

Baby Milk Action Comments on Proposed Medical Foods (England) Regulations 2000

January 2000

Summary

Baby Milk Action welcomes the opportunity to comment on proposed regulations which implement the European Commission Directive 1999/21/EC on Dietary Foods for special medical purposes.¹

The comments below apply to the Regulations, the Directive 1999/21 and to Codex proposals ALINORM 99/22A.

The EU Directive on Dietary Foods for Special Medical Purposes (1999/21/EC), adopted in March 1999 applies to infants with 'limited, impaired or disturbed capacity to take, digest...ordinary foodstuffs.' and hands to the baby food companies just what they have been waiting for - permission to make a host of new claims, which, although violating the International Code, may not actually break European law.

We are now seeing a marked increase in the promotion of specialised formulas which claim to tackle 'problems' such as colic, crying, vomiting and allergies. Extraordinary claims are being used, many of them unfounded or based only on industry-funded studies. These proposals open the door to unethical marketing including a host of health claims which can be used unless they are proven to be invalid.

Sometimes the claims promote new 'biological ingredients' and suggest that the formulas match human milk. Others compare one artificial milk to another - and simply ignore breastfeeding. A generous explanation could be that breastfed babies do not get ill so often. A more likely explanation may be that companies want health workers to believe that breastfeeding is simply not an option for sick babies.

¹ Even if carried out with good quality products in good conditions, artificial feeding presents considerable risks to infant health and considerable costs to the health care system and families "More mothers breastfeeding would bring health gains to mothers and babies and savings for the NHS in both the short and longer term. Breastfeeding reduces the risk of a range of diseases including gastro-enteritis in babies, neonatal necrotising enterocolitis (in pre-term infants), child onset diabetes mellitus and middle ear and respiratory infections. The benefits for the mother include a reduced risk of death from breast cancer under the age of 35. The main cost saving to the NHS comes immediately in the form of reduced hospital admissions for gastro-enteritis. The rate of admissions in babies bottle fed or breastfed for only a short period is just over 5 times more than in babies breastfed for 13 weeks or more. At a cost per inpatient stay of about £1200, the saving associated with each one percentage point increase in breastfeeding in the average health district is about £4,000 - about a half a million pounds in England and Wales. If all babies were breastfed this would be equivalent to almost £300,000 a year for the average district or £35 million for the country as a whole." *Breastfeeding: Good Practice Guidance to the NHS* 1995 Department of Health

We believe that this will have grave consequences for infant health, both in the UK and globally and have no confidence that systems are in place to evaluate them effectively.

We have expressed our concern about the proposals many times, and many questions remain:

- Why did the UK support the adoption of the Directive in December 1999? What was the urgency, given that the controls - including the provisions regarding health claims foods for adults are so inadequate?
- What steps has the UK Government taken to ensure that the Directive does not have a damaging effect in Third countries?
- What steps have been taken to propose an amendment to the Directive.

Concern about the Directive in Europe

At the IBFAN European Regional meeting in Sweden, a letter to the new European Commissioner for Health and Consumer Protection, David Byrne, was endorsed by 54 health professional and consumer advocates from 28 countries in Europe, CEE/CIS and the Baltic States. The letter asks the Commission to amend the new Directive on Dietary Foods in line with the International Code and Resolutions.

In addition Glenys Kinnock MEP asked the following questions of the Commission on 27 October 1999:

“What is the process by which annual declarations of interest of past and current members of the Scientific Committee for Food are sought, submitted and published?
1 What measures will the Commission take to ensure that the Dietary Foods Directive meets the requirements of the International Code on the marketing of breast milk substitutes and subsequent Resolutions?
1 What consultation took place with experts on infant foods and their marketing when formulating the Dietary Foods Directive?

The answers provided by the Commission so far have been completely unsatisfactory and the logic for not including promotion and labelling controls rests entirely on the notion that since the market for these products is so small, mass media advertising would not be feasible. This is entirely false.

