4th March 2005

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Dear Akki,

New Version of the Commission's working document for a recast Directive on Infant Formulae and Follow-on Formulae.

Thank you for the opportunity to send comments on the above proposal. You will have received our comments in May, October and December. This is such an important issue, I would like to reiterate, extend and add some further points here, but our position has not changed: we believe that the Directive should implement the WHO Code and subsequent resolutions in full.

The National Childbirth Trust is the largest and best-known childbirth and parenting charity in Europe. It provides a range of information and support services for parents at local level. As such we have had a consistent policy of support for full implementation of the *International Code of Marketing of breastmilk substitutes* and subsequent Resolutions in UK law with independent monitoring. We are also involved in monitoring the implementation of the Infant Formula and Follow-on Formula Regulations in the UK.

Since the adoption of the 1995 infant Formula and Follow on Formula Regulations implementing the 1991 EU Directive, manufacturers have continued to promote their products and it seems this has become more aggressive with advertising on television and in mother & baby magazines, promotion on the internet, development of Carelines and direct marketing.

Following adoption of the *Global Strategy on infant and young child* feeding at the WHA in 2002 and the *European Blueprint for Action,* launched in August 2004, it is

timely to use this opportunity to implement the *International Code of Marketing of breastmilk substitutes* and *Resolutions* in full.

The WHA Resolution adopting the *Global Strategy* achieved global consensus which affirmed the importance of exclusive breastfeeding for 6 months. This Directive should therefore refer to all breastmilk substitutes, not only to formula milks and follow-on formulae, and should prevent the labelling of any foods as suitable for babies less than six months old. It is inappropriate for complementary foods (weaning foods) and other substances such as teas and juices to be promoted for use before 6 months of age.

Implementation of the *Code* would, for instance include:

- a complete ban on the advertising of breastmilk substitutes, bottles and teats in all media, websites, etc.
- and on the provision of information on infant feeding from breastmilk substitute, bottle or teat manufacturers to the general public,
- no health or nutrition claims on breastmilk substitutes including follow on milks
- no direct marketing to the public,
- tighter controls on the provision of scientific and factual information about breastmilk substitutes to health professionals and trade associations such as training and study days funded by manufacturers.

There are many other areas to consider and the NCT appreciates the opportunity to contribute to further development of this Directive.

In this response:

Code refers to the International Code of Marketing of breastmilk substitutes and subsequent relevant Resolutions of the World Health Assembly**.**
Manufacturer – means a manufacturer of breastmilk substitutes, bottles or teats.
Breastmilk substitutes includes infant formulae, formulae for special medical purposes intended for infants, other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats**.**
In line with UNICEF and many other organisations, the NCT considers that follow on milks are clearly breastmilk substitutes as they are advertised, marketed and used as a substitute for breastmilk after six months. In addition the World Health Assembly Resolution of 1986 stated that follow on milks are *'not necessary'.*
Comparison of Annex I and Annex II indicates that there are few compositional differences in the permitted levels of nutrients in these categories, except to make it possible to include a wider range of carbohydrate sources in follow-on milks.

National Childbirth Trust comments on the draft recast Commission Directive on Infant formulae and Follow-on Formulae
SANCO D4/HL/mm/D440180 Rev. 2

General points

The NCT is disappointed to find that the Commission has not taken this opportunity to fully implement the WHO Code of Marketing of breastmilk substitutes and subsequent Resolutions of the World Health Assembly[1]. We believe the health of mothers and babies in EU Member States needs the protection of **all** Articles of the Code and Resolutions. The Code was intended as a "**minimum *requirement and only one of several important actions required in order to protect health practices in respect of infant and young child feeding"*** to be implemented by governments. It seems the Commission is again intending to ignore the many health and consumer groups as well as European parliamentarians who have consistently called for full implementation.

There are some helpful changes to this draft, relating to composition and labelling, but the Commission do not seem to have recognised the very real confusion experienced by parents who are faced by advertisements and promotions for formula milk and follow on milks, the continued influence on health professionals and the many other ways in which the Code and Resolutions are contravened in Europe today. We are particularly concerned that there are no proposals to act on the key areas of the marketing and promotion of infant formulas and follow on formulas.

