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29th March, 2006

Working Document on the Commission Directive on Infant Formulae and follow-on formulae (REV4)

Dear Akki Khan

I enclose a short summary of the main points of concern regarding the above document which was discussed at the Baby Feeding Law Group meeting on Monday 26th March. Members expressed the wish to have more time to fully consider some of the changes made, especially those concerning compositional changes.

These comments are endorsed by the organisations listed below.

The Baby Feeding Law Group is very disappointed that this new draft still fails to address the important concerns raised by us and summarised on page 2. These concerns have been echoed by nearly all the relevant public interest NGOs in Europe and many of the points have also been called for by the UK Government and other Member States.

Patti Rundall,

on behalf of the following members of the Baby Feeding Law Group:

Midwives Information and Resource Service (MIDIRS)
The Royal College of Nursing (RCN) Midwifery Society
Community Practitioners and Health Visitors' Association (CPHVA)
The Breastfeeding Network (BFN)
La Leche League GB (LLLGB)
National Childbirth Trust (NCT)
Association of Radical Midwives (ARM)
Baby Milk Action.
Association for Improvement in the Maternity Services (AIMS)
Association of Breastfeeding Mothers (ABM)
The Food Commission
Lactation Consultants of Great Britain (LCGB)

Member organisations: Association of Breastfeeding Mothers - Association for Improvements in the Maternity Services - Association of Radical Midwives - Baby Milk Action - Breastfeeding Network - Food Commission - Community Practitioners and Health Visitors' Association - Lactation Consultants of Great Britain - La Leche League (GB) - Midwives Information and Resource Service - National Childbirth Trust - Royal College of Midwives - Royal College of Nursing - Royal College of Paediatrics and Child Health - Unicef UK Baby Friendly Initiative.

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Summary of changes that the Baby Feeding law Group is calling for:

- European legislation should, as a minimum, be in line with the *International Code of Marketing of Breast-milk Substitutes* and the subsequent relevant WHA Resolutions
- European legislation should not permit the promotion of any breastmilk substitute or any food or drink marketed as suitable for babies under 6 months of age, or any promotion of bottles and teats.
- Health and nutrition claims on foods for infants and young children undermine breastfeeding and are misleading in that they imply equivalency or health benefits for breastmilk substitutes. Nutrition and health claims are not the same as nutrition information (which is essential) and, in creating a perceived advantage, they confuse parents. Breast milk substitutes have no health advantage over breastfeeding. Health and nutrition claims violate the *International Code of Marketing of Breast-milk Substitutes* and the subsequent relevant WHA Resolutions and should not be permitted.
- Ingredients should be permitted for use in breastmilk substitutes only when shown by independently-funded research to be safe and essential for infant health. Such ingredients should be mandatory.
- Powdered infant formulas (including powdered breastmilk fortifiers) must carry explicit warnings that the product is not sterile and may be contaminated by *Enterobacter sakazakii* and/or other pathogens.
- No food other than infant formula (or formulas for special medical purposes) should be labelled as suitable for infants under the age of 6 months.
- The safety of soya should be questioned and, if permitted, its risks explicitly stated on the label continued.
- Follow-on milks are not necessary. If these products are permitted on the market, their promotion should be prohibited
- Free and low-cost supplies of breastmilk substitutes should not be allowed in any part of the health care system.

Comments on Working Document on the Commission Directive on Infant Formulae and follow-on formulae (REV4)

The BFLG comments on the previous proposals for a Recast Directive, which endorsed the IBFAN comments, still apply. The following comments relate to the changes in Rev 4

Whereas: No 9 Microbiological criteria must be established as soon as possible. No date is given.

Whereas: No 26 This calls for “**health claims**” on infant formula to be first authorised by EFSA. There is no mention of nutrition claims or follow-on formulae. The BFLG position – supported by IBFAN and NGOs throughout Europe - is that there should be **NO HEALTH or NUTRITION claims on any foods for infants or young children** – authorised or not. This paragraph should reflect this.

