

IBFAN COMMENTS ON THE EUROPEAN COMMISSION'S PROPOSALS FOR A RECAST DIRECTIVE ON INFANT FORMULA AND FOLLOW-ON FORMULA (REV 5 SANCO/2256/2006)

July 18th 2006

Summary

It is of great concern that this Directive, which contains so many controversial and unresolved issues regarding its impact on breastfeeding and infant health, is being pushed to conclusion so quickly. IBFAN consider that the text as it stands will prevent Member States from carrying out their responsibilities under the International Code and Subsequent Resolutions, and their obligations under the Convention of the Rights of the Child.

The Directive is also likely to have a damaging impact on policy setting in Third countries and on international arenas such as Codex Alimentarius and the World Health Assembly. It will convey the impression that this flawed and dangerous Directive, and the marketing practices it legalizes, is somehow approved by Europe's health community. In fact, nothing could be further from the truth. All the health, consumer and development bodies consulted have criticised it and warned that it could do harm to public health.

We call on the Government to reject these proposals as they now stand, call for a revision of the PARNUTS Directive (89/398/EEC), and seek assurance from the European Commission that the UK or any other Member State will not face legal challenges if they implement provisions of the Code and Resolutions in their efforts to protect infant health.

We would also request that the points raised in previous comments submitted are borne in mind along with the comments submitted by the UK Baby Feeding Law Group.¹

Below are the comments on the Questions set out in the FSA letter of 30th June (CPD/0012)

Question 1: Pre-market approval of new ingredients in infant formula:

Are stakeholders content with the proposals outlined in Article 9?

No. IBFAN is extremely concerned that the issue of pre-market approval seems to have been dismissed in favour of a notification procedure. The fragile argument put forward by the Commission that pre-authorisation is not permitted by the PARNUTS Framework Directive

¹ The UK Baby Feeding Law Group is an adhoc group of 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 *Community Practitioners and Health Visitors' Association*, *Lactation Consultants of Great Britain*, *La Leche League (GB)*, *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*.

(89/398/EEC) does not seem credible. If true then IBFAN urgently suggests that the Directive is put on hold until the PARNUTS Directive is revised.

In this context we would like to draw attention to the comments by ESPGHAN on the conclusion of the International Expert Group report (1) on the composition of infant formulae.² and the issue of established history of apparently safe use. ESPGHAN rightly comments that problems with infant formulas are not always disclosed, and one should certainly not rely - as ISDI suggests - on consumer phone lines (especially industry-sponsored ones) as evidence of safe use.

“ESPGHAN wishes to emphasize that there is no evidence available to show that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of infant formulae. On the contrary, for example the very severe adverse effects recently induced by an infant formula with inadequate contents of vitamin B1 (thiamine), which resulted in failure to thrive, severe neurological damage, severe lactic acidosis and even infant deaths (2-4), were not detected by the distributor’s consumer phone line services....”

As commented before, IBFAN considers that if an ingredient is essential for health and has proven to be safe by independently funded and reviewed research, then it should be a mandatory requirement for all formulas. The fact that the proposals open the door for any number of new ingredients which have not been authorised – all of which could carry highly promotional claims – is unacceptable.

Question 2

Recital 26 – Are we content with the assessment of new infant formula claims?

No. As mentioned before, IBFAN is completely opposed to the use of any claim which implies a health advantage on any food for infants or young children, including infant formula or follow-on formula. IBFAN is not content with the assessment of new claims, and is also not content that Annex 4 contains four new nutrition claims and one disease risk reduction claim.