Parents and infants and young children in the European Union (and those in countries where EU products are exported) have a right to the protection from commercial exploitation which is outlined in the Code and the subsequent Resolutions which all EU member states support and have an obligation to implement. The Commission has a responsibility to help governments fulfil these obligations.

Member States have also supported the Convention of the Rights of the Child and the WHO Global Strategy on Infant and Young Child Feeding, which calls for urgent implementation of the Code and subsequent Resolutions[1]. It is time this support was translated into action.

Since this Directive was first adopted in 1991 further scientific evidence has demonstrated the many ways that lack of breastfeeding increases mortality and the risk of infectious diseases, chronic diseases and auto-immune diseases, offers less than optimal development and growth, lowers cognitive and visual development and increases the risk of obesity. The seven year study carried out by the WHO shows that babies exclusively breastfed for six months are healthier and leaner than artificially fed babies.[2] It is now clear that the disadvantages of formula feeding can

[1] Hereinafter referred to as the *International Code*
[2] *The WHO Multicentre Growth Reference Study (MGRS) :* presentation at a conference School of Oriental and African Studies in London on 4th February 2005.
http://news.bbc.couk/2/hi/health/4236229.stm, www.timesonline.co.uk
www.guardian.co.uk/uk_news/story/0,,1406303,00.html

extend throughout life, with a lower risk of blood pressure, and risk factors for heart disease in later life.

The original Directive, although full of loopholes, did make provision (in Article 9) for Member States to implement a critically important provision of the Code, specifically allowing the prohibition of all promotion of infant formula. However, since 1992, amending Directives and the *Directive on Dietary foods for special Medical purposes (EC 199/21)* have undermined this, opening the door for a flood of health claims, which now are driving and expanding the infant food market, thwarting governments efforts to protect, promote and support breastfeeding. [3]

We believe it is unacceptable to allow the introduction of new ingredients to formula milks or follow on milks without first having to demontrate a need and evidence of their safety in suitably controlled studies carried out according to guidelines published by COMA or similar.

If an ingredient is essential for health and has been shown to be safe through independently-funded and systematically-reviewed research, it should be mandatory and available to all infants who need them.

The proposal runs counter to the recommendations of the scientific community, including the Commission's own advisory body, the Scientific Committee for Food. The *SCF Report on the Revisions of Essential requirements of Infant formulae and Follow-on Formulae* [4] calls for strict scrutiny of new ingredients before they are placed on the market and for a substantial review of the claims listed in Annex IV. Significantly it questions the basis of the allergy risk reduction claim (which was added by an amending Directive in 1996 and remains in the new proposal) [5] and suggests that nutrition labelling should be used to indicate the presence of ingredients such as DHA. The use of nutrition claims is misleading and should not be allowed.

Specific changes needed

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, giving the

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[3] *Breaking the Rules stretching the Rules, 2004, Evidence of violations of the International Code of Marketing of breastmilk Substitutes and subsequent Resolutions.* International Baby Food Action Network. The report analysed 3000 complaints of industry promotion over the past 2 years, and noted a huge upsurge in health and nutrition claims. 11 out of 16 companies analysed are now using claims.

[4] Report of the Scientific Committee for Food on the Revisions of Essential requirements of Infant formulae and Follow-on Formulae. SCF/CS/NUT/IF/65 Final. 19th May 2003.

[5] Commission Directive 96/4/EC OJ No. L49, 28.2.96 amending Commission Directive 91/321/EEC (OJ No. L175, 4.7.91, p.35)

impression that formula milks can provide the same protection from infection, for instance through the addition of one ingredient, as breastmilk. 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 shown by independently-funded research to be safe and essential for infant health 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.

Starches should not a be permitted at up to 30% of the carbohydrate in formula milks.

Specific Textural changes

TITLE:

Change text to read: *"**Commission Directive on Breastmilk substitutes, including foods for special medical purposes intended for infants.***

Rationale:
This is very important as 'specialised' formula milks are being promoted to parents with fewer restrictions than formula milks for healthy babies. All breastmilk substitutes are covered under the *International Code* and Resolutions and should be included in this Directive to give the most vulnerable babies protection.

