

Revised IBFAN/ Baby Milk Action Comments on the working document on the draft Commission Directive on Infant formulae and Follow-on Formulae (SANCO D4/HL/mm/D440180 rev 2 of February 2005)

The following comments are a revised version of those sent to the European Commission at the start of the consultation period.

General points and summary

This proposal for a recasting of the *Commission Directive on infant formulae and follow-on formulae* (91/321/EEC) is inadequate and in some senses unethical. Apart from some welcome changes relating to composition and labelling, it has changed very little since April 2004, when the first draft was circulated. The Commission is clearly reluctant to take on board the concerns of Member States, European Parliamentarians and the thousands of NGOs, who have been calling for greater protection for infant health ever since the *International Code of Marketing of Breastmilk Substitutes* was first passed in 1981.

It is worth recalling that the Resolution which adopted the Code in 1981 (WHA 34.22) stated that:
“...the adoption of and adherence to the International Code...is 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... [WHA] urges all Member States to give full and unanimous support to the ...International Code **in its entirety** as an expression of the collective will of the membership of the World Health Organisation.”

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 *International Code* and the subsequent relevant WHA Resolutions and the international agreements which all EU member states support and have an obligation to implement.¹ The Commission has a responsibility to help governments fulfill these obligations. It should not hamper them, as it is now doing.²

Since this Directive was adopted in 1991 scientific evidence has consistently demonstrated that artificial feeding increases mortality rates, increases rates for illnesses such as 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.³ The benefits of breastfeeding extend throughout the whole life cycle. In the global context, breastfeeding and appropriate complementary feeding help fulfil the Millennium Development Goals and have the potential to reduce under-5 mortality by 19%.⁴

¹ EU Member States also have obligations under the Convention of the Rights of the Child and the WHO Global Strategies on Infant and Young Child Feeding and Diet and Physical Activity. *All Member States have Ratified the Convention on the Rights of the Child and are obliged under Art. 24 “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, etc”.*

² <http://www.ibfan.org/english/activities/trade/euoct01.html>

³ *The WHO Multicentre Growth Reference Study (MGRS) : rationale, Planning and Implementation*, Food and Nutrition Bulletin, Volume 25, Number 1, March 2005. Suppl 1 <http://news.bbc.co.uk/2/hi/health/4236229.stm>, www.timesonline.co.uk www.guardian.co.uk/uk_news/story/0,,1406303,00.html

⁴ Jones G et al. (2003) *How many child deaths can we prevent this year?* The Lancet, no 362, 65-71.
Risks of formula feeding A brief annotated bibliography INFACT Canada, updated May 2004
http://www.who.int/child-adolescent-health/NUTRITION/infant_exclusive.htm
<http://www.babyfriendly.org.uk/home.asp>,

The original Directive, although full of loopholes, did at least 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 safeguard, 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.⁵

Instead of protecting breastfeeding and infant health, the current proposal, if adopted, will protect the interests of the baby food industry. It will allow manufacturers to introduce new formulations onto the market without first having to demonstrate their safety or expected benefit. It will promote the notion that certain ingredients should be 'optional.' Furthermore, that information about these ingredients should be conveyed, not through nutrition labelling, but through yet more health and nutrition claims.

IBFAN believes that if an ingredient is essential for health and has been shown to be safe through independently-funded and systematically-reviewed research, it should be a legally required ingredient available to all infants. The current proposal turns this concept on its head and creates a double standards. It suggests that an infant's health and development should depend on a mother's chance sighting (and understanding) of a health claim at point of sale and/or their ability to afford a higher priced milk.

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*⁶ 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)⁷ and suggests that nutrition labelling should be used to indicate the presence of ingredients such as DHA. The proposed Directive allows nutrition claims for such ingredients.

The proposal also fails to address the issue of contamination by *Enterobacter sakazakii* and other pathogens and the need for hazard warnings, or the risks of soya on the developing infant.

