



**BFLG /IBFAN comments on proposed Commission Regulation authorising certain health claims made on foods and referring to children's development and health
July 2015 - SANTE/1089/2-15**

These comments are prepared by the Baby Feeding Law Group (BFLG), a coalition of 20 leading UK health professional and lay organisations, and the International Baby Food Action Network (IBFAN) a global network of 273 groups in 168 countries.

General comments:

BFLG and IBFAN totally oppose the adoption of the proposed regulation authorising health claims for Thiamine, Alpha Linolenic Acid, Magnesium, Vitamin A, Iron, Riboflavin, Pantothenic acid, Vit C, Iodine, Vitamin D, Zinc, DHA and Selenium.

We consider the claims to be unjustified and request that they are not be permitted for the following reasons:

1. Health and nutrition claims of foods for infants and young children contravene the Convention on the Rights of the Child - that all EU Member States have endorsed and are minimum requirements for ALL countries. ¹

2. The adoption of this regulation will undermine the intent of International Code and subsequent WHA Resolutions including 63.23 that urges Member States to: *“end inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation.”*

3. The claims are highly promotional, unnecessary and misleading. The highlighting of certain ingredients masks the risks and disadvantages linked to the use of the whole product.

¹ All EU MS have also ratified the Convention on the Rights of the Child, a Human Rights Treaty that came into force in 1990. Article 24 of CRC calls on governments to provide parents with information on nutrition and breastfeeding and the CRC General Comment No. 15 explains what this means. It stresses the obligation for States to protect, promote and support breastfeeding through the implementation of the World Health Assembly Global Strategy for infant and Young Child Feeding. (GSIYCF)¹ It also sets a direct obligation to companies to abide by the IC universally. Nations that ratified the Convention are bound to it by international law and thus have clear obligations. Member states (MS) must ensure that the Commission does not undermine a human right international law and thus misinterpret duty/obligation under it. The IC and WHA Resolutions are embedded in many global declarations, standards and strategies, including the EU Action Plan of Childhood Obesity and the INC2 Political Declaration and Framework for Action² adopted just last November. Breastfeeding is one of the EUs CORE Health Indicators for Determinants of Health. The regulations could undermine implementation and thus success of these initiatives – wasting public resources

4. Most of the ingredients (Thiamine, Alpha Linolenic Acid, Magnesium, Vitamin A, Iron, Riboflavin, Pantothenic acid, Vit C, Iodine, Vitamin D, Zinc, and Selenium.) to which the claims are linked are mandatory ingredients and the claim can be made if they follow the content of the directive. **If the ingredients are mandatory the claim is entirely unnecessary.** The General Labelling Directive. Article 2 (1) 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”*

The suggested wording to accompany mandatory ingredients provides an inadequate safeguard: *All [category of foods] contain xxxx. Xxx contributes to normal development of xxxx*

5 The claims will undermine optimal Infant and young child feeding The EFSA opinions cited state clearly that *“Such amounts [of each ingredient] can be easily consumed as part of a balanced diet.”* The claims will discourage appropriate complementary feeding and suggest that commercial products are superior to home prepared, bio-diverse foods. Breastmilk and bio-diverse family foods contain all these ingredients, are safer, healthier, less environmentally harmful and more appropriate. But they are not marketed on shelves next to these products - so they can never hope to compete. The claim will suggest that the commercial product is superior to home prepared foods.² Optimal infant and young child feeding should be promoted based on the *Guiding Principles for Complementary Feeding of the Breastfed Child.*³ Guidance should emphasize the use of suitable locally available foods which are prepared and fed safely.⁴

6. In general authorisation of promotional claims for Infant formula 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. Para 16 of the regulations states: *“Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.”*

7 Risks of Claims EFSA has not even looked at the risk management of these claims. This is a great oversight that Member States need to consider carefully.

8 The adoption of these regulations will pre-empt new safeguards being proposed by the European Commission in delegated acts that are set to substantially change the legal situation. The new Commission Delegated Regulations currently propose to ban all health and nutrition claims for **Foods for Special Medical Purposes**, products that are recognised to be

² The claims will also contravene the intent of Resolution (WHA 55.25) May 2002 that endorsed the Global Strategy on Infant and Young Child Feeding: *“Recognizing that infant and young-child mortality can be reduced through improved nutritional status of women of reproductive age, especially during pregnancy, and by exclusive breastfeeding for the first six months of life, and with nutritionally adequate and safe complementary feeding through introduction of safe and adequate amounts of indigenous foodstuffs and local foods while breastfeeding continues up to the age of two years or beyond”*

³ Pan American Health Organization and World Health Organization. *Guiding Principles for Complementary Feeding of the Breastfed Child.* 2003. <http://www.who.int/maternalchildadolescent/documents/a85622/en/>.

⁴ WHO/UNICEF. *Global Strategy for Infant and Young Child Feeding*, Geneva. 2003. <http://apps.who.int/iris/bitstream/10665/42590/1/9241562218.pdf?ua=1&ua=1>.

inappropriately marketed.⁵

9 The claims will set a bad precedence for the ongoing Codex discussions on follow-on formula. The regulations will have a damaging impact globally.