Codex Alimentarius has now brought all infant formulas, including those for Special Medical Purposes, under one standard with two parts. The Commission should follow this model and ensure that all breastmilk substitutes are covered by the more stringent marketing restrictions contained in this Directive. The Directive on Dietary foods for Special Medical purposes (EC 199/21) is not the appropriate instrument to deal with the marketing of products which replace breastmilk (a living product) and which constitute the sole source of nourishment for infants for the first six months of life.

All babies, and especially sick babies need the protection of the International Code and subsequent relevant WHA Resolutions. Because it has proved impossible to

provide a definitive list of products covered by the Medical Foods Directive, the situation has become more confused and inappropriate and aggressive marketing has increased.

The formulas designed for special medical purposes contain many of the same ingredients as standard infant formulas. During the UK FSA Consultation Meeting in October 2004, the baby food industry representative was asked whether a formula designed to control reflux would fall under the Medical Foods Directive. The industry replied that this would be decided by the health professional according to how they use it with patients. The marketing of these products should therefore clearly be included in this Directive. Any special compositional or labelling requirements for the small number of specialised formulae that might be needed could be included in an Annex or subsection of this Directive. It is essential that products, such as formula for PKU babies, are clearly labelled, but there is no need for health or nutrition claims. If follow on milks are permitted, it is helpful if there is a clear distinction between infant formulae, follow-on formulae and foods for special medical purposes.

Whereas (1)
Insert new text: "**No product should be promoted in any way which undermines the practice of exclusive breastfeeding for 6 months or continued breastfeeding into the second year."**
Bottles and teats will be dealt with by a separate Directive, which will be completed by the year….

Rationale: This provision is appropriate and necessary and reflects the requirements of the International Code of Marketing of Breastmilk Substitutes and the subsequent relevant WHA Resolutions. The Commission made a commitment to deal with Bottles and Teats in the 1980s.

Whereas (2)

The essential composition of infant formulae and follow-on formulae must satisfy the nutritional requirements of infants. **DELETE:** ~~in good health as established by generally accepted scientific data.~~

RATIONALE: It is important that babies who have to fed on special formulae have the protection of the International Code and these products are not marketed to parents of healthy babies. Despite many attempts to do so, the medical profession is unable to define the term "good health." The words are unnecessary and create loopholes. See comments on the Title.

Whereas(3)
Delete**: "**if necessary**"** in the penultimate line.
Whereas(3) bis1 Replace **"**appropriate studies**"** by **'independent scientific evidence."**
Question the use of Soy protein

Rationale:
The words **"if necessary"** allow for subjectivity that could lead to difficulty and inconsistency in interpretation and implementation.

There are no guidelines which determine which body is assigned to decide on these matters.
See comments on Article 4.

The use of soya protein should be questioned as an ingredient in infant formula. Consistent with the precautionary principle soya should either be banned or its availability strictly controlled, for example, on prescription only. If permitted, soya formula should carry prominent warnings about the risks for infants. The UK Committee on Toxicity (COT) and the Scientific Advisory Committee on Nutrition (SACN) on Phytoestrogens and Health have both questioned the use of soy in infant formula. The SACN report concludes:[6]

"… SACN is in agreement that the use of soy-based infant formulae is of concern. Whilst there is clear evidence of potential risk, there is no evidence that these products confer any health benefit or therapeutic advantage over products based on cow's milk protein isolates. ….there are no substantive medical or clinical indications for the use of soy-based formulae and, [*there are*] potentially important sequelae, principally amongst young infants. If the use of soy-based formula is to continue on "clinical" grounds, responsibility is placed upon health professionals rather than the industry and consumers. The issue appears to be one of consumer choice, but there must be an onus on industry to better inform firstly the general public and, secondly, through a health professional, parents actually using these products to feed their infants."

Whereas 4

A helpful distinction but, as discussed above, we believe Foods for Special Medical purposes (FSMP) should be included in this Directive. It is important to question whether follow-on milks, whose composition under these proposals is even closer to infant formula than before, are necessary.