It is a slight improvement that Rev 5 defines claims more specifically, but no acknowledgement is made that breastmilk substitutes should be treated in an entirely different from other foods and once more it seems that the automatic pre-authorisation procedure for new claims outlined in the draft Nutrition and health Claims regulations do not apply to infant formula because of

² ESPGHAN Comments on the Circular Letter CL 2005/53-NFSDU and on the Synopsis of comments received until 30 April (prepared by Germany) *“The question arises whether the ranges of nutrient levels in infant formulae that are reported by ISDI, without documented occurrence of side effects, suffice to establish a “history of safe use”, or even of adequacy of such nutrient levels for infant formulae. ISDI suggests that a history of apparently safe use of products might be based on the use of commercially produced infant formula and the monitoring of spontaneous consumer reports of observations that may indicate a problem with a specific batch of formula. In some areas, such as Europe, Israel and the USA, there are consumer phone line services have been established where parents may call in, usually free of charge, to place questions or complaints to the manufacturer or distributor of an infant formula. ISDI explains that such customer reports are monitored and should provide a tool for post-marketing surveillance of infant formula safety. Based on the evaluation of these consumer phone line services and the absence of detected serious side effects, ISDI implies that a history of safe use has been established for the nutrient levels reported in their compilation. ESPGHAN wishes to emphasize that there is no evidence available to show that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of infant formulae.”*

weaknesses in the PARNUTs Directive, (89/398/EEC)

IBFAN would welcome an explanation of the legal status of the assurances given by the Commission and outlined in **Annex A**. As they stand they are ambiguous and as a long-term safeguard seem very weak. For example, new claims that the Commission consider ‘simple’ would be submitted to the ScoFCAH for discussion/*possible* vote. But only those that the Commission considers would have an impact on public health would be automatically referred to EFSA. Even if EFSA gives a negative opinion on a claim, according to Annex A, it is only ‘unlikely’ that the Commission would draft an amendment. Given that the Commission has already included several highly controversial claims which are known to increase sales³ and therefore will have an impact on breastfeeding and public health, and without wishing to cast doubt on the competence of the ScoFCAH, this safeguard does not really inspire confidence in the process.

IBFAN would welcome an explanation of why the European Commission seems to have ignored the advice contained in the report of the Scientific Committee for Food in relation to the labelling of products. The SCF recommended the removal of all the nutrition claims in the original Directive, apart from the lactose free claim. The report deliberately avoided the use of the word CLAIM, recommending instead NUTRITION LABELLING or Statements for ingredients such as long-chain fatty acids.

The Nutrition Claim about: ***Added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid***

Even a simple claim such as “contains DHA” can convey the misleading impression that the product is equivalent or better than breastmilk. The commercial promotion of foods which are perceived by parents to be breastmilk substitutes exacerbates the situation. The health benefits of Long Chain Fatty acids are widely promoted across a range of foods, and are also cited in promotional literature for breastmilk substitutes - often extolling the virtues of breastfeeding. In this context it is inevitable that any claim on the label of formula or on any accompanying material highlighting the presence of LCPs or other ingredients, will imply equivalence with breastmilk.

For examples see:

<http://www.babyfeedinglawgroup.org.uk/monitoring/monreportcompanies.html>

The SCF Reports states:

“Babies fed with breastmilk may have more mature sight skills and a higher IQ (Intelligence Quotient) than babies fed formula. It has been suggested that low levels of longchain polyunsaturated fatty acids (LCPUFA) found in formula may contribute to lower IQ levels and sight skills. Some formulas are available with added LCPUFA. This review of trials found that there was not enough evidence to show a longterm benefit of LCPUFA supplementation but that LCPUFA supplementation was safe. More research is

³ Baby formula boom boosts Martek sales By Clarisse Douaud
<http://www.nutraingredients-usa.com/redirect.asp?idc=11298>
6/7/2006 - Increased international sales from a thriving infant formula market drove up Martek's net income by almost 85 percent in Q2, and new deals point to positive results for the remainder of the year.

needed to assess whether LCPUFA supplementation results in mild improvements in problem solving ability.