10 Follow-on milks are not necessary WHA Resolution 39.28 adopted in 1986 states that *the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary.*

WHO, in its *Information concerning the use and marketing of follow-up formula* (WHO July 2013) clearly warns that the promotion follow-up formulas is misleading.⁶

The UK Government's Scientific Advisory Committee on Nutrition (SACN) 2007 stated:
" *There is no case for allowing the 'advertising' of follow-on formula... there is no scientific evidence demonstrating nutritional advantage of this product over infant formula...[both these] are breast milk substitutes as defined by the Code (which sets no upper infant age limit on this term)... We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupported. 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. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods.*"

The claims that IBFAN and BFLG oppose:

Thiamine: EFSA Opinion Q-2008-183 *Thiamine contributes to normal carbohydrate and energy-yielding metabolism.*

If the addition of thiamine is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain thiamine. Thiamine contributes to normal carbohydrate and energy-yielding metabolism.

EFSA clearly states that *“Such amounts can be easily consumed as part of a balanced diet*

Alpha-linolenic acid contributes to brain and nerve tissue development.

If the addition of alpha-linolenic acid is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

Magnesium - Q-2008-150

⁵ . *“...Differing interpretation and enforcement of the definition of FSMPs by national authorities has contributed to a proliferation of these products in the market (the examples of products based on rice protein, not allowed for infant and follow-on formula, and of some anti-regurgitation products were mentioned). This in turn led to the use of wider and often similar distribution channels as those for infant formula and inevitably to labelling, advertising and marketing practices that were taking advantage of the absence of relevant rules for these products.”*

Summary Record of the Standing Committee on the Food Chain and Animal Health, 22 June 2012

⁶ *“As reported in a number of studies, while follow-up formula may not be explicitly promoted as a breastmilk substitute, documented marketing strategies, such as packaging, branding and labelling may induce mothers to use follow-up formula in the first six months of life and/or to stop breastfeeding after this period. If follow-up formula is marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement for breast milk, it is covered by the Code. In addition, where follow-up formula is otherwise represented in a manner which results in such product being perceived or used as a partial or total replacement for breast milk, such product also falls within the scope of the Code.”*

Magnesium contributes to normal development of bone. If the addition of magnesium is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following: All [category of foods] contain magnesium. Magnesium contributes to normal development of bone.

Vitamin A Proposed claim: ***Vitamin A contributes to the normal function of the immune system.***

If Vit A is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain vitamin A. Vitamin A contributes to the normal function of the immune system.

EFSA opinion Q-2008-160 clearly states that ***Such amounts can be easily consumed as part of a balanced diet.***

Iron contributes to normal cognitive development. If the addition of iron is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain iron. Iron contributes to normal cognitive development

Iron contributes to normal formation of haemoglobin and red blood cells.

If the addition of iron is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following: All [category of foods] contain iron. Iron contributes to normal formation of haemoglobin and red blood cells.

EFSA: Such amounts can be easily consumed as part of a balanced diet. The

IBFAN comments: There is No risk assessment here or Maximum limits set
Nothing about Iron overload.

Iodine contributes to normal thyroid function.

If the addition of iodine is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following: ***All [category of foods] contain iodine. Iodine contributes to normal thyroid function.***

Iodine contributes to normal cognitive development.

If the addition of iodine is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain iodine. Iodine contributes to normal cognitive development.

Vitamin D contributes to normal development of bones and teeth.

If the addition of vitamin D is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain vitamin D. Vitamin D contributes to normal development of bones and teeth.

Zinc contributes to normal function of the immune system.

If the addition of zinc is mandatory for the category of the food for which the claim is made,

the wording to be used shall be the following: All [category of foods] contain zinc. Zinc contributes to normal function of the immune system

DHA contributes to normal brain development

If the addition of DHA is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain DHA. DHA contributes to normal brain development.

Selenium contributes to the protection of DNA, proteins and lipids from oxidative damage.

If the addition of selenium is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain selenium. Selenium contributes to the protection of DNA, proteins and lipids from oxidative damage

Zinc contributes to normal growth [in infants and young children].

If the addition of zinc is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain zinc. Zinc contributes to normal growth [in infants and young children].

Riboflavin Riboflavin contributes to normal energy-yielding metabolism.

If the addition of riboflavin is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain riboflavin. Riboflavin contributes to normal energy-yielding metabolism.

Such amounts can be easily consumed as part of a balanced diet.

“Pantothenic acid contributes to normal energy-yielding metabolism”.

Such amounts can be easily consumed as part of a balanced diet

Vitamin C contributes to increasing non-haem iron absorption.

If the addition of vitamin C is mandatory for the category of the food for which the claim is made, the wording to be used shall be the following:

All [category of foods] contain vitamin C. Vitamin C contributes to increasing non-haem iron absorption.

EFSA Such amounts can be easily consumed as part of a balanced diet.

“iodine is important for thyroid function”.

Lastly – not related to the children’s claims:

Carbohydrate claim: SANTE/10889/2015 Annex

The only restriction to the claim **“Carbohydrates contribute to the maintenance of normal cognitive function”** seems to be that it can’t be used on foods that are 100% sugar.

The reference is also to an EFSA paper that refers only to Glysemic carbohydrates for the general population. (EFSA journal 2015;13 (2) 4027