNICEF and most leading health bodies that there should be no health or nutrition claims on any foods for infants and young children.

6. The WHA 2010 Resolution on Infant and Young Child Nutrition (63.23) which all EU Member States have a responsibility to implement specifically calls on Member States 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.”*
7. The Codex Guidelines on Health and Nutrition Claims 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.”
8. The claims conflict with the opinion of the UK Scientific Advisory Committee on Nutrition (SACN) 2007 which 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. There is evidently widespread concern about the need for greater care regarding the procedures on the authorisation of claims on foods for infants and young children. During the European Parliamentary debate on the DHA claim concern was expressed by 328 MEPs, WHO, UNICEF, Save the Children, the UK Royal College of Paediatrics and Child Health, the Standing Committee of European Doctors (CPME), the European Midwives Association, Eurochild, Association of European Cancer Leagues, the European Federation of the Association of Dieticians (EFAD), the European Federation of Nurses Associations (EFN), COFACE (the Confederation of Family Organisations in the European Union), EPHA (the European Public Health Association) BEUC (the European Consumers Association), the German Midwives Association, the California Women Infants and Children Association, Sustain’s Childrens Food Campaign, the National Childbirth Trust, the Baby Feeding Law Group and regional and national members of the International Baby Food Action Network.
10. EU authorisation of these claims 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 may not be challenged because policy makers will assume that the EU follows the highest standards
11. The Baby Feeding Law Group position is that 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 and listed clearly in the ingredients panel. It should not be promoted with a claim for commercial advantage.

In addition to the above points which are made by IBFAN and the Baby Feeding Law Group, Baby Milk Action would like to request further information on the research used to support the efficacy of the claims as it relates to all the products concerned: the funding, whether it is ‘proprietary’ and whether it is supported by any independent systematic reviews. We would also like to request further information regarding the role played by certain members of the EFSA panel who seem to have unacceptable conflicts of interest.

Finally we would like to ensure that Member States are aware of the considerable concern about the impact of health claims on formulas and baby foods in the USA and the US Food and Drug Administration’s proposal to carry out a study of the understanding of 10,000 women study of health claims such as *“supports brain and eye development.”* (<http://edocket.access.gpo.gov/2011/2011-4740.htm>). Can we suggest that the EU Commission instigates a similar study before authorising any further claims in the EU?

Yours sincerely



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cc: Christina Antoniou, European Commission  
Juliane Kleiner, EFSA  
Glenis Willmott, MEP  
Dr Peter Liese, MEP  
Chris Davies, MEP