The author of the independent Cochrane review examined nine randomised controlled trials and concluded:

“At present there is little evidence from randomised trials of LCPUFA supplementation to support the hypothesis that LCPUFA supplementation confers a benefit for visual or general development of term infants. Minor effects on VEP acuity have been suggested but appear unlikely when all studies are reviewed. A beneficial effect on information processing is possible but larger studies over longer periods are required to conclude that LCPUFA supplementation provides a benefit when compared with standard formula.”⁴

The Hambricht and Quist Spot Report on pharmaceuticals recommendation for Martek Biosciences, (manufacturers and distributors of *Formulaid*, an artificial source of DHA and ARA) referred to *Formulaid* as a ‘strong buy’ on the following basis:

"Infant formula is currently a commodity market, with all products being almost identical and marketers competing intensely to differentiate their product. Even if Formulaid has no benefit, we think it would be widely incorporated into formulas, as a marketing tool and to allow companies to promote their formula as "closest to human milk".

Recent reports show just how lucrative the claims are.⁵

The nutrition claims about **Fructo-oligosaccharides and galacto-oligosaccharides**

Companies are already making claims which imply that these ingredients protect babies from infection, despite the lack of evidence of the health benefits of these ingredients. **It is seriously misleading and illogical for products that could contain unacceptably high levels of disease-causing bacteria to carry such claims.**

The SCF report in Para 3.2.2 on the Health benefits of FOS and GOS in children stated:

“Modifications of the faecal microflora per se do not demonstrate the prebiotic nature of an ingredient, which by definition includes the demonstration of a beneficial effect on host health. Data on potential health benefits of oligofructosyl-saccharose and oligogalactosyllactose in infants are rare. No information is available as to whether or not the supplementation of infant and follow-on formulae with oligofructosyl-saccharose and/or oligogalactosyl-lactose may have a preventive effect on the incidence of infectious and allergic disorders. Potential clinical benefits of oligofructosylsaccharose and

⁴ Simmer K. Longchain polyunsaturated fatty acid supplementation in infants born at term. *The Cochrane Database of Systematic Reviews* 2001, Issue 4. Cochrane reviews are considered the gold standard of quantitative research, are regularly checked and updated if necessary.
Baby formula boom boosts Martek sales By Clarisse Douaud
<http://www.nutraingredients-usa.com/redirect.asp?idc=11298>
6/7/2006 - Increased international sales from a thriving infant formula market drove up Martek's net income by almost 85 percent in Q2, and new deals point to positive results for the remainder of the year.
<http://www.nutraingredients-usa.com/news/ng.asp?n=66267-pbm-products-martek-biosciences-omega-dha-infant-formula>

oligogalactosyl-lactose in young infants need to be further assessed.”

The nutrition claim about **Taurine**. The SCF report said “*It is added to many infant formulae without adverse effects and little evidence of benefit and mostly because it is found in human milk.*”

The **Disease risk reduction claim**: It is astonishing and disturbing that no reassessment seems to have been made regarding the disease-risk reduction claim relating to a “*reduction of risk of allergy to milk proteins.*”

‘*Hypoallergenic*’ claims have not been permitted on infant formula labels in the US since 1989 when nine US authorities took legal action to stop Nestle Carnation making these claims. Several infants had suffered anaphylactic shock after being fed Nestlé formula which had been advertised as ‘*hypoallergenic.*’ The claim was refused once more by the US Food and Drug Administration in May 2006 on the grounds that there is no credible evidence to support it.⁶ The allegedly falsified research of Canadian scientist, Dr Ranjit Chandra, which has been used as the basis of many of the ‘*hypoallergenic claims*’, was the subject of three Canadian Television exposures in February this year.

The SCF Report found “*no scientific foundation to base a claim that a formula induces “reduction of risk of allergy to milk proteins” or is “hypoallergenic” on a content of immunoreactive protein of less than 1% of nitrogen-containing substances, as is presently the case.*”

Question 3: Are we content with a single conversion factor of 6.25 for all protein sources.

No comment, except that this seems to be in line with the SCF report.

Question 4. Further comments:

All the concerns expressed by IBFAN throughout this consultation remain, because only a few of the amendments that were called for have been incorporated.

Second preambular paragraph: Does the new reference to EFSA mean that the recast Directive in its entirety will be presented to EFSA for a considered view?