Rationale:

The provisions in this proposal make a welcome attempt to ensure that a clear distinction is made between follow-on milks, FSMPs and infant formulae. If follow on milks are allowed at all, it is essential that advertising and all forms of promotion must be stopped, as parents often think they have seen advertisements for formula milks when follow on milks are advertised. A short survey on the NCT website found that 36% of the 7,729 respondents believed that they had seen infant formula advertisements on television or in magazines outside the health service in the UK in the preceding 4 weeks. Since the UK regulations do not allow formula milk advertising, they had probably seen advertisements for follow-on milks.

The inclusion of follow-on milks in the Directive and Codex Standards was the result of pressure from industry, using experts who at that time did not declare their interests. In 1985 the Consumer Committee of the EU Parliament questioned their scientific basis saying "The need of follow-up milks is extremely dubious (page 14) and there is no need whatsoever for a new specially manufactured product." WHO have also stated that these products are unnecessary.

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6 www.food.gov.uk/multimedia/pdfs/fsa030503.pdf

Whereas (6) (Microbiological contamination)

Delete **"Given the complexity of the subject these should be adopted at a later stage."**

Rationale: Following the recent outcome of the discussion in the Joint FAO/ WHO workshop on Enterobacter Sakazakii, the discussion in the Codex Committee for Food Hygiene and the EFSA opinion related to microbiological risks in infant formulae and follow-on formulae, drafting should start immediately. If a final conclusion cannot be found before the finalisation of this recast Directive, the Directive should make provision for explicit warnings that the product is not sterile on labels and in publications on formula feeding, and to provide adequate preparation instructions so that caregivers are properly informed about how to reduce the risk of contamination for babies. It is irrational to cite the precautionary principle in Whereas 9, yet fail to cite it here.

Whereas (19)
Delete **"four to"** and keep **"six"** in the text. **Delete** the text "**up to the introduction of appropriate complementary feeding".**
For constistency the last line should also read "**during the first six months**" rather than **"during the period"**.

Rationale: The text as drafted is completely illogical as parents - or babies themselves - decide when complementary foods are taken, and it is not possible to state that infant formula could continue to wholly satisfy the nutritional requirements of babies whose parents decided not to give them complementary foods. We believe that this could be dangerous as it sets no guidance about the appropriate age of weaning and could lead to detrimental health outcomes from inappropriate and early weaning. In order to avoid confusion, the EU should follow the WHO recommendation for breastfed babies.

Whereas (23) and **23 bis**
Change the text to read: **In view of the risks of promotion of breastmilk substitutes, health and nutrition claims will not be permitted. All ingredients, especially those that have particular ethical or religious significance must be fully disclosed in the nutrition panel along with relevant independently product verification marks, denoting, for example, that the product is organic or kosher.**

Rationale:
Claims of nutritional superiority, equivalency or health benefits for breastmilk substitutes are deceptive and violate the provisions of the International Code and subsequent WHA Resolutions. There is no health advantage for any breastmilk substitute over breastfeeding. Scientific evidence confirms that artificial feeding increases mortality rates, increases rates for illnesses such as infectious diseases, chronic diseases and auto-immune diseases and offers less than optimal development and growth, for example, lower cognitive and visual development and increased risk of obesity.

Nutrition and health claims are not the same as nutrition information (which is essential) and are intended to create a perceived advantage, or to idealise

commercial foods for babies and young children. Increasingly companies are turning to claims which medicalise normal feeding occurrences or sound 'scientific.' [7]

As the WHO paper[8] on trade in relation to the *International Code* points out, because breastmilk is not on sale, claims made for substitutes will inevitably imply a benefit and distort public perceptions of the risks of artificial feeding. A mother's milk is a living substance, tailor-made for her baby. Its anti-infective, anti-viral and growth factors even now, are not fully understood ; factors which can actively destroy many bacteria, viruses and parasites and is tailored to the baby's individual environement. Breastmilk is also delivered in a uniquely safe way.

If an ingredient is essential for health and shown to be safe through independently funded and systematically reviewed research in line with the guidelines referred to in Whereas (3), then it should be mandatory in all infant formulae and available to all babies.

The SCF Report on the Revisions of Essential requirements of Infant formulae and Follow-on Formulae[9] questioned the basis of the allergy risk reduction claim and called for nutrition labelling, not claims, to indicate the presence of ingredients such as DHA.

