

Protecting breastfeeding - Protecting babies fed on formula

Why the UK government should fulfil its obligation to implement
the *International Code of Marketing of Breastmilk Substitutes**



BFLG
Baby Feeding Law Group

**Response to the consultation on the
revised Infant Formula and Follow-on
Formula regulations**



Produced by Baby Milk Action for the Baby Feeding Law Group

Written by:

Patti Rundall
Policy Director
Baby Milk Action

Mike Brady
Campaigns and Networking Coordinator
Baby Milk Action
And Coordinator of the BFLG monitoring project

Rosie Dodds
Policy Researcher
National Childbirth Trust

**Baby Milk Action is the secretariat for the BFLG
and the UK member of the International Baby Food Action Network (IBFAN)**



IBFAN

Baby Milk Action
34 Trumpington Street
Cambridge
CB2 1QY
Tel: 01223 464420

www.babyfeedinglawgroup.org.uk



The Baby Feeding Law Group and its members (listed on the back cover) are also members of the Breastfeeding Manifesto Coalition, an alliance of 39 organizations including five Royal Colleges, UNICEF, and the trade unions UNISON and UNITE. The Breastfeeding Manifesto outlines 7 key objectives and the Coalition are working to implement these objectives into UK and policy and legislation. Implementation of the International Code is objective 7 of the Breastfeeding Manifesto and is also relevant to objectives 1 and 6. The Breastfeeding Manifesto Coalition fully support this report.

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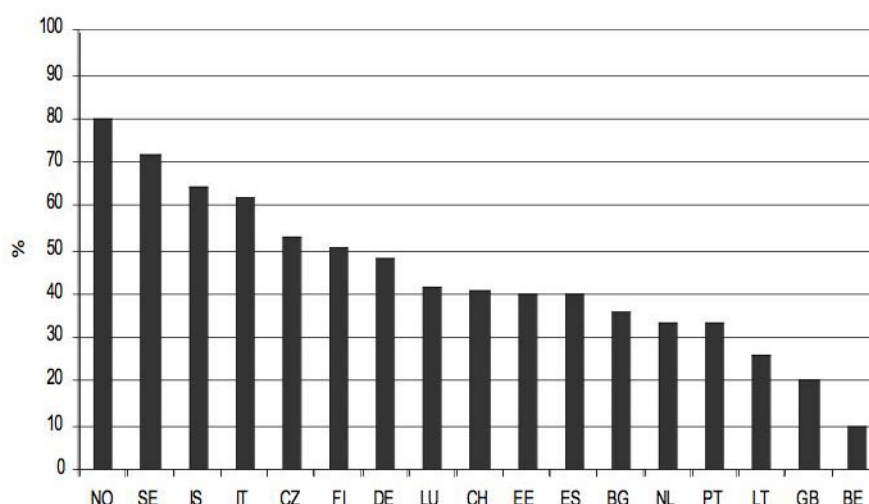
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* In this document the International Code means the WHO/UNICEF International Code of Marketing of Breastmilk Substitutes¹ (1981) plus subsequent relevant World Health Assembly Resolutions². The International Code is also known as the WHO Code.

WHO has stated³: "*The Code and subsequent WHA Resolutions must be considered together in the interpretation and translation into national measures. These Resolutions have further clarified or extended certain provisions of the Code.*"

UK breastfeeding rates - nearly the worst in Europe

EU Breastfeeding rates at 6 months. 2002



Although the UK's initiation rates are starting to improve, duration rates are amongst the lowest in Europe. The chart above shows the rates of *any* breastfeeding at 6 months in 17 European countries. Britain is at position 16. *Promotion of Breastfeeding in Europe, a Blueprint for Action*. EU Project Contract N. SPC 2002359

Table 6.7: Reasons given by mothers for stopping breastfeeding by duration of breastfeeding (United Kingdom, 2005)