In addition

Health and medical claims

Baby Milk Action, together with its partners in the International Baby Food Action advocates that no health or nutrient function claims should be made about any food product - especially any food product intended for use by infants or young children. If

nutrient content statements are permitted - in addition to what should be mandatory full disclosure of ingredients - they should not be used to imply a benefit.

It is vital that ingredients are properly specified in order to ensure the correct use of the product - for example a milk with a special composition for a specific illness.

In addition the proposals fail to demand that in the case of the labelling and marketing of infant foods it is essential that the requirements International Code, and all subsequent relevant World Health Assembly Resolutions are adhered to, namely that advertising and promotion is not permitted, that adequate warnings (rather than health claims) are carried, etc etc

Who will test the claims?

Infatrini - a test case

Baby Milk Action sent a complaint about Infatrini, a high energy milk for babies who fail to thrive to MAFF in July. Maff sent it on to the Trading Standards Authority (LACOTS) and to the Medicines Control Agency. Four months later, the MCA replied that because Infatrini is a food rather than a medicine it does not fall within their remit. Baby Milk Action has referred the case to LACOTS and awaits a reply.

A few days before a story about Infatrini was featured on the BBC consumer programme, Watchdog, in August 1999, Nutricia mailed dieticians saying that it did not intend to repeat the advert and that it had no objection to "Infatrini becoming a prescription only product, but for this to happen, current legislation would have to change." Yet the previous year the industry was lobbying against putting the products on prescription and in favour of the weak Directive.

Costs of the new Regulation

Why do the proposals provide an estimate of the costs incurred to companies, but fail to indicate the profits that will be made or the health costs to infant health if such unrestricted marketing is encouraged.

Get exact wording from letter to R Hignett. Re specialised formulae and the Code

Validation of health claims

Health claims, nutrient function claims or medical claims attribute properties to a product or to a specific nutrient that it can prevent, treat or cure disease. Their validity can and should be challenged.

Nutrient statements, in contrast, such as ‘Lactose free,’ are a matter of fact which can be tested by analysis of the product. Nutrient statements act like claims when they are presented in a way which implies a benefit.

Current EU law (for infant formula for babies in good health) allows: 6 nutrient content claims: Adapted protein; Low sodium; Sucrose free, Lactose only, Lactose free; iron enriched and 1 nutrient function claim: a claim related to “reduction of risk to allergy to milk proteins [which] may include terms referring to reduced allergen or reduced antigen properties.”

The Medical Foods Regulations impose an impossible burden on states who would have the responsibility to ‘disprove’ claims. The burden of proof should be on the companies who stand to make a profit from the products.

Nothing is said about the need for independent research to back up claims.

Baby Milk Action recommends that a precautionary principle should be used, which does not allow any health claim - unless they can be proven to be true. IBFAN supports this prohibition on the basis that claims idealize infant formulas and complementary foods; they are a marketing and promotional device; they distort nutrition information; they mislead and are difficult to substantiate scientifically. Moreover, they overemphasize the importance of certain nutrients outside of the context of the total diet. As well, cultural, social and religious global diversity makes consistent interpretation very difficult.

As signatories to the *International Code of Marketing of Breast-milk Substitutes*, subsequent relevant World Health Assembly Resolutions and to the *Convention on the Rights of the Child*, the UK Government has a responsibility to ensure that parents receive accurate, unbiased and full information and are not misled by unsubstantiated claims. The *International Code* calls on manufacturers to ensure that their information is ‘scientific and factual.’

Claims on baby foods compete unfairly against a product that is not packaged or put on sale. Similarly claims made on foods for adults, novel foods whatever, compete unfairly against fresh fruit and vegetables and other staple foods which, although on sale, and not packaged or promoted aggressively.

Examples

“Nutritional additives may face shorter approval processes than pharmaceutical products...The commercialisation...of nutritional additives... represents a significant avenue to near-term revenues for the Company” Neose Technologies

“5.6 average hours crying/day cow’s milk formula
0.7 average hours crying/day Nutramigan
50% stopped crying completely...”

