

Comments on the European Commission's Consultation on the revision of Directive 91/321/EEC on infant formula and follow-on formula

From the Royal College of Nursing, UK

1. Introduction

With a membership of over a third of a million, the RCN is the largest professional association and union of nursing staff and students in the UK. As such, it is an influential voice for nursing at home and abroad. The RCN promotes nursing interests on a wide range of issues by working closely with the Government, parliament, unions, professional bodies and voluntary organisations.

The RCN campaigns on behalf of its members and the people they care for, and is a leading player in the development of nursing policy and practice, and standards of care. In responding to this consultation we represent the views of Neonatal and Children's Nurses, Midwives and Specialist Public Health Nurses. This response is based on our belief in the overarching principles of the importance of protecting the health of babies and infants and the protection, promotion and support of breastfeeding.

2. General Comments

2.1 As the UK member of the Standing Committee of Nurses of the EU (PCN) we are pleased that they are being consulted on this important issue but we are disappointed that one of the organisations not listed as being consulted is the European Midwives Association (EMA).

2.2 Breast milk substitutes – in replacing breastmilk as the sole source of food for infants – are unlike other foods and require special marketing. Correct labelling including information about the potential risks must be an important component of risk management in food safety for these products.

2.3 We believe that in the interest of parents, infants and the public health European legislation should be brought into line with the requirements of the *International Code of Marketing of Breast-milk Substitutes* and the subsequent relevant World Health Assemblies Resolutions.

We express our concern that no changes around the two key issues of the marketing and promotion of infant formulas and follow on formulas.

2.4 While we recognise the potential for bias present in all research, this is reduced if research is commissioned and funded by a disinterested party rather than one active in the market. We believe it is essential that research into infant feeding which influences public health policies must be free from commercial influence. However, this does not prohibit manufacturers carrying out essential research with the aim of improving products and ensuring their safety.

All available data should, in addition, be subject to independent scientific review.

3. Specific Comments

(3) We agree with the addition of recitals (3) bis 2 and (3) bis 3 - additional means for monitoring new ingredients in infant formulae and the proposed system for exchange of information involving Member States (MS) and the Commission is valued.

(7) It is unclear what relevance trade barriers have to the health of infants and the EC Directives. This statement appears unnecessary when low common limits are being set within the Directive.

(17) We agree with the precautionary principle and very low levels set for pesticides incorporated within points 11-16. However we find the language of 17 that refers to “a harmonised approach should be followed” is vague and needs to be explained and clarified.

(23) We support the recommendation that factual information regarding the contents be provided to ensure those groups of people with religious or ethical consideration can make an informed choice.

Article 2

The terminology “during the first months of life” is very unhelpful and could, we consider, be dangerous as it sets no guidance about the appropriate age of weaning and could conceivably lead to detrimental health outcomes from inappropriate and early weaning. In order to avoid confusion it would be better to follow the WHO recommendation for breast fed babies. For consistency the statement should read “during the first six months”.

Article 5

Ingredients shown by independently-funded research to be safe and essential for infant health should be mandatory.

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.”

8.5

Powdered infant formulas including powdered breastmilk fortifiers must carry explicit warnings about the hazards and risks of infant formula. Limiting communication about potential harm that may be caused by powdered infant formula to health professionals and health care systems only is inadequate. Parents and other care-givers do not have regular access to health care providers after they leave hospital in many settings.

We recommend the following mandatory particulars be added as
(b) *a statement concerning the hazards of incorrect preparation*

(c) a statement that this product is not sterile and may be contaminated by *Enterobacter sakazakii* and/or other pathogens.

By the same principle in the case of soya, its risks should be stated on the label.

8.7

The labelling with nutrition and health claims is detrimental to breast feeding and is not appropriate. Health and nutrition claims on foods for infants and young children are misleading in that they imply equivalency or health benefits for breastmilk substitutes. In creating a perceived advantage, they confuse parents. Breast milk substitutes have no health advantage over breastfeeding.

It is essential that infant feeding products carry factual nutrition information –and that this is based on sound, independently funded science. Health and nutrition claims for these products are not only unnecessary but are misleading. The rationale, which underpins national legislation on health and nutrition claims, is based on there being a health advantage. Since there can be no scientific substantiation for claims of superiority and equivalency for breastmilk substitutes to human milk, this principle does not apply to infant foods.

The purpose of health claims is to gain a competitive advantage, increase sales and recoup expenditure on research - not to communicate important information to consumers. In 1995 the European Commission issued a discussion paper for Member States about whether health claims should be permitted. The paper clearly showed that from the industry's perspective health claims have far more to do with providing benefits for the producer than informing the consumer.¹ It stated: "... [The claim] would allow the company to gain a competitive advantage and allow it to recover its investment in research.

Health and nutrition claims violate the *International Code of Marketing of Breast-milk Substitutes* and the subsequent relevant World Health Assembly Resolutions and should not be permitted.

Article 9

Follow-on milks are not necessary but if these products are permitted on the market, their promotion should be prohibited within this EC Directive.

9.1

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.

Article 10

10.2

¹ *Claims for infant formulae* European Commission DG III paper, 27 March 1995. III/5185/95-EN iii.E.1-BM/cvi

A new point 2 (b) should be added to read

(b) the hazards and health risks of infant formula

If parents are to make an informed choice this must be included in information and education material dealing with infant feeding and is as important as the benefits and superiority of breast feeding.

The following paragraph also fails to mention the hazards and health risks of infant formula and we recommend the following amendment.

“ the hazards and health risks of infant formulae, inappropriate foods or feeding methods...”

Parents have a right to make an informed choice with regards to infant feeding and full and accurate information must be communicated to parents. The hazards and health risks associated with poor preparation techniques are high and must be explicit. Powdered infant formula is not sterile and this fact is recognized in all expert communications, including the European Food Standards Agency (ESFA).²

The risks of contamination by *Enterobacter sakazakii* and other micro organisms are real and parents have the right to be informed about these risks and appropriate risk reduction strategies. This will not arouse undue concern, but will help them make knowledgeable decisions about how to feed their infants.

10.3

Donations of information or education material with the companies' name or logo is in our view against the *International Code of Marketing of Breast-milk Substitutes*. It places names and logos on material that will be recognised by healthcare staff and parents in the healthcare system and is a promotional strategy whether the brand of infant formula is referred to or not.

10.4

Free and low-cost supplies of breastmilk substitutes should not be allowed in any part of the health care system. Donations of infant formula to institutions or organisations undermine the *International Code of Marketing of Breast-milk Substitutes* and should not be allowed within this EC Directive.

**Royal College of Nursing, UK
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