	Less than 1 week	Baby's age when breastfeeding ceased 1 week, less than 2 weeks	2 weeks, less than 6 weeks	6 weeks, less than 4 months	4 months, less than 6 months	6 months, less than 9 months	All mothers giving up [†]
	%	%	%	%	%	%	%
Why stopped breastfeeding							
Insufficient milk	26	41	53	48	37	24	39
Baby rejected breast	34	21	17	13	11	16	20
Painful breasts/nipples	24	29	17	9	1	2	14
Took too long/tiring	11	17	19	19	5	5	14
Mother was ill	8	11	9	8	5	5	8
Domestic reasons	4	7	9	10	3	2	7
Returned to work/college	1	-	1	8	15	22	7
Too stressful	7	7	6	4	3	1	5
Baby ill	6	7	5	3	2	1	4
Baby could not be fed by others	1	5	4	6	4	3	4
Didn't like breastfeeding	2	5	4	1	1	*	3
Breastfed for as long as intended	1	1	1	4	10	6	3
More settled on formula	1	2	2	4	8	3	3
Baby not gaining weight	*	1	2	6	4	3	3
Teething/biting ^{††}					3	14	2
All Stage 3 mothers who stopped breastfeeding during survey period	1143	351	1087	1284	195	727	4827

* Includes some cases where mother's breastfeeding duration not known

†† Code introduced at later Stages

Percentages do not add to 100% as some mothers gave more than one answer

The chart on the left from the *Infant Feeding Survey 2005*, Office of National Statistics, shows the reasons given by mothers in the UK for stopping breastfeeding. "Around nine in ten mothers who breastfed for less than six weeks said that they would have liked to continue longer, this proportion declining to 40% of mothers who breastfed for at least six months."

The overwhelming reasons are 'insufficient milk' and other problems that can be overcome with good management. Companies prey on mothers' difficulties and insecurities presenting formula as the solution. See monitoring examples in this report such as the claims for milks 'for hungry babies.'

Executive summary

The need for the long-overdue implementation of the International Code of Marketing of Breastmilk Substitutes is pressing

1. The UK Government has international obligations to implement the International Code and Resolutions, recognised by EU Directives on formula marketing. Leading health bodies in the area of infant feeding and parliamentarians have called for full implementation since 1981. These are **minimum standards** to be **implemented in their entirety** in all countries to protect breastfeeding and ensure breastmilk substitutes are used safely if needed¹.
2. According to a UK government survey 90% of mothers who stopped breastfeeding before 6 weeks said they wanted to breastfeed for longer, as did 40% of those who breastfed for 6 months². In Sweden 98% of mothers initiate breastfeeding³, compared to 76% in the UK. In the UK, rates decline rapidly with less than half of babies (48%) breastfed at 6 weeks. Our rates are almost the lowest in Europe³. In Sweden over 70% of mothers are still breastfeeding at 6 months.(see charts on Page 4)
3. Formula companies do not provide accurate information on differences between brands and essential information on how to reduce risks. Those who use formula need protection and independent information.
4. It is a risk to health to allow manufacturers to put new ingredients onto the market without adequate safeguards and pre-market authorisation.

Background

Twenty-six years ago, in recognition of the damage to infant health caused by the promotion of breastmilk substitutes, the world's highest health policy setting body – the World Health Assembly (WHA) - adopted the International Code of Marketing of Breastmilk Substitutes. The Resolution¹ which adopted the Code stated that it was intended “*as a minimum requirement*” to be “*implemented in its entirety*” by “*all countries.*”

The Code is a set of marketing rules which aim to ensure that all parents - those who decide to breastfeed and those who decide to feed their babies with breastmilk substitutes - are protected from commercial exploitation and receive unbiased and appropriate information.

The UK Government spoke strongly in support of the Code at the time and has since supported the adoption of the 12 subsequent, strengthening and clarifying WHA Resolutions which must be considered together in the interpretation and translation into national measures. (Hereafter the *International Code* or *Code* includes the subsequent, relevant Resolutions).

Current UK Legislation arises from two European Directives⁴, which cover marketing within the EU and exports from it. The Directives themselves came about because of demands by the European Parliament for the Code to be implemented in Europe. The UK called for a strong Directive covering follow-on milk and bottles and teat promotion, but the result was a compromise with many loopholes. The Internal Market Directive⁵ was revised in 2006 and regulations implementing it must be in place in all Member States by 31st of December

2007. Despite its strong support for the Code in international arenas, the UK's record on implementing it has so far been so partial as to be largely ineffective. In 1995, when transposing the Directive, it ignored the advice of 47 health and consumer organisations and brought in a law which was in line with industry's demands. The UK now has an opportunity to take the advice of health experts and fulfil its promises to bring UK legislation into line with the International Code for the protection of ALL mothers and babies.