Whereas (24)
After the *International Code* add **" and subsequent, relevant World Health Assembly Resolutions."**

Ten further World Health Assembly Resolutions on infant feeding have been adopted, with the support of all EU Member States. These Resolutions have the same legal status as the *International Code* and should therefore be included here and taken into consideration in the text as appropriate.

Whereas (25)
Insert the following words in bold. *Given the important role which information on baby feeding plays* ***in decisions*** ~~*choosing*~~*,* ***by parents to be and parents of babies*** ~~*by pregnant women and mothers of infants,*~~ ***about*** *the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information* ***is independent of commercial influence and*** *ensures an appropriate* ~~*adequate*~~ *use of the products in question* ~~*and is not counter to the promotion of breastfeeding*~~ ***when they are necessary and in order to promote and protect breastfeeding and infant and young child health..***

Rationale: These changes reflect gender issues adequately and ensure that breastfeeding is protected as well as promoted. Many women feel that they are not

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7 Martek Biosciences, for example, quoted in its 1996 Investment Thesis, states:"We continue to recommend purchase of Martek Biosciences with a STRONG BUY rating. The company's lead product is Formulaid, a blend of two fatty acids (DHA and ARA) that are found in human milk..... Infant formula is a commodity product, with all products being almost identical and marketers competing intensely to differentiate their product. Even if Formulaid had no benefit, we think that it would be widely incorporated into most formulas, as a marketing tool and to allow companies to promote their formula as 'closest to human milk.' LCPs & breastfeeding - 10 things every mother should know. Martek, science for Life leaflet.

8 Infant formula and related trade issues in the context of the International code of Marketing of breast-milk substitutes. www.who.int/nut/documents/infant_formula_trade_issues_eng.pdf

9 SCF/CS/NUT/IF/65 Final. 19th May 2003.

able to make the choices they might in an ideal world. The word “decision” takes this into account.

Whereas (26)

Change text to read: This Directive ~~does not~~ includes ~~concerns the~~ conditions of sale **and promotion** ~~of~~ **in** publications specialising in baby care and of scientific publications.

Rationale: There is no reason – constitutional or otherwise – to prevent the European Community from banning the promotion of breastmilk substitutes on health grounds in line with the International Code and Resolutions.

Whereas (28)
Products intended for export to third countries should follow the same criteria as those for the internal market.

Article 1, third line.

Delete “in good health”

Article 2(c)
See comments on Whereas 19.

This text introduces confusion for parents and is unnecessary for babies. Parents are capable of understanding the recommendation that for the majority of babies around 6 months is an appropriate age to introduce solid foods. If their baby is slighter younger or is older than this they will be able to make decisions based on the advice of their health professionals and knowledge of their baby. It is illogical and not in the interests of harmonisation for the Commission to undermine the policy that was adopted by the World Health Assembly in 2002[10], and is already incorporated into over 82 national policies, including 12 countries in the European region.[11]

The WHA Resolution 54.2 2002 called on governments to:

> *“strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding, and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond.”*

In our view manufacturers need to change their labels to reflect and support this policy as soon as possible to reduce the risks of early introduction of solid foods

[10] WHA resolution 54.2 2002
[11] European countries with official policies or recommendation supporting 6 months exclusive breastfeeding: Bosnia, France, Belarus, Bulgaria, Czech Republic, Georgia, Germany, Luxembourg, Netherlands and Slovakia., UK.

which displace breastmilk.[12] Too many babies are given solid foods too early at present, when their kidneys, gastrointestinal systems, oro-facial anatomy and immune systems are not sufficiently developed.[13] The draft text will exacerbate this problem, lead to confusion, and possible overfeeding of babies with all the resulting consequences, including an increase in obesity.

Article 2(d) Delete when appropriate complementary feeding is introduced, add "over 6 months". See comments on Whereas 19. If follow on milks are permitted they should only be used for babies older than 6 months. It is not logical to change the wording on this to when complementary feeding is introduced – the drafting team have realised in Article 4 number 3. which mentions ingredients suitable for use by infants over six months.

Replace "foodstuffs" by "breastmilk substitute"

Rationale: According to WHO's global recommendation (WHA Res 54.2) breastfeeding can and should continue alongside complementary feeding with the "widest possible use of indigenous nutrient-rich foodstuffs". Any liquid introduced during this period is replacing breastfeeding.