If follow-on milks are permitted - and the BFLG position is that they are unnecessary - any safeguards relating to infant formulae should also apply to follow-on formulae.

Article 2 c The reference to “*use by infants during the first months of life*” should be changed to “*use by infants during the first SIX months of life*”

Article 2 d The definition for follow-on formulae fails to state an appropriate age. This is inconsistent with the labelling requirement in Article 9.2.b which states that Follow-on formulae are suitable only for infants “**over the age of 6 months.**”

It also ignores the fact that 82 of the 192 Member States of WHO – including 12 European countries have policies which recommend exclusive breastfeeding for 6 months: Azerbaijan, Belarus, Bosnia, Bulgaria, Czech Republic France, Georgia, Germany, Luxembourg, Netherlands, Slovakia, UK.

Full Breastfeeding Duration and Associated Decrease in Respiratory Tract Infection in US Children. This study documents increased risk of respiratory tract infection including pneumonia and recurrent ear infections in children who were fully breastfed for 4 versus those breastfed for 6 months. These findings support current recommendations that infants receive only breast milk for the first 6 months of life.

DOI: 10.1542/peds.2004-2283 2006;117;425-432 Pediatrics Caroline J. Chantry, Cynthia R. Howard and Peggy Auinger.

NEW ARTICLE 5 This deals with the placing of new products on the market. It is totally inadequate. It could easily be changed by the following which would be much safer and would entail less work for Member States.

“DELETE: *When* INSERT: *Before* the product is placed on the market for the first time, the manufacturer or, where the product is manufactured in a third State, the importer, shall notify the competent authority of the MS where the product is being marketed by forwarding it a model of the label used for the product INSERT: *together with a dossier which demonstrates through independently funded and reviewed evidence, including a report from EFSA, that the new product has a health benefit and is safe.*”

Article 9.1 As before replace text ‘**infant formula**’ with ‘**artificial breastmilk substitute**’ The Lithuanian translation should be changed. At present it refers to 4-6 months. The product name should clearly reflect that it is an artificial replacement for breastmilk (as in Swedish, Danish and Finnish).

Article 8 7 “*Microbiological criteria shall be established (DELETE: ~~as necessary~~) INSERT: AS SOON AS POSSIBLE BY xxx Date.*”

Article 9 2.b “*In the case of follow-on formulae (INSERT: *if permitted*)that it should form only part of a diversified diet (DELETE: ~~and that it is not used as a substitute for breastmilk during the first six months of life~~)any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other (INSERT: *‘independent’*) professionals responsible for maternal and child care, based on the individual infant’s specific growth and development needs*”.

The current text implies that follow-on formulae are not breastmilk substitutes. Our position is that they are substitutes for breastmilk for the older baby.

Article 9.2.e The reference to ‘*storage and disposal*’ is good.

Article 9.4 The reference to the ban on the term '*adapted*' is good.

Article 9.5 ,9.6 All the safeguards relating to infant formula should also apply to "follow-on formulae if permitted."

Article 9.7 *"The labeling may INSERT: NOT bear nutrition and health claims concerning the special composition of an infant formula INSERT: or follow-on formulae if permitted."*

This paragraph is not consistent with **Whereas 26** which refers only to health claims.

Article 10 This Article is very weak. The BFLG position is that there should be no promotion of any breastmilk substitute or any food or drink marketed as suitable for babies under 6 months of age, nor any promotion of bottles and teats. This prohibition should undoubtedly include follow-on formulae and '*publications specialising in baby care and scientific publications.*' This article should at the very least specify that Member States may prohibit follow-on formulae promotion, as requested by the UK and several MS.

Article 11.3 This section relating to donations of educational materials is not consistent with WHA Resolutions 49.15 and 58.32. The BFLG supports these Resolutions and the safeguards outlined in the Convention on the Rights of the Child.