The enlargement of European Community provides the Commission with a long overdue and important opportunity to bring the European Directives into conformity with the recommendations of the United Nations. This would contribute to the optimum protection of infant and young child health within the EU and outside it – both in the short and long term. It would also facilitate the provision of independent information throughout the Community.

⁵ *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.

⁶ SCF/CS/NUT/IF/65 Final. 19th May 2003.

⁷ 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)

Summary of changes that need to be made:

- 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 labeled 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.
- Bottles and Teats should be covered by additional legislation to control marketing and composition. This work should be initiated immediately.

SPECIFIC COMMENTS

TITLE:

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

Rationale:

- *After many years of delay, Codex Alimentarius has 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.*

The market for specialised foods has expanded, fuelled by unregulated health claims and promotional tactics which the industry considers to be appropriate for these products.⁸ The claims used are invariably supported only by industry-funded research and the marketing exploits parents concerns about normal feeding occurrences which are classified as “ill health” or ‘symptoms of illness’ (regurgitation, colic, sleep disorders, intolerance, etc) Specialised formulae are often presented as the first option for care in these cases. There is evidence from the USA, where restrictions on marketing are minimal, that 40% of mothers switch to specialised formulas even though published evidence indicates that only 2-7% should need them. This increases the proportion of babies fed soy formula ((In the USA 26% of babies are fed on soy formulas.) and encourage parents to believe that their babies are allergic or otherwise abnormal..⁹

- *The formulas designed for special medical purposes contain many of the same ingredients as standard infant formulas and should be governed by the strictest of safeguards.*
- *Any special compositional or labelling requirements for the small number of specialised formulae that might be needed could very easily be included in an Annex or subsection of this Directive. It is essential that products, such as formulas for PKU babies, are clearly labelled, but there is no need for health or nutrition claims. IBFAN welcomes the requirement that a clear distinction should be made between infant formulae, follow-on formulae and foods for special medical purposes.¹⁰*
- *The baby food industry does not seem able to provide a definitive list of products covered by the Medical Foods Directive so the situation has become very confused and illogical. During the UK FSA Consultation Meeting in October 2004, when asked which Directive a formula designed to control reflux would fall under, the baby food industry representative replied that this would be decided by the health professional according to how they use it with patients*□

⁸ SMA High Energy is a food for special medical purposes not suitable for normal healthy babies. A promotion for this infant formula to health visitors in Wales, contained 20 health claims, no breastfeeding is best notice and an offer of winning £39 worth of play equipment. April 2004.

⁹ Polack FP et al. *Changing partners : the dance of infant formula changes*. Clinical Pediatrics, Vol 38, no 12, December 1999, pp 703-708

¹⁰ Comments by International Association of Consumer Food Organisations (IACFO) on the PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA (CODEX STAN 72 – 1981) ALINORM 03/26 Comments at Step 3 of the procedure, Room Document no 13

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 shall 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:

- *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) and Whereas(3) bis1

- Delete: **“if necessary”**
- Replace **“appropriate studies”** by **“independent scientific evidence.”**
- Question the use of Soy protein

Rationale:

- *The words “if necessary” allow for subjectivity which 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 its risks for infants. The UK Committee on Toxicity (COT) and the Scientific Advisory Committee on Nutrition (SACN) on Phytoestrogens and Health (<http://www.food.gov.uk>) have both questioned the use of soy in infant formula.¹¹*

Whereas 4

- 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, foods for special medical purposes and infant formulae. However, if follow on milks are allowed at all, it is essential that their promotion is banned. The inclusion of follow-on milks in the Directive and Codex Standards was the result of*

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The SACN report states: “20.... 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, secondly on grounds of 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. ”

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.” The European baby food industry (IDACE) responded: “No scientific references are given to support these statements. In the opinion of the paediatric experts of the SCF a standard is necessary. There are many papers which support this scientific opinion....”