Article 2(f)
If the words ***"infants in good health"*** are not removed, then **insert a new definition** of the term here. See comment on Whereas (2)

Article 2 (g)

Insert new definition: 'independent' means free from commercial interest.

Article 3 Delete when appropriate complementary feeding is introduced, add "over 6 months". See comments on **Whereas 19.**

Article 4 Paragraph 1

Introduce in the 3rd line of para 1, the words **"systematically-reviewed, and independently funded"** between **'generally accepted scientific data'** to read **"generally accepted systematically-reviewed and independently funded scientific data"**

If EFSA is doing this review than it should be named here. If another body is envisioned it should be named in the interests of transparency.

[12] Wilson AC, Forsyth JS, Greene SA, et al. Relation of infant diet to childhood health: seven year follow up of cohort of children in Dundee infant feeding study. *BMJ* 1998; 316(7124):21-5. Cohen RJ, Brown KH, Canahuati J, et al. Effects of age of introduction of complementary foods on infant breast milk intake, total energy intake, and growth: a randomised intervention study in Honduras. *Lancet* 1994;344(8918):288-93.

[13] Naylor AJ, Morrow A. Developmental readiness of normal full term infants to progress from exclusive breastfeeding to the introduction of complementary foods: review of the relevant literature concerning infant gastrointestinal, immunologic, oral motor and maternal reproductive and lactational development. San Diego,CA.: Wellstart International; 2001.

Article 4 Paragraph 2

Delete the whole of paragraph 2 and replace with: **A manufacturer wishing to market a breastmilk substitute containing an ingredient which is not specified in the Annex of this Directive must first apply for approval to the competent authorities and show that its expected benefit and safety has been demonstrated and undisputed by systematic review of all the available evidence which must include a substantial proportion of independently-funded scientific data.**

Rationale: This new section introduces a dangerous and unethical prospect that novel foods may be introduced onto the market without adequate safeguards. The requirement that the importer simply forward the label to the competent authorties and the exchange of information suggested in Paragraph 3 is hardly adequate to deal with the impact such changes might have on babies' health. It makes a nonsense of the Directive and the work carried out by the Scientific Committee For Food, SACN other scientific bodies which have studied the composition of infant formulae in detail.

The scientific basis for many of the ingredients included in Annex IV is not clear, especially the new ingredients listed as 'optional.' Yet here the Commission is opening the door to many more without proper controls. New developments in formulae, especially if accompanied by health and nutrion claims, do not necessarily lead to improvements in public health. In addition to the harm that can be caused by babies being fed an inappropriate formulae, breastmilk substitutes have more potential to increase the risk of disease and malnutrition than other foods because they replace breastfeeding – the optimum way to feed babies. In addition they are often the sole source of nutrition and babies are particularly vulnerable because of their developmental stage and the fact that they consume more per Kg bodyweight than other groups.

If an ingredient has proven health benefits, it should be a legal ingredient and available to all babies who need it.

In order to guarantee optimal levels of protection of health as well as public trust, the suitability of permitted ingredients should be primarily based on research which is free from commercial influence. The potential for bias – present in all research – is reduced if research is commissioned and funded by a disinterested party rather than one active in the market. There is widespread recognition that funding has an influence on the publication of studies in the pharmaceutical field, for instance.[14]

Article 5.
This should specify that the water used should be suitable for drinking and boiled before use.

Article 7.7
There is an urgent necessity to establish criteria. See comments on **Whereas 6**

[14]Lexchin J, Bero LA, Djulbegovic, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. BMJ 326 1167-76.

Article 8
We recommend the following statement be added to this article.
"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."

Article 8.1
Replace text **'infant formula'** with **'artificial breastmilk substitute'**

Article 8.2 (b)

Insert the word **'independent'** after **'other'** to read: *" …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 **'independent'** professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs.*

Article 8.2 insert new (f)

See comment on Whereas 6.

Insert a prominent warning that powdered formula is not a sterile product, linked to revised preparation, storage and administration instructions stressing the need for care because of risk of contamination with *Enterobacter Sakazakii* and other pathogens.[15]

Article 8.5 and 8.6
Insert after "labelling of formula milk" and "**follow-on formulae**"

Follow-on formula needs to be included in these labelling requirements in order to guarantee that partial breastfeeding along with complementary food is protected for as long as recommended in the *Global Strategy on Infant and Young Child Feeding*.

