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24 December 2004

Dear Akki Khan,

Recast Commission Directive on Infant Formulae and Follow-on Formulae.

Thank you for the opportunity to send comments on the above proposal. I appreciate your willingness to extend the deadline. You will have received our comments in May and October. 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 Commission may wish "to concentrate on the highlighted text of the working document" it is timely for the original Directive to be reviewed for the reasons outlined below..

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 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, development of Carelines and direct maketing.

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. It is, therefore, appropriate for this Directive to refer to all breastmilk substitutes, not only to formula milks and follow-on formulae. 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 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.

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

In these notes:

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.

Specific points in the Draft Commission Directive as recast

Page 2 under Whereas:

Insert:

1) The adoption of the *Global Strategy on infant and young child feeding* and the *Blueprint for Action on Breastfeeding in Europe* with the support of all Member States necessitates the implementation of the *International Code of Marketing of Breastmilk Substitutes* and subsequent relevant Resolutions within the European Community to protect the health of infants and their mothers.

(2) We believe that this Directive should protect all infants and therefore the words "in good health" should be deleted. Obviously this will have further ramifications in relation to compositional requirements. However, implementation and consumer protection would be improved if all breastmilk substitutes, including specialised formulae for medical purposes were included in the one Directive. At present there are anomalies where some foods for special medical purposes are allowed to be promoted at point of sale, for instance, whereas formula milks for healthy babies are not.

The 25th Codex Committee on Nutrition and Foods for Special Dietary Uses agreed that all infant formula products should be covered by the same standard. It would be more appropriate if one Directive covered Foods for Special Medical Purposes (FSMPs) for children, Infant Formula and Follow on Formula. If this is not possible at this stage, the relevant Directive covering FSMPs should be amended to include the relevant sections on Marketing, promotion, labelling and advertising in line with the Code.

(3) The Scientific Advisory Committee on Nutrition and the Committee on Toxicity have both considered the use of soya based formulae and warned about their potential risks.

The NCT therefore questions the use of soya as a substantial ingredient in formula and, consistent with the precautionary principle, believes its use should be restricted. If soya formulae are permitted for use in the Community, their availability should be strictly controlled, for example, on prescription only, and the product should carry prominent warnings about the risks of soya formulae for infants.

(3) (bis) delete **"**when necessary, by appropriate studies**."** Insert **"**by independent studies, including exclusive breastfeeding control groups**".**

At the end of this point: Such guidance should be adhered to ~~taken into consideration~~ when ingredients are considered for ~~introduced into~~ infant formulae or follow-on formulae." See comments on article 4.

(4) We support the clear distinction between partially hydrolysed protein products and semi-elemental diets but believe that both should be included in a recast Directive covering the presentation, labelling and marketing of breastmilk substitutes. Compositional requirements can be considered separately where necessary. Therefore this point should be deleted if possible.

(6) after microbiological criteria and maximum levels for contaminants 🕮 should be laid down insert " as soon as possible". In view of the EFSA's Scientific Panel on Biological Hazards (BIOHAZ Panel) opinion relating to microbiological risks in infant and follow-on formulae released in November, and further deaths linked to Enterobacter sakazakii' this issue is of great concern.

(19) There was sufficient evidence to enable consensus support for a recommendation on six months exclusive breastfeeding at the World Health Assembly in 2002. Codex Alimentarius has also supported six months as the minimum age appropriate for labelling foods for babies. The NCT supports the substitution of "six months" for the phrase "up to the introduction of appropriate complementary feeding" throughout the Directive. Parents will be looking for clear labelling in line with independent scientific evidence and several European countries have already updated their policies in line with this evidence.

(23) and 23 (bis) Delete and insert "In order to protect infant health, claims (nutrition claims, health claims or other claims) should not be permitted**.**
(see Article 8 (7).