WHA Resolution 58.28 urges Member States: *(4) to ensure that financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest;*

Convention on the Rights of the Child: **Article 24** calls on States Parties to "*recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. (e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents; Article 36* calls on States Parties to "*protect the child against all other forms of exploitation prejudicial to any aspects of the child's welfare.*"

Article 11.4 This section relating to donations of supplies of infant formula is way out of date and not consistent with WHA Resolution 47.5 and subsequent WHA resolutions. The BFLG position is that free and low-cost supplies of breastmilk substitutes should not be allowed in any part of the health care system.

Article 12 This article is a complicated set of safeguards which is unlikely to work. It applies only to products which are placed on the market after the Directive comes into effect. It does not apply to products which are currently on the market or may be placed on the market before the Directive comes into effect. The recent expose regarding the validity of the research of RK Chandra in Canada has highlighted the lack of evidence to support the claims made for formulae containing partially hydrolysed proteins, yet these products remain on the market. (<http://www.babymilkaction.org/press/press3feb06.html>)

To repeat the concerns of the report of the Scientific Committee for Food on this Point.

Page 48: *"it has been shown for some products that they were nutritionally inadequate. It is unknown if such products were removed from the market. The inherent claim that hydrolysates result in less allergic diseases cannot be deduced from technical data alone and needs substantiation in clinical trials. Surprising is the total lack of clinical studies published on follow-on formulae based on partially hydrolysed proteins."*

Pages 50 & 51: *"To our knowledge there are no systematic studies to assess growth and biological parameters of infant formulae with partially hydrolysed protein to determine the minimal safe protein content."*

Page 161: *"The Committee concludes that there is 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 immuno-reactive protein of less than 1% of nitrogen-containing substances, as is presently the case."*

If health and nutrition claims are not permitted this article is not needed.

Annex 1 The essential composition has changed in several places. The group would like more time to consider the implications of these changes. For example, regarding the inclusion of Fructo-oligosaccharides and Galacto-oligosaccharides as optional ingredients. The group considers that if an ingredient is proven to be safe and essential and of benefit to infant health, through independently-funded and independently-reviewed research (for example by EFSA) then it should be a requirement in all formulas

A note regarding the link between Obesity and artificial feeding:

Although, more work needs to be done, epidemiological evidence - 17 of the 21 studies - strongly suggest that breastfeeding represents an ideal window of opportunity for obesity prevention. Once a child becomes obese, it is quite likely that s/he will remain obese as an adult. Breastmilk could influence the development of a taste receptors profile which fosters a preference for lower energy diets later on in life.

Some references relating to Obesity and infant feeding.

Artificially fed infants consume 30,000 more calories than breastfed infants by 8 months of age. This is equivalent to 120 Mars bars - 4 a week/ (Riordan and Aerbach *Breastfeeding & Human Lactation* Jones and Bartlett 1999)

The USA Centre for Disease Control and Prevention (CDC) considers that there are only two potential, cost-effective interventions that can be put into place immediately to deal with the childhood obesity epidemic: decreased television viewing and breastfeeding promotion. (Dietz WH. *Breastfeeding may help prevent childhood overweight*. JAMA. 2001; 285:2506)

The seven-year WHO Multicentre Growth Reference Study (MGRS) of 8,500 children in 6 countries (Brazil, Ghana, India, Norway, Oman and the USA) is due to be published next month and will show that babies exclusively breastfed for six months are healthier and leaner than artificially fed babies..Planning and Implementation Food and Nutrition Bulletin, Volume 25, Number 1, March 2005

Baby Feeding Law Group Members. February 2006

- 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 **The Breastfeeding Network (BfN)** is a mother-to-mother support and membership organisation with over 800 members. BfN takes no money from the infant feeding industry.
- 6 **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.
- 7 **The Community Practitioners and Health Visitors Association (CPHVA)** represents its 21,000 members who are community health professionals.
- 8 **Lactation Consultants of Great Britain (LCGB)** represents over 100 Lactation consultants in Great Britain.
- 9 **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 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.
- 10 **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.
- 11 **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.
- 12 **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.
- 13 **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.'
- 14 **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