Mead Johnson claims based on a study of 24 babies.

Industry has bought science

precautionary content listing, but highlighting for promotion or marketing purposes. no marketing based on contentAnti reflux. Baby Milk Action's experience of monitoring the use of health claims in the UK has demonstrated the complexity of proving that one claim or another is "true".

We understand that our position regarding a prohibition on health claims was supported by several delegations including the Consumer's International (CI) and Norway reiterated their positions that no claims should be permitted. As well the International Association of Consumer Food Organization (IACFO) expressed their position that in the only two operating models where health claims are operational, declining standards for scientific substantiation and declining pre-market approval systems existed and therefore it was premature to proceed with a standard on health claims for Codex.

Other delegations stated that standards on health claims should be left to national governments to reflect their national positions.

The US "graciously" volunteered their member Dr. F.E. Scarborough who "is an expert in these matters" to convene the Working Group. At the Working Group a discussion document (prepared by France), ***Proposed Draft Recommendations for the Use of Health Claims*** was tabled detailing definitions and criteria for consideration by the Committee. Thus the question of whether health claims should even be permitted was by-passed. In conclusion the chair recommended a further Working Group to be chaired by the US and Canada and assisted by France and the UK which would meet prior to the next session of the CCFL.

Why claims can undermine infant health

Breastmilk is a living substance, with almost as many live cells as blood itself. It can actively destroy many bacteria, viruses and parasites - practically anything the new-born infant may confront. Its anti-infective, anti-viral and growth factors are entirely missing from artificial substitutes. Added to this - breastmilk is a naturally renewable resource, which requires no packaging or transport, results in no wastage and is free.

It should not surprise us that companies claiming that their products are 'equivalent to' or to 'close to' breastmilk - the gold standard - resort to using genetically modified ingredients and processes. Nor should it surprise us that there is a conspiracy of silence which surrounds the manufacture of artificial feeding products. We should instead be ask whether we have given consent to be part of a mass uncontrolled trial.

Breastmilk is not on sale and is never packaged and rarely promoted in glossy brochures. So any claims made about artificial feeding invariable create an imbalance. Indeed they

have convinced many that it is possible to make breastmilk substitutes which are equivalent to breastmilk. surely it would be more accurate to say that we are all taking part in a mass uncontrolled trial?

Our previous comments regarding the proposed *Commission Directive on Foods for Special Medical Purposes (111/5318/98-EN-Rev.1)* , the European proposals regarding limits for pesticides residues in baby milks and foods, and the UK regulations regarding the marketing of bottled water, all contain Baby Milk Action recommendations for safer labelling and explain why such care needs to be taken with infant feeding products. Although our concerns relate mainly to nutrient function claims, nutrition information can also seriously distort parents perceptions of the risks involved in the artificial feeding of infants.

Claims about breastmilk substitutes and complementary foods invariably promote artificial feeding and compete with breastfeeding and the use of locally prepared and home made foods. This is because the nutrient composition of artificial baby foods is very different from the ideal nutrition provided by breastfeeding: important nutrients found in breastmilk are missing, nutrient ratios, in amino acids, or essential fatty acids are very different from those in breastmilk; breastmilk contains vital living anti-bodies and anti-infective properties which are absent in artificial formulas and foods and the nutritional composition of breastmilk changes as the baby's nutritional needs change, whereas artificial foods are non-living products which do not adapt to the infants needs. These differences have a significant and negative impact on the health and development of infants and young children, which are carried through into adulthood.

Although current UK regulations control - to a limited extent - claims which can appear on infant formulas, these controls are already subject to abuse, and with the implementation of new regulations on medical foods, more claims may be permitted. Already manufacturers use illegal nutrition claims such as 'gluten free' on infant formulas simply as a promotional tactic. The "sucrose free" claim on infant formula, although legal, is also misleading, when products contain other sugars which cause harm to teeth.