(24) Delete "principles and the aims of". Obviously it should be in line with the principles and the aims of the Code but this phrase seems to allow only a vague resemblance to the Code in places. In common with the European parliament, the NCT would like to see the Code implemented in full. Delete "bearing in mind the particular legal and factual situations existing in the Community" and insert "subsequent relevant WHA Resolutions and the Global Strategy on Infant and Young Child Feeding."

(25) After "for Member States to take appropriate measures in order that this information" delete " ensures an adequate.. " to the end and insert "is independent of commercial influence, ensures an appropriate use of the products in question when they are necessary and does not reduce confidence in breastfeeding. "

(26) Delete

(28) Products intended for export to third countries should follow the same criteria as those for the internal market, with labelling in the language of the country or area of destination, in line with the Code and Resolutions.

(30) and (31) Member States should be obliged to transpose this Directive into national law within a limited time following adoption.

Articles

Article 1
reword the first sentence as follows:

This Directive is a 'specific Directive' within the meaning of Article 4 (1) of Directive [89./398/EEC] and lays down compositional, labelling and marketing requirements for breastmilk substitutes and feeding devices intended for use by infants in the Community. It also provides for Member States to give effect to the International Code of Marketing of Breastmilk substitutes and subsequent relevant Resolutions.

Article 1 and wherever the International Code is referred to either add " and subsequent relevant WHA Resolutions" or include a note to this effect throughout the document. .

Articles 2 (c)and 3 see point (19) above. Follow on mil is unnecessary – therefore the Directive should not imply that babies should be fed follow on milk after 6 months. Babies may continue to take formula milk if they are not breastfed, once they start on solid foods. See discussion on follow on formulae in Notes box on page 1.

Insert the definition of breastmilk substitute from the *International Code* :

(d) **"**Breastmilk substitute means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose, for infants and young children up to two years or beyond."

(f) "feeding devices" means feeding bottles and teats and all infant feeding devices, including feeding cups with spouts and other special devices suitable for feeding infants and young children."

'Promotion' 'special medical purposes' 'independent' 'healthcare system' 'health professional' and other concepts may need to be defined more clearly.

Article 3 reword:
Member States shall ensure that the products referred to in points (c) to (f) of Article 2 may be marketed within the Community only if they conform to the definitions and rules laid down in this Directive. No product other than infant formula or a formula for special medical purposes may be represented as suitable for satisfying by itself the nutritional requirements of infants during the first six months of life.

Article 4
The phrase "generally accepted scientific data" is too vague. The history of medicine is full of examples of generally accepted treatments which were not supported by evidence of efficacy and safety. Both "generally accepted scientific data" and "expert guidance" must be independent from commercial interests.

Inclusion of new ingredients
This needs strengthening, it is not enough to say that such guidance should be taken into consideration as some very poor studies have been sited as references by formula manufacturers. We suggest "New ingredients should only be added if health benefits are demonstrated in independent studies including exclusively breastfed control groups in line with guidance published by SCF, UK COMA "

New ingredients should only be added following notification to the appropriate authorities with adequate time for them to assess the value of the proposed ingredients. A need for an additional ingredient should have been demonstrated by independent, randomised controlled trails of sufficient size and duration with exclusively breastfed babies as controls.

The National Childbirth Trust is concerned that, in recent years, several ingredients have been added to formula milks without adequate safeguards as recommended by the COMA committee[1] such as

- randomised, controlled studies using an exclusively breastfed control group
- sufficient numbers in the study groups
- adequate duration to study the effect on growth and other long term outcomes

We would not agree with the Commission that there has been "no abuse of the existing system which does not currently require notification". Omneo Comfort was launched on to the market in the UK with very little supporting data available to health professionals. All that was available seemed to be conducted by the company themselves. I would argue that it is still unclear whether there is any benefit to babies with the introduction of prebiotic ingredients by other companies, yet they are heavily advertised in the UK.