Failing mothers and babies for 26 years

A mother walking into a supermarket in the UK is likely to be confronted with a promotion like this in Tesco in September 2007, claiming that formula builds a baby's immune system. The claim is illegal if on an infant formula label and the Advertising Standards Authority has ruled against the claim in a follow-on formula advertisement, but this promotion escapes through loopholes in current and proposed regulations. The Baby Feeding Law Group says it is time to fulfil our obligations to ensure information on infant feeding is objective and independent to protect breastfeeding and babies who are fed on formula.



The Government can and should implement the International Code

"The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution."

"Believing that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products."

International Code, World Health Assembly, 1981¹

The Food Standards Agency consultation on implementing the EU Directive offers two options. Option 1 (do nothing), Option 2 (minor changes falling far short of the Code). The Baby Feeding Law Group proposes that the Government take our Option 3: implement the International Code.

On 25 July 2007, Public Health Minister, Dawn Primarolo, said²:

*"Any responses received, **including those that suggest alternative options**, will be considered as part of the consultation exercise."*

In 2002 the United Nations Committee on the Rights of the Child report³ on the UK recommended that: *"the State party takes all appropriate measures to...promote breastfeeding and adopt the International Code for Marketing of Breastmilk Substitutes."*

"[EU Directive 2006/141/EC] provides for Member States to give effect to principles and aims of the International Code of Marketing of Breastmilk Substitutes dealing with marketing, information and responsibilities of health authorities".

EU Directive 2006/141/EC

"A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities".

Article 152 (1) Treaty of Rome, European Union⁴

"The Government is fully committed to the promotion of breastfeeding, which is accepted as the best form of nutrition for infants to ensure a good start in life. Breastmilk provides all the nutrients a baby needs. Exclusive breastfeeding is recommended for the first six months of an infant's life. Six months is the recommended age for the introduction of solid foods for infants. Breastfeeding (and/or breastmilk substitutes, if used) should continue beyond the first six months along with appropriate types and amounts of solid foods. Mothers who are unable to, or choose not to, follow these recommendations should be supported to optimise their infants' nutrition."

Department of Health, Policy and Guidance, 2007⁵

The Baby Feeding Law Group position

The International Code of Marketing of Breastmilk Substitutes and the 12 subsequent, relevant Resolutions (the International Code) are a set of marketing rules from the World Health Assembly – the world's highest health policy body and part of the United Nations.

It aims to remove obstacles to breastfeeding and protect mothers and babies (both breastfed and artificially fed) from commercial promotion. It is a minimum requirement for all countries. It is most effective if written into national laws but companies are required to abide by it, independently of government action. It covers breastmilk substitutes,** feeding bottles and related equipment.

The Baby Feeding Law Group is calling for the following safeguards to be included in the Infant Formula and Follow-on Formula Regulations 2007 to implement some aspects of the Code. The law should:

- ban all promotion of breastmilk substitutes (including follow-on formula, specialised formulas and other bottle-fed products)
- prohibit baby feeding companies from seeking direct or indirect contact with pregnant women and mothers and carers of infants and young children and other members of the public (including a clear ban on company 'carelines', pamphlets, mailshots, emails and promotional websites),
- prohibit baby feeding companies from offering sales incentives and bonuses or setting sales quotas linked to breastmilk substitutes for personnel employed by or on behalf of the company,
- prohibit all idealising text and images from all breastmilk substitutes,
- prohibit company-produced or sponsored materials on pregnancy, maternity, infant feeding or care (the Government must provide objective information on infant feeding, avoiding conflicts of interest in funding infant feeding programmes),
- where possible prohibit all health and nutrition claims on foods for infants and young children. Require any permitted claims to be placed at the back of the package near the nutrition panel,
- require clear warnings about the fact that powdered formula is not a sterile product and may contain harmful bacteria, alongside clear instructions on how to reduce risks from possible contamination,
- prohibit the promotion of names associated with breastmilk substitutes and their use on other products.
- prohibit the promotion of any product in a way that could lead to it being used for babies under 6 months (complementary foods should not be marketed in ways that undermine breastfeeding).
- restrict information for health professionals to scientific and factual matters with no idealising text or images,
- prohibit promotion in healthcare facilities and gifts to health workers (allowing only single samples for evaluation),
- require a pre-authorisation procedure for all new ingredients and addition of authorised ingredients to the annex of EU Directive 2006/141.
- introduce regulations for the marketing of feeding equipment, feeding bottles, teats, dummies etc. in line with the International Code.