Article 8.5(a) and (b)
The font size and a percentage of the labelling space used for the important notices and warnings should be defined.

Article 8 .5(b)
Insert the word "independent' before the word 'professional' to read:
"*a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other **independent** professionals responsible for maternal and child care*

Article 8.7 See comments on Whereas 23
Change to read: **The labelling may NOT bear nutrition or health claims.**

[15] Preparation and handling of Powdered Infant formulae, ESPGHAN Commentary, Journal of Pediatric Gastroenterology and Nutrition, **39**/320-322 October 2004; Occurrence of Enterobacter sakazakii in food production environments and households. *Lancet.* 2004 Jan 3; 363(9402): 5-6.

Rationale: Health and nutrition claims on breastmilk substitutes are promotional and inevitably undermine breastfeeding, so it is essential that they are not permitted.

To give a specific example of how misleading claims are currently used to promote products: Prebiotics are highlighted currently in formula milk and follow-on milk advertising. According to Gibson[16], quoted by ESPHGAN, the definition is:

> *prebiotics are non digestible food components that beneficially affect the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon and thereby improving host health". (my emphasis)*

The recent Commentary by the ESPGHAN Committee on Nutrition concluded that:

> *'"Although administration of prebiotic oligosaccharides has the potential to increase the total number of bifidobacteria in feces and may also soften stools, there is no published evidence of clinical benefits of adding prebiotic oligosaccharides to dietetic products for infants*."[17]

As a health benefit is an integral part of the definition, we would argue that the formula and follow-on milks with these products added do not actually contain prebiotics.

The Committee further pointed out:

> *"The induction of more watery stools may provide relevant benefit in infants suffering from constipation but has the potential to increase the risk of dehydration in some infants. There is concern (discussed in detail by SCF)[18] that a particular risk may exist for infants during the first months of life with renal immaturity and a poor ability to concentrate urine if an additional stress on water balance is induced, for example, by fever, respiratory distress, infectious diarrhea, high dietary renal solute loads, or refusal of the infant to accept appropriate quantities of fluids. Furthermore, an increase of stool frequency and change in stool consistency might theoretically interfere with the bioavailability of nutrients, although available data do not show this to be a major problem*. "

Article 8.9

Add new wording after the first sentence: "***Labelling must not imply that products (other than infant formulae) are suitable for very young babies or for bottle feeding."***

Article 9

Change the sentence to read: **Advertising of infant formula and follow-on formula shall be banned**.

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[16] Gibson GR, Roberfroid MB. Dietary modulation of the human colonic microflora: introducing the concept of prebiotics. *J Nutr* 1995; 125: 1401-12.

[17] Agostoni C, Axelsson I, Goulet O, et al. Prebiotic oligosaccharides in dietetic products for infants: a commentary by the ESPGHAN Committee on Nutrition. *J Pediatr.Gastroenterol.Nutr.* 2004;39(5):465-73.

[18] Scientific Committee on Food. Report of the Scientific Committee on Food on the revision of essential requirements of infant formula and follow – up formula (adopted on 4 April 2003). SCF/CS/NUT/IF/65 Final 18 May 2003.

Rationale: Advertising restrictions are admissible in all Member States provided they are based on considerations of public welfare and provided the restrictions are in line with the basic principle of proportion.[19] The term, *publications specialising in baby care,* is interpreted differently in different Member States and this opens the door for advertising which targets parents. Such advertising is in violation of the *International Code* (Article5.1). Scientific publications must contain only scientific and factual information as defined in the International Code.

Article 9.1, 9.2. and 9.3.
Add to read in 9.1 and 9.2.: after infant formula " **and follow-on formulae** …" and add to read in 9.3: "Manufacturers and distributors of infant formulae **and follow-on formulae**…**"** to protect continued breastfeeding and to be consistent with the provisions of the International Code (article 5.1).