The Directive indicates that the suitability of ingredients for the particular nutritional use of infants should have been established by generally accepted scientific data. In practice almost all the research in this area is funded by formula manufacturers themselves, which makes it difficult to evaluate the necessity or usefulness of new ingredients objectively. It is well recognised within pharmaceutical research that commercial funding introduces a bias into the publication of results.

If the European Food Safety Authority is an independent body, whose members do not have financial links with the infant feeding industry, we would support the idea that '*specific guidance on the level and type of evidence that companies should collect and evaluate before the commercialisation of a product containing a new ingredient could be developed by the European Food Safety Authority*' as indicated in the Working Paper. However, new ingredients should not be an excuse to make claims about a product (see point 23)

[1] Department of Health 1996. Report of the Working Group on the Nutritional Assessment of Infant Formulas of the Committee on Medical Aspects of Food and Nutrition Policy. Guidelines in the Nutritional Assessment of Infant Formulas. Report in Health and Social Subjects 47. London, The Stationery Office.

In its report **Revision of Essential Requirements of Infant Formulae and Follow-on Formulae (18 May 2003), t**he Scientific Committee for Food states:

"The Committee notes that some dietetic products intended for infants with minor and mostly transient health complaints, such as repeated possetting or intestinal discomfort, are currently marketed as Dietary Foods for Special Medical Purposes. Neither the nature of the complaints concerned nor the recently adopted definition of Dietary Foods for Special Medical Purposes (Directive 1999/21/EC) justifies such presentation for the vast majority of these products. The Committee also notes that such presentation has implications for the labelling and marketing practices of these products. The Committee recommends that the scientific basis for the use, potential benefits and compositional aspects of such products should be reviewed. "

Point 2) under Article 4 as currently worded seems to imply that when new ingredient is added to formula milk, the relevant, competent authority should be notified at the same time as the poroduct is placed on the market. This does not give sufficient safeguard to vulnerable babies who are given the formula. As one product is often the baby's only food, it is essential that it is as safe as it is possible to make it. Competent authorities should be notified in advance – eg three months in advance.

Article 7.
In 1 and 2 Delete " infant formulae and follow on formulae" and substitute " all breastmilk substitutes covered by this Directive"

Reword point 7 as follows:
"Microbiological criteria shall be established as ~~necessary~~ a matter of urgency and consumers should be informed on labels and information materials that dried products are not sterile."

Article 8

The NCT would prefer follow-on milks to disappear as they are confusing for parents and unnecessary for children – see box on page 2. In 2(b) the statement that "it is not to be used as a substitute for breast milk during the first six months of life" implies it should be a substitute for breastmilk after 6 months. This is another confusion that would be removed if follow on milks were removed from the market. Parents, and even health professionals, are not fully aware of the benefits of continuing to breastfeed after six months. Indeed, there is evidence of reduced rates of intolerance when babies are breastfed while solid foods are introduced and the immunological, psychological and emotional benefits continue as breastfeeding continues.

In 2(c), (d) and (e) and point 4: Delete " infant formulae and follow on formulae" and substitute " all breastmilk substitutes covered by this Directive"

Point 4. delete "so as not to" before "discourage breastfeeding" and insert "and shall not"

Note: Any suggestion that labelling of infant formula should be extended "to include the product's suitability when breastmilk is not sufficient to supply the requirements of the infant" brought up at the Dietetic Foods Expert Working Group is likely to add to the lack of confidence in breastfeeding already very apparent in some Member States.

Point 5. Full information as required for infant feeding should be included on labels (see below)

- maternal nutrition, and the preparation for and maintenance of breastfeeding;
- the negative effect on breastfeeding of introducing partial bottle feeding;
- the difficulty of reversing the decision not to breastfeed; and
- where needed, the proper use of infant formula, whether manufactured industrially or home prepared.

They should also include information about how to prepare the product safely, and

- the social and financial implications of its use;
- the health hazards of inappropriate foods or feeding methods; and, in particular,
- the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes.
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(b) delete "care" at the end of this point and insert "health". Nursery workers, child minders and other childcare specialists do not necessarily have the skills and training to enable them to fulfil this role.

7. The NCT believes that health and nutrition claims should not be permitted for breastmilk substitutes and for any foods for babies and young children. This includes their use in promotion, presentation and labelling. Claims are used to promote products, mislead consumers and do not provide additional useful material to enable parents to make decisions about infant feeding.

   In fact these claims have been used by manufacturers to imply that formula milk is equivalent or even superior to breastfeeding. The inclusion of specific ingredients is promoted in a way that idealises the products over and above breastfeeding. This misleading information may be detrimental to individual babies – for instance who are transferred on to a low lactose formula or thickened feed instead of breastfeeding. It also contradicts the promotion of breastfeeding and has an overall harmful impact on public health.

   No reference is made to the advantages of clear QUID labelling which would enable consumers to choose products on the basis of ingredients they felt to be important, within the limitations imposed by the compositional requirements. **(delete Annex IV).**

Justification

It is clear that breastfeeding provides for the optimum growth and development of babies with individually tailored immune factors, as well as numerous short and long

term benefits to the health of both babies and their mothers. Babies who are not breastfed are at increased risk of a range of infectious diseases, asthma, eczema, as well as diabetes, increased blood pressure, obesity and lower average intelligence as children.

Since breastmilk is not on sale or packaged and promoted alongside artificial substitutes, claims which imply a benefit from any of these substitutes create an imbalance and inevitably mislead, undermining breastfeeding. Babies and young children are particularly vulnerable, both because of their relative underdevelopment physiologically and because they are reliant on a small number of foods for the first year in particular.

All EU member states endorse the World Health Assembly Resolution (2002) that recommends exclusive breastfeeding for 6 months and appropriate complementary feeding with continued breastfeeding for two years and beyond. EU regulations should facilitate national governments in carrying out their responsibilities as outlined in this Resolution, and should promote strict safeguards for babies and young children, including a ban on health and nutrition claims on their foods.

There has been an increase in the use health claims in the marketing of breastmilk substitutes and complementary foods in recent years. The claims play on parent's worries, while promising to solve 'problems', some of which may be physiologically normal. Companies seem to be intent on creating a market, and thereby increasing their competition with breastmilk. There is a clear need for greater consumer protection in this sector.

9. This is a step forward but does not go far enough. Advertising and all forms of promotion of follow-on 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 products covered by this Directive shall be labelled in such a way as to avoid any risk of confusion between infant formula and products that are not suitable for use below six months.
Parents have generally received the message that cow's milk is not suitable as a main drink for children under one year from their health visitors and health promotion materials. There is no need for follow on formula manufacturers to advertise their products. This just adds to the confusion as some mothers are led to believe that follow on milks are preferable to breastmilk, some that they must not give unmodified cow's milk to children at all– yet they can give yogurts and cheeses. There should not be any concern that parents will inappropriately substitute with cows' milk if follow-on formulas are not advertised.

Article 9.

No products in the scope of this Directive should be advertised or otherwise promoted. This is in line with Article 5 of the Code: "*There should be no advertising or other form of promotion to the general public of products within the scope of this Code.*"

As drafted this Article does not protect parents and children from misleading information, nor does it protect breastfeeding. Publications specialising in baby care are probably the worst place to allow advertising. They are bought by pregnant women, who are then exposed to pervasive advertising at a time when they are most vulnerable to new information. New mothers, similarly would be exposed to advertising at a time when they may establishing breastfeeding. There is absolutely no logic to it, particularly in view of the continued expressed support by Member States and the European Parliament for the Code and, more recently, for the Global Strategy.

Years of experience of Codes, regulations and restrictions which state that advertisements in scientific journals shall only include information of a scientific and factual nature demonstrate that it does not work. Misleading statements are included, inadequate, poor research is referenced and health professionals have insufficient time and resources to check. The numerous advertisements in scientific publications do not restrict themselves to scientific and factual material. Manufacturers have consistently exploited this loophole in the Directive over the past decade or more. The NCT believes full implementation of the Code and Resolutions is a matter of urgency. Parents and babies in Europe should have the protection now enjoyed by parents in India and Brazil for instance, and the EU should stop exporting publications as well as products which contravene the Code.

Note: 8(b) seems not to exist, perhaps this now refers to 10 (b)

2 and 3 delete "infant formula" and insert "products under the Scope of this Directive".

Article 10

Doesn't seem to make sense in this draft. Manufacturers of breastmilk substitutes, bottles and teats should not be permitted to produce this information for parents and parents to be.

1. Member States shall ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. Delete: ~~covering the planning, provision, design and dissemination of information and their control~~.

This is in line with obligations under the Convention on the Rights of the Child and the Global Strategy. Guidelines covering the planning, provision, design and dissemination

of information and their control will be necessary for those producing information. Manufacturers of products under the scope of this Directive should not produce information for parents and parents to be not have direct contact with expectant and new parents through the provision of Carelines, weaning talks at health service premises, etc.

2. replace "pregnant women and mothers of infants and young children" with "parents to be and parents of infants".

3. Adapt to read: Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall not be made unless ~~only~~ on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. No logos or references to proprietary brands of infant formula or follow on formula should be carried.

4. Member States shall ensure that donations or low price sales of breastmilk substitutes (including follow on formula) are not permitted in any part of the healthcare system.

Further Articles and points will be necessary to fully enact the Code and Resolutions, including, but not limited to:

There should be no promotion of bottles and teats.

No food or drink other than infant formula (or specialised medical formulae) should be labelled or promoted as suitable for babies under the age of six months.

Manufacturers and distributors should not distribute to parents of young children or parents to be any gifts of articles or utensils which may promote the use of breastmilk substitutes or bottle feeding.

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

No financial or material inducements to promote products within the scope of this Directive should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families. This includes the provision of training on infant feeding and sponsorship of materials or facilities so as to avoid conflicts of interest.

Personnel employed in marketing products within the scope of this Directive should not, as part of their job responsibilities, perform educational functions in relation to parents of young children or parents to be. This would include the "Carelines " heavily

advertised by manufacturers. NHS Direst should provide information in addition to health visitors, midwives, pharmacists and dietitians free from commercial influence.

Arrangements for the implementation and monitoring of the provisions of the Directive.

Annex 1

Carbohydrates in breastmilk substitutes:

We are concerned that this Directive allows starches to be used in infant formula. Babies have not evolved to digest starches in early life. Lactose is the natural sugar found in breastmilk; it is less sweet than other sugars and promotes healthier gut flora in comparison to other sugars. It is less cariogenic than glucose and sucrose. The Directive does not seem to be protecting the health of young children but bowing to the wishes of manufacturers. Lactose should be the carbohydrate in breastmilk substitutes unless there is a specific health problem necessitating the use of alternative sources, such as galactose intolerance.

Thickening agents should not be added unless clinically necessary (a tiny minority of babies with severe problems). Unnecessary use of thickeners is likely to lead to further doubts about the superior qualities of breastmilk, which are exacerbated by advertising at present.

9. Fructo-oligosaccharides and galacto-oligosacharides
The evidence on the necessity of oligosaccharides in breastmilk substitutes is not convincing. Further, independent research is required into these relatively new ingredients and which, if any, babies benefit from their inclusion.

Annex IV, delete
Nutrition claim is a generic term which can be interpreted very loosely; health claims are often misleading and have not been shown to be necessary or useful. It is much safer to ban all nutrition and health claims and to ensure that labels provide clear and complete information without claims. Parents should not be expected to decide at point sale the relative value of these optional ingredients. If these ingredients are considered safe and important they should be in all infant formula.

If babies need specialised formulae, parents need to be advised by an independent health professional .

Annex II (5,3), Annex VI and removal of Annex VII

NCT supports the inclusion of breastmilk only as the reference for formula milks.