** A breastmilk substitute is any food or drink given to a baby of any age which replaces breastmilk. The World Health Organisation recommends six months of exclusive breastfeeding with continued breastfeeding alongside family foods for up to two years and beyond¹.

History of the Code in Europe (Baby Milk Action chronology¹)

May 1981 The UK and EEC Member States voice strong support for the *International Code of Marketing of Breast-milk Substitutes* at the World Health Assembly. The Code is adopted as a *minimum requirement for all Member States to be implemented in its entirety*. The USA is the only country to vote against. During its formation industry described the Code as “*unacceptable, restrictive, irrelevant and unworkable*.”

Oct 1981 The European Parliament (EP) votes overwhelmingly in favour of implementing the *International Code* as a Directive.

1982 - 2006 12 WHA Resolutions clarify and extend the Code.

1982 The Commission starts work on a Directive on quality, composition and labelling. It proposes a voluntary code drawn up by the Association of Dietetic Food Industries of the EEC (IDACE) to cover marketing. The Commission claims a ban of advertising would go against the rules of free competition and would pose problems to the Commission. It alleges that there is no proof that advertising increases bottlefeeding - it merely affects choice between brands.

1983 The EP passes another resolution rejecting the IDACE Code, calling once more for the *International Code*. The UK Manufacturers Federation (FMF) led by Wyeth – produce a voluntary Code (*FMF Code*). This does nothing more than legitimise current marketing practices. Promotion increases and breastfeeding rates do not rise.

1984 The Commission issues draft proposals with the IDACE Code as an Annex. In the UK Wyeth launches £1/2 m promotion of *Progress* follow-on milk for babies of 4 months in the UK. Health Visitors report widespread confusion and misuse and mount a campaign saying their health advice is being undermined.

1985 Three EP committees (Economic & Social, Development and the Environment, Public Health and Consumer Protection) reject the Commission's proposals again. The Consumer Committee questions the scientific basis for including follow-on milks in the Directive: “*The need of follow-up milks is extremely dubious and there is no need whatsoever for a new specially manufactured product*.”

1986 EP votes by a sweeping majority for amendments incorporating much of the Code. Commissioner Lord Cockfield accepts 33 amendments including, in principle, Amendment No 8 on bottles and teats. The Commission submits a Council Directive which again fails to include all the EP amendments. Leading nutrition expert, Prof Michael Crawford says *Progress* is more like rhinoceros milk than breastmilk. WHA Res 39.28 says “*Follow-on Milks are not necessary*” UK Government Panel on Child Nutrition says follow-on should not be used before 6 months.

1986-1989 The issue is stuck in a bureaucratic limbo as the EU legislative process is transformed. A *Framework Directive for Foodstuffs for Particular Nutritional Uses* (PARNUTS) is adopted by the Council. The Commission – an unelected body – now has the power to finalize legislation for these foods without having to consult the EP. PARNUTS legislation was, and still is, discussed in closed meetings with technical experts from Member States.

1989 UK Health Minister, Edwina Curry bans free and low-cost supplies and issues a strengthened Circular (HC (89)21)

1991 The Commission receives over 1,500 letters calling for the Directive to be strengthened. UNICEF Executive Director James Grant writes to the President of the Commission, Jaques Delors, saying the Directive is “*a serious setback in our efforts to promote exclusive breastfeeding*.” WHO provides comments to the UK and Netherlands highlighting over 20 weaknesses. The Chair of EP

Consumer Committee complains that the Commission draft does not reflect its promise to the EP. The Commission accepts that the purpose of the Directive is to “*provide better protection for the health of infants*” and agrees to propose key changes to allow Member States to carry out their obligations under the Code.