Follow-on milks are not necessary, cause confusion and create opportunities for inappropriate marketing which undermines infant health.¹² WHA Resolution 39.28 adopted in 1986 requested the Director General to

(2) 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.

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, this directive should make provision for explicit warnings that the product is not sterile on labels and in every publication about formula feeding, and to provide adequate preparation instructions so that care-givers are properly informed about how to reduce the risk of contamination of infants. This is especially relevant to exports, since the risk in low-income countries and communities may be significantly greater. It is illogical 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
- Last line: **“during the period”** should be replaced by **“the first six months”** to be consistent with 2nd line of same paragraph.

Rationale: *It is illogical and not in the interests of harmonisation for the Commission to undermine the policy which was adopted by the World Health Assembly in 2002 and which is already incorporated into 82 national policies, including 12 countries in the European region. The Resolution calls 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, (note 1) and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond.”

- *The proposals do little to ensure that manufacturers will change their labels to reflect and support this policy, and may lead to confusions over the introduction of complementary feeding and overfeeding of infants with all the resulting consequences, including an increase in obesity.*

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**

¹²

Follow-on formulas : are the necessary and should they be promoted ? Baby feeding Law Group briefing. 2004. www.babyfeedinglawgroup.org.uk/

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 “idealize” commercial foods for infants and young children. Increasingly companies are turning to claims which medicalise normal feeding occurrences or sound ‘scientific.’*¹³

- Paragraph 4 of WHA RESOLUTION 55.25 of 2002 called on Member States to ensure that: “that the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding”

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 - practically anything the new-born infant may confront. Breastmilk is also delivered in a uniquely safe way.

- *Ingredients should be permitted for use in breastmilk substitutes only when shown by independently-funded and systematically reviewed research to be safe and essential for infant health. Such ingredients should be mandatory for all infant formulae and available to all infants who are not breastfed.*
- *Nutrition information on a breastmilk substitute should never be presented in a promotional way. It is worth noting the cases in Israel in November 2003 where several babies died after using a nutritionally deficient soya formula which was presented as Kosher. The SCF Report on the Revision of Essential requirements of Infant formulae and Follow-on Formulae¹⁴ questioned the basis of the one health permitted allergy risk reduction claim and called for nutrition labelling, not claims, to indicate the presence of ingredients such as DHA. The proposals suggested by the Commission clearly favour the European infant feeding industry (IDACE) which in its written comments, specifically in Paper 1, call for permission to make an unlimited number of claims to ‘health effect’, suggesting that this is in line with the proposal of the Scientific Committee for Food.*¹⁵

¹³ 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.

¹⁴ SCF/CS/NUT/IF/65 Final. 19th May 2003.

¹⁵ IDACE COMMENTS ON EC Working document: Preliminary Draft of a Commission Directive on infant formulae and follow-on formulae (Recast version), dated 5 April 2004. IDACE is concerned about the fact that no procedure has been put in place in order to allow specific nutrition and health claims other than the ones listed in Annex IV. Nutrition and health claims, being true statements/information regarding the compositional and dietary properties of the foods, provide important

IDACE suggests that a prohibition of claims on infant formulae would lead to ~~the~~ inappropriate use of other foods which bear health claims. This is not logical and ignores the safest solution which is of course that ~~claims~~ on all foods intended for infants and young children should be prohibited.

IDACE's Paper 1, also falsely suggests, in Paragraph 3.4, that claims are in line with the International Code of Marketing of Breastmilk Substitutes and the Global Strategy on Infant and Young Child Feeding. IDACE uses the faulty rationale that nutrition and substantiated health claims are always scientific and factual, are essential in order to provide incentives for innovation, and that they encourage optimised nutrition for infants who are not breast-fed. This is a gross distortion of the aims and provisions of the Code and Global Strategy.