Article 10.2
See comments on Whereas 25
In the last sentence **insert the words** 'or text' **after** 'pictures' **and replace the words** 'infant formulae' **with** 'breastmilk substitutes' **to read:**

> ***'***Such materials should not use any pictures or text which may idealise the use of breastmilk substitutes***.'***

Rationale: This ensures that the text is consistent with Article 4.2 of the International Code.

Article 10.3
In the fifth line**, insert "**not**" before "**bear the donating companies's name or logo"**.**
Change "but" to "and" at the end of the line and
Delete from "infant formulae" to the end of the para.

Rationale: Manufacturers have changed their labelling and branding so that the logo and name of the company normally promotes the breastmilk substitutes. These donations should certainly not be allowed within the healthcare system.

Article 10.4
Change text to read: 'Member States shall ensure that free and low-cost supplies of breastmilk substitutes should not be allowed in any part of the health care system.'

Rationale: This ensures that the text is consistent with subsequent WHA Resolutions, specifically WHA 47.5 adopted in 1994.

[19] Implementation of the International Code of Marketing of Breastmilk Substitutes in CEE countries: Can the countries of Central and Eastern Europe (CEE) adopt the International Code of Marketing of Breastmilk Substitutes and Subsequent Relevant World Health Assembly Resolutions (the Code) as a minimum requirement, without affecting any existing legal commitments or prejudicing eligibility to join the European Union(EU)? *Paper commissioned by UNICEF.*

Article 11.

A new section needs to be added on MONITORING:

In order to be effective there need to be arrangements to monitor and police the implementation of this Directive in each Member State. The competent authorities are likely to need training to enable them to carry out this surveillance.

COMPOSITION and CLAIMS

Annex I and II
Review soy as an ingredient. See comments on **Whereas 3**

8. We are pleased to see that sucrose and glucose are not to be added to formula milks except those based on protein hydrolysates.

Maltodextrins, glucose syrups and starches are not components of breastmilk and it is strange to see them permitted here. We would query the safety of adding up to 30% of the total carbohydrates as starch. What is the rationale for this from a health point of view? Babies do not have the full complement of enzymes to digest starches. Thickened feeds have not be shown to be useful for the majority of babies, even those with reflux. This is another example of a misleading claim but here it seems to be altering the compositional requirements.

For follow-on milks these compositional requirements leave babies open to rampant tooth decay, as their newly emerging teeth will be bathed in the sweet and/or starchy solution. Tooth decay is a particular problem in some disadvantaged communities, and babies in poorer families are much less likely to be breastfed. Drinking milk from a bottle or 'sippy' cup with a spout, keeps the milk in contact with the teeth for long periods of time. It is not feasible for children's teeth to be cleaned after every feed and this should be taken into account in the compositional requirements.

9. delete the second sentence. Any new ingredient should be subject to the same criteria. This sentence is unnecessary. It would be preferable to state: "No claims shall be permitted. "

Annex IV Compositional Criteria warranting a corresponding claim.

Delete this Annex

Rationale: See comments on Whereas 23 and Article 8.7

In line with the recommendations of Chapter X of the SCF[20] this Annex is no longer necessary. The SCF recommends a review of all the claims, and apart from the

[20] Report of the Scientific Committee for Food on the Revisions of Essential requirements of Infant formulae and Follow-on Formulae. SCF/CS/NUT/IF/65 Final. 19th May 2003.

Lactose Free claim, finds the majority of claims redundant. SCF refers instead to nutrition labelling.

During the existence of this annex no independent scientific evidence has been conclusive on the claims made. This view is supported by the report of the SCF:

Page 48 states: "*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 state: "*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 states*: "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."*

HA or Hypoallergenic claims are not permitted in North America following Nestlé/Carnation's launch of Good Start HA in the US in 1988, when several allergic babies suffered from anaphylactic shock. Nine US States and the Food and Drug Administration investigated and forced Nestlé to stop using 'hypoallergenic' claims which they said were: "Misleading and deceptive..."

Annex V and VI

The Commission should be clear about the references for the changed values for human milk. Are these the "right values"? Human milk composition is changes during the course of breastfeeding and during each feed. There are circadian changes in composition too. Since this list fails to consider these changes and cannot offer unique tailored nutrition for the optimum nutrition of human babies, it should be highlighted that any breastmilk substitute produced in line with this list will only approximate the nutritional composition of breastmilk.