May 1991 Directive 91/321/EEC is adopted. Member States accept a new clause permitting a ban of advertising and the strengthening of the section on free supplies. The Netherlands vote against because it did not fully implement the Code. The Danes vote against because the Directive permits high sugar levels. The UK makes a statement regretting that the Directive was not stronger on bottles and teats, exports and follow-on milks.

1992 Export Directive (92/52/EEC) requires labels to be in the correct languages. Council Resolution (92/C 172/01) requires EU-based companies to comply with the Code outside the EU.

1993 - 95 UK Draft proposals initially propose a ban on advertising of infant formula. 47 health, consumer and development NGOs welcome this and call for follow-on formula advertising to be banned also. The UK weakens the proposals in line with industry's demands. The Labour Party leads a ‘prayer’ against the proposals saying the Government is putting commercial interests before health. There are debates in the House of Commons and Lords. 6 EU countries ban all advertising of infant formula.

May 1994 Global consensus is reached on the Code as the USA supports WHA Resolution 47.5 which bans free and lowcost supplies throughout the health care system and recommends complementary feeding from ‘about six months.’

1996, 1999 Amendments to the Directive improve controls on pesticides but allow a controversial reduced risk to allergy claim.

1997 UK Health Professional and lay organisations coordinate as the BFLG to bring UK and EU legislation into line with the Code.

1999 900 European NGOs petition the EU to include the Code in the Directive on *Dietary Foods for Special Medical Purposes* (1999/21/EC). EU Commission resigns over charges of corruption and in the interim the Directive is adopted unchanged.

2000 Baby Milk Action and Glenys Kinnock MEP successfully persuade the Commission to require Scientific Committee for Food members to make public declarations of interest.

2002 The UN Committee on the Convention on the Rights of the Child recommends that the UK increases breastfeeding rates and adopts the *International Code*.

2003 Birmingham Trading Standards presses charges against Wyeth/SMA which argues that advertising is information and that UK legislation “*fetters the free movement of goods*” and should be no stricter than the weakest of any other country in Europe. The argument fails and Wyeth is convicted of illegal advertising.

2004-6 European Commission issues proposals for a revised EU Directive. The UK FSA calls for amendments in line with IBFAN and BFLG suggestions, including calling for a ban of follow-on milk advertising or an option to decide this issue at national level.

2005 The Lisbon Strategy aims to make the EU the most competitive trading block in the world by 2010.

Dec 2006 The Directive (2006/141/EC) is published to be implemented in all 27 EU Member States by December 2007.

Legal arguments surrounding the UK's ability to implement the International Code

The EU and the Code

The baby food issue highlights conflicting values that lie at the heart of the European Union (EU). Since its establishment in 1957 one of the aims of the EU is to harmonise trade rules and encourage the free movement of goods within the community. At the same time there is a horizontal duty in the EC Treaty to promote public health through all the activities of the Union: *"A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."* There have also been repeated calls from the European Council of Ministers and Parliamentarians that health inequalities and food-related illnesses should be addressed.

The Lisbon Strategy adopted in 2005, complicates things further since it aims to make the EU not only the biggest, but the most competitive trading block in the world by 2010: *"We will further open markets, cut red tape and invest in modern infrastructure so that our enterprises can grow, innovate and create new jobs.....Boosting growth and creating jobs are the keys for unlocking the resources needed to meet our economic and social ambitions and are important to reach our environmental objectives....There is no time to lose."* This strategy, unless carefully applied, can mean that concerns about health and diet related problems such as obesity take second place to the interests of trade.