Article 13.7 Clear labelling:

Since Revision 3 the proposals have included a provision that manufacturers should make a clear distinction between the labelling of follow on milks and infant formulas. This provision has been reworded in Revision 5 but is essentially the same. However, this is unlikely to solve the problem of confusion as long as the advertising and promotion of follow-on milks continues. This safeguard should also cover foods for special medical purposes, since these often share the same branding and packing and could be even more important that these products are not confused with regular infant formulas. This recommendation was included in the report of the Scientific Committee for Food. These foods are already mentioned several times in the Directive – for example in recital 30 and 31.

⁶ <http://www.dairyreporter.com/news/ng.asp?id=67769-nestle-infant-formula-allergy-symptoms>
http://seattlepi.nwsource.com/health/1500AP_Nestle_Infant_Formula.html
<http://www.cfsan.fda.gov/~dms/qhewhey.html>

Article 14: Advertising of Follow-on milk:

IBFAN seeks an explanation of why the Commission is refusing to allow Member States to extend the controls on advertising to follow-on milks. The UK have provided the Commission with ample evidence to show that follow-on milk promotion is undermining health advice in the UK and misleading parents. The Mori poll last year⁷ found that 30% of mothers had received the impression from advertising that formula was 'as good as' or 'better' than breastfeeding and many parents were giving these products at far too early an age – 17% under 3 months of age. Several Member States included some controls on the marketing of follow-on milks after the original Directive was adopted in 1991.⁸

Member States need to be empowered to take action on follow-on formulae marketing as they see fit as requested by the UK, Finland and other Member States.

Article 14 needs to be amended to read:

“Advertising of infant formulae AND FOLLOW ON FORMULAE shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising.”

There does not seem to be any basis for the Commission – or any other Member State - to object to such wording since it does not stop any Member State continuing with promotion in their own country.

For examples see:

<http://www.babyfeedinglawgroup.org.uk/monitoring/monreportcompanies.html>

Recital 9 IBFAN requests that a reference is made to the subsequent relevant Resolutions of the World Health Assembly.

Recital 13 - Exports: We welcome the fact the reference to exports to Third Countries has been deleted. However, it is clear that this Directive, and the EU Commission position, will have a damaging impact on development of the Codex Standard on infant formula, which is now at Step 5.

Soya formula: There is still no reference to the risks of soya infant formula. If these products are to be permitted on the market they need to carry clear warnings on the label of the risks.

Warnings about contamination:

As mentioned above the proposals allow several highly promotional claims, while failing to allow provision for adequate warnings about possible contamination by **Enterobacter Sakazakii and other pathogen contamination.**

⁷ www.babyfriendly.org.uk/mailling/updates/research_update_20050919.htm
www.nct.org.uk/media/pressrelease?prid=43

⁸ WHA 39.28 1986: Requested the Director General to “specifically direct the attention of Member States and other interested parties to the following... (b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary.”

Article 13 of the proposed draft states that:

“The labelling shall bear ...the following mandatory particulars: In the case of infant formulae and follow-on formulae, instructions for appropriate preparation storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.”

IBFAN requests an assurance that the provision in Article 13 will allow an adequate warning on formula labels along the lines recommended by Codex:

The Codex Working Group Meeting on Infant Formulae, Ottawa, Canada, May 15-17, 2006, considered again the draft Code of Hygienic Practice. A chapter "Control measures for safe preparation of formula" was added. A text was agreed: **"Powdered infant formula is not a sterile product and may be contaminated with pathogens that can cause serious illness. Correct preparation and handling reduces the risk of illness"**

Discussion on Draft COMMISSION REGULATION *authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cows' milk protein for a two-year period*

IBFAN requests clarification on the following point:

In relation to the positioning of these products, under which Directive will the product fall? The latest revision of the Infant formula Directive (Rev 5) includes new references for foods for special medical purposes but it is not clear how the marketing of these particular products will be controlled. This Directive seems to authorise the 'marketing' of these products with no constraints.