Whereas (24)

- After the *International Code* add “ **and subsequent relevant World Health Assembly Resolutions.**”
- Since the 34th WHA ten WHA 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 infant feeding plays **in decisions choosing, by parents to be and parents of infants 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.

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 UN requirements.*

Whereas (28)

- Products intended for export to third countries should follow the same criteria as those for the internal market.

Article 2(c) See comments on Whereas 19.

Article 2(d)

information to parents. A closed list of nutritional and health claims would impede innovation and progress in infant nutrition. IDACE wishes that a procedure be developed for nutritional and health claims based on the recommendations of the SCF¹⁵. As a result, IDACE believes that the following 2 types of claims should be allowed¹⁵:

- 1) Nutrition claims and other statements that provide for simple descriptions related to the composition of infant formulae,
- 2) Claims related to health effects.

- 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 A NEW DEFINITION: ‘independent’** means free from commercial interest.

Article 3 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.

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 forwards the label to the competent authorities and the exchange of information suggested in Paragraph 3 is hardly adequate to deal with the impact such changes might have on infant 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 many more without proper controls. New developments in infant formulae, especially if accompanied by health and nutrition claims, do not necessarily lead to improvements in public health. In addition to the harm that can be caused by infants 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 an infant.*

However, if an ingredient has proven health benefits, artificially-fed infants should not be deprived of it: it ought to be a legally required ingredient available to all infants. An infant’s health and development should not depend on a mother’s chance sighting and understanding of a health claim at point of sale and/or their ability to afford what is usually a higher priced milk.

*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. The need for independently-funded and commissioned studies and independent reviews of all data is evident in the case of contamination by *Enterobacter sakazakii*, where industry-funded studies have led to weak, inadequate conclusions.*¹⁶

Article 5.

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

Article 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 7.7

- There is an urgent necessity to establish criteria. See comments on Whereas 6

Article 8.1

- Replace text ‘**infant formula**’ with ‘**artificial breastmilk substitute**’
- The Lithuanian translation should be changed. At present it refers to 4-6 months.

Rationale☐

- The product name should clearly reflect that it is an artificial replacement for breastmilk (as in Swedish, Danish and Finnish).

Article 8.2 (b)

Insert the word ‘**independent**’ so 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 *Enterobacteria Sakazakii* and other pathogens.

Article 8.5(a) and (b)

Insert the following words in **bold** to read☐*The labelling of infant formula **and follow on formula** shall in addition bear the following mandatory particulars, **in a label that is not easily removed, a prominent and CLEAR Notice** preceded by the words ‘Important Notice’ or their equivalent **in a size no smaller than the largest text on the package.***

a statement concerning the superiority of breast-feeding **and the risks of artificial feeding;**

¹⁶ *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.

- Add follow-on formula to 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 8.6□

Insert the words ‘**and follow-on formulae**’ after ‘**infant formulae**’ and replace the word ‘**may**’ with ‘**must**’ to read□The labelling of infant formulae **and follow-on formulae** shall not include pictures of infants, nor shall it include other pictures or text which may idealize the use of the product. It **MUST** ~~may~~ however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

Article 8.7

- Change to read□The labelling may **NOT** bear nutrition or health claims.

Rationale:

- Health and nutrition claims on breastmilk substitutes are promotional and inevitably undermine breastfeeding, so it is essential that they are not permitted. **See comments on Whereas 23**

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

1. Change the sentence to read: Advertising of infant formula **and follow-on formula and other forms of promotion, including by electronic means is prohibited.** .
- **Rationale:** *One rationale used by the Commission in 1991 for not implementing the WHO requirements in full was that this would pose constitutional problems for several countries. In fact 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.¹⁷ The term, publications specialising in baby care, is interpreted differently in different Member States and opens the door for advertising which targets parents. Advertising and promotion of breastmilk substitutes is in violation of the International Code (Article 5.1). Scientific publications must contain only scientific and factual information as defined in the International Code.*
 - **WHA Resolution 54.2 states:** ‘*Conscious that despite the fact that the International Code of Marketing of Breastmilk Substitutes and relevant, subsequent Health Assembly resolutions state that there should be no advertising or other forms of promotion of products within its scope, new modern communication methods, including electronic means, are currently increasingly being used to promote such products...*’

Article 9.1., 9.2. and 9.3.

- Add to read in 9.1 and 9.2.: “of infant formulae **and follow-on formulae** ...” and add to read in 9.3: ‘Manufacturers and distributors of infant formulae **and follow-on formulae**...’
- **Rationale:** there is a need to protect continued breastfeeding in line with article 8.4 and the provisions of the International Code (Article 5.1).

Insert New Article 9.4:

¹⁷ *The constitutional relevance of advertising restrictions for Breastmilk Substitutes in Germany*, presented to Eurodiet by Andreas Adelberger, AGB, May 2000
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.

- **Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with parents, parents to be or carers of infants and young children.**

RATIONALE:

- *This is consistent with Article 5 of the International Code*

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 10.4

- **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.*

COMPOSITION and CLAIMS

Annex I and II

Review soy as an ingredient. See comments on Whereas 3

Annex IV Compositional Criteria warranting a corresponding claim.

- **Delete this Annex**

Rationale: In line with the comments on Whereas 23 and the recommendations of Chapter X of the SCF¹⁸ this Annex is no longer necessary. The SCF recommends a review of all the claims and, apart from the Lactose Free claim, finds the majority redundant. SCF refers instead to nutrition labelling and that, *mechanisms and criteria should be developed for communication..”*

While this Annex has been in existence manufacturers have produced no conclusive, independent scientific evidence regarding the claims made. This view is supported by the report of the SCF.

The Lactose free statement is important for a very small number of infants who will in any case be under close medical supervision and could easily be accommodated in the nutrition panel.

Allergenicity claims are particularly problematic and would be more safely handled with a nutrition statement such as, *‘contains hydrolysed proteins’* alongside generic product descriptions and warnings that the product should be used only under the guidance of an independent health professional. □

The SCF report states on 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.”

¹⁸ 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.

and on 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.”*

and 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.”*

The claims for hydrolysed proteins and the development of the market for infant formulae containing partially hydrolysed proteins was underpinned by the work of Dr R.K.Chandra, a Canadian researcher who has in recent years been discredited and whose entire body of work is now under investigation.¹⁹

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...Those babies who had severe reactions to Carnation Good Start have paid a high price for the company's irresponsible conduct.”*

Leading Swedish allergy specialist, Prof Bengt Bjorksten, questioned the European ESPGHAN support for hypoallergenic milks: *“The conclusions drawn by the Committee [ESPGHAN]...differ substantially from what most American and European researchers suggest, and they are almost identical to those suggested by the company marketing the partially hydrolysed product direct to the public... Why did the Committee not properly address this important controversy but merely uncritically quote a review published in a company sponsored book by an employee of the company?”* (Acta Paediatrica,1993)

Annex V and VI

The Commission should be clear about the references for the changed values for human milk. Are these are 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.

¹⁹

Canadian medical journals such as *Nutrition*, have called for an investigation into Chandra’s entire body of research on the basis that his research on vitamins and dementia is fundamentally flawed. The *British Medical Journal* refused to print Chandra’s work saying the paper had: ***“All the hall marks of being entirely invented.”*** An editorial in *Nutrition* said Chandra failed to provide raw data so that experts could check his statistics: *“As a journal, we regret that our peer-review process failed to identify these problems before publication,”* acknowledging that the incident reflected badly on the peer-review process: *“Sometimes the peer reviewers...just [take] the data for face value. They aren't statisticians.”* www.cbc.ca/stories/2004/06/10/sci-tech/chandra040610, www.biomedcentral.com/news/20040511/02, <http://bmj.bmjournals.com/cgi/eletters/328/7431/67#48196>,