When, in 1981, the European Parliament first proposed that the International Code should be implemented in a Directive for Europe there were only 10 (and later 12) EU Member States. So the opinions of the countries and calling for the Directive to be strengthened (the UK, the Netherlands, Denmark and others) alongside the strong consumer pressure were significant and did succeed in bringing the Directive closer to the Code. Today, with 27 Member States, the task is more difficult, since the Commission makes amendments, if at all, only when a large majority of Member States insist. The negotiations also take place in closed Expert Meetings which are chaired by the Commission and not fully minuted. This is because, since 1989, when the PARNUTS Directive (89/398/EC) was adopted, the Commission has had the right to make amendments and finalise the Directives on baby foods without consulting Parliament on the basis that the changes are merely 'technical': *"Whereas the drawing-up of specific Directives implementing the basic principles of Community rules and amendments thereto are implementing measures of a technical nature; whereas their adoption should be entrusted to the Commission in order to simplify and expedite the procedure...establishing close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs....Provisions likely to have an effect on public health shall be adopted after consultation of the Scientific Committee for Food."*

The FSA's proposed regulations

During negotiations on the revised Directive (2006/141/EC), the UK Food Standards Agency (FSA) presented evidence,

provided by BFLG members and the Department of Health, that the promotion of follow-on milk and other promotional tactics are undermining the Government's efforts to protect and support breastfeeding. The UK's views were supported by several Member States, some recommending that decisions on follow-on milk promotion should be taken at national level. All the European NGOs who were consulted criticised the Directive and called for stricter safeguards but most of the comments were ignored.

The FSA proposals for the Regulations issued in July 2007 reflect the provisions, though not the aim, of the Directive more or less as it is, going further only where the text specifically permits and in some sections falling short. The FSA say the reason for failing to implement the *International Code* is that *"it is no longer open to Member States to introduce national rules in this area except in so far as they are specifically authorised by the Directives."* The BFLG has sought several legal opinions about this and has met with the FSA and DH to discuss this. We have also entered into correspondence with the European Commission. The FSA has indicated to the BFLG that they are willing to 'go further' and take up our recommendations, for example to control follow-on milk advertising, provided the Directive is a 'Partial' not 'Total' Harmonisation Measure.

The aim of the Directive

Action by EU Member States is subject to the conditions laid down in the EC Treaty¹ in which Article 30 (ex 36) & 95 (ex100a) outline a procedure for taking additional measures necessary for the protection of health, provided that such action does not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. *"Member States have a certain degree of discretion and are therefore not required to reproduce the text of a directive exactly in the implementing legislation as long as it can be demonstrated that the national law complies with the Directive. However, the more detailed their provisions the less able a Member State is to depart from it... The margin of discretion available to Member States is determined by the directive itself and must be inferred from its wording, purpose and structure."*²

The purpose of the Directive is stated in its opening paragraphs to: *"provide better protection for the health of Infants"* and to ensure that the rules of composition, labelling and advertising are *"in conformity with the principles and the aims of the International Code of Marketing of Breast-milk Substitutes."* Article 1 of the Directive also provides for Member States to *"give effect to principles and aims of the International Code...."* All these references to the International Code and the provisions arising from them were inserted at the specific request of the European Parliament and were agreed by the Commission in 1986. (see History of the Code page 8). The aim of the Directive was, from the very beginning, to harmonise in the interests of health and to ensure Code implementation throughout the EU.

Article 1 of the Directive not only permits, but could be said to require, Member States to act in accordance with the *International Code* which prohibits the promotion of all breastmilk substitutes. As such it should not matter greatly whether the Directive is a Total or Partial Harmonisation measure - states should act in accordance with the Code in either case. However, since the Directive both permits and prohibits advertising there is an inherent contradiction.

The argument that in order to be validly adopted on the basis of Article 95 EC a measure should improve the conditions for the operation of the internal market should be used to raise safety standards not lower them. Member States were in any case keen to increase safety and harmonise the ingredients through a pre-authorisation procedure but were blocked by the Commission on the grounds that there was no legal basis in PARNUTS for doing so. (see Mass Uncontrolled trial below) The fundamental variation of composition which the Directive permits is an unacceptable and unethical risk. Breastmilk substitutes, unlike any other foods on the market, are the sole food of non-breastfed infants in the first 6 months of life and should be subject to the strictest safeguards.