Baby Milk Action was pleased to receive confirmation from Rosemary Hignett ² MAFF in response to our comments on pesticide levels, that *"any measures adopted should not undermine consumer confidence in the safety or benefits of breastfeeding and fresh foods used to make home produced weaning foods."*

Baby Milk Action recommends that the UK Government takes great care to ensure that all nutrient claims regarding artificial baby foods are subject to the most stringent controls, in line with the International Code and subsequent relevant WHA Resolutions, and that the application of the regulations is monitored closely.

² Letter from Rosemary Hignett, Food Labelling and Standards Division, MAFF to Baby Milk Action regarding Draft Directive on Pesticides, 15 December 99

PR January 1998

the product *'decreases the incidence of diarrhoea'*

the product is *'gentle on your baby's digestive system'*

the product provides *'essential amino acid patterns close to those of breastfed infants'*

the product *'supports visual, cognitive and psychomotor development close to that of breastfed infants'*

the product has *'all the benefits of iron fortification without the worry of constipation'*

the product *'confers reduced incidence of atopy in high risk infants'*

that the product will *'stop dietary related colic in 48 hours'*

that the product is *'organic'*

Breastmilk substitutes compete with a product that is not on sale, and does not have the benefit of being marketed and packaged. Because breastmilk is rarely promoted in glossy brochures in the same way or to anything like the same extent as artificial milk, there is an imbalance in the information and advice that parents receive. Manufacturers compare their products to breastmilk because it is acknowledged to be the 'gold standard,' They make claims about breastmilk substitutes which highlight only the aspects of the products which they want to promote, concealing the intrinsic hazards. The impression is given that it is possible to make an equal 'choice' between breastfeeding and artificial feeding.

The *International Code* aims to protect breastfeeding and infant infant and ensure that parents receive accurate, unbiased and full information. The *International Code* requires manufacturers to ensure that their information is 'scientific and factual.' Health claims about breastmilk substitutes are contrary to the *International Code*. They inevitably promote artificial feeding and compete with breastfeeding:

the nutrient composition of infant formulas is very different from the ideal nutrition provided by breastfeeding:

important nutrients found in breastmilk are missing in infant formulas.

nutrient ratios, in amino acids, or essential fatty acids in infant formulas, are very different from those in breastmilk.

breastmilk contains vital living anti-bodies and anti-infective properties which are absent in artificial formulas

the nutritional composition of breastmilk changes as the baby's nutritional needs change. Infant formulas are non-living products and do not adapt to the infant's needs.

These differences have a significant and negative impact on the health and development of infants and young children, which are carried through into adulthood.

IBFAN is concerned that the new Directive will create new opportunities for the unethical marketing of breastmilk substitutes and will allow foods for particularly vulnerable infants to be marketed without any of the safeguards applicable to other breastmilk substitutes.

It is recommended that the proposals for the Regulations be amended in the following ways:

- 1 The Regulations should include provisions which ensure that the marketing of all breastmilk substitutes is controlled in line with the *International Code* and subsequent WHA Resolutions, which the UK has consistently endorsed.
- 3 The Regulations should not permit the use of any health claims or nutrient function claims for any breastmilk substitute or any product whose marketing may interfere with lactation, for example specialised formulas, drinks for infants, long chain fatty acid supplements, or foods for breastfeeding women. Nutrient content claims and/or statements should be strictly controlled. Since these products should only be used under medical supervision, the relevant scientific data will have been considered. Promotional claims on labels and information materials are not necessary. All ingredients and contraindications should be clearly listed on the label.
- 4 Manufacturers of breastmilk substitutes (and any products whose marketing may interfere with lactation (see above)) should be required to register all products marketed under this Directive with the appropriate government authority, and to forward labels and all information for health workers for approval prior to publication.
- 5 The appropriate government department (for example the Ministry of Agriculture, or the Department of Health) should provide a non-promotional, up-to-date comparison chart and relevant risk/ benefit analysis of all breastmilk substitutes, giving research-based evidence of health outcomes. This should be written in a way that will be useful for health workers and parents and the evidence should be publicly available.