If a Community measure is a ‘*minimum harmonisation measure*’ Member States are permitted to maintain or introduce more stringent regulatory standards than those laid down by Community legislation, provided that such requirements are in accordance with the Treaty. *Ultimately, should there be a challenge, it is for the European Court of Justice to decide whether harmonisation covers the whole field or whether it leaves room for national regulatory initiatives.*³

The EC Treaty and public health

As said before there is a horizontal duty for the EU to promote public health through all its activities. Article 152(1) EC states: “*A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.*” This indicates that any interpretation of this Directive should favour compliance with the *International Code*. The definition of what constitutes a high level of protection is within the discretion of the ‘institutions’ with proper regard to international practice, scientific information and the application of the precautionary principle.⁴ The BFLG, which represents UK health professional opinion, in this report is submitting evidence that inappropriate artificial feeding risks infant and young child health⁵ and that the promotion of follow-on milks and other promotional strategies are undermining breastfeeding. Indeed the failure of the weak UK Regulations to protect breastfeeding and the need for new action is evident from the fact that breastfeeding duration rates have failed to increase despite substantial input from the Government, health professionals and the UK voluntary sector and are even falling in some regions, according to the latest government Infant Feeding Survey.⁶

A mass uncontrolled trial?

In addition to the risks to health from promotion of breastmilk substitutes, the new Directive encourages the inclusion of ‘*optional ingredients*’ and fails to require a pre-authorisation of new ingredients. The industry has claimed that it is able to demonstrate a ‘*history of apparently safe use*’ and has

suggested that the monitoring of spontaneous consumer reports on consumer phone lines provides a tool for surveillance of product safety. There is no evidence that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of the use of breastmilk substitutes and serious compositional failings which have resulted in harm and even death of infants within Europe have not been detected by company monitoring systems in the past.⁷ Effective regulation in this area is essential to prevent a mass uncontrolled trial.

The Directive also fails to require an **independent** systematic review of evidence (called for by the Scientific Committee for Food in its *Report on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae* 2003) or substantiation of safety by independently-funded research. The Danes in particular were concerned that manufacturers could add new ingredients to follow-milks without informing the authorities. The Directive increases the potential for disagreement between Member States about what is and is not a safe ingredient.

Follow-on milks:

The Directive contains no specific reference to the advertising of follow-on milks apart from an ambiguous reference in Article 13.8 (b). The Scope of the *International Code* clearly covers all breastmilk substitutes, even if they are complementary foods used as substitutes, and so includes follow-on milks. Manufacturers state that follow-on milks are not breast-milk substitutes but know that they are used as such and replace the liquid part of an infant and young child’s diet which should ideally be provided by breastmilk exclusively in the first 6 months and continued along side complementary foods thereafter. A non-breastfed child should continue to have infant formula as the milk component of its diet.

The SMA case - the european point:

An important precedent was set in 2003 when Wyeth/SMA advertised its infant formula in *Prima* magazine. Birmingham Trading Standards Legal Unit pressed charges and an 8-day trial ensued. The judge convicted the company of “*cynical and deliberate breach of regulations.*” Wyeth tried to argue that the UK advertising ban “*fetters the free movement of goods*” and that the UK legislation should be no stricter than the weakest of any other country in Europe, for example, Germany where advertising of infant formula is permitted to the public. Defending the UK’s right to legislate more strictly, Judge Ross said: “*In my view the manufacturers are playing on a ‘level playing field’...It is clear that it is important to uphold the law of the land in the public interest bearing in mind the stability in our society.*” The company had not exercised ‘*due diligence.*’ In mitigation SMA claimed that it had been ‘*misled*’ by the activities of other companies.

The European Court ruled in the Keck and Mithouard Case (Cases C-267/91 and C-268/91 [1993] ECRI-6097) that “*Selling arrangements are matters extrinsic to the goods themselves, which do not hinder trade between Member States, do not fall within the scope of Article 30, provided they affect all traders operating in the Member State concerned and that they affect in the same manner in law.*”

The Directive is not Total Harmonisation

The following points demonstrate that the argument that Directive is a Partial Harmonisation measure and that there is nothing to stop the Government implementing the Code

1. Wide variation of interpretation

Both the previous and the new Directives expressly permit - and could be said to require - Code implementation and allow variation in advertising measures. Some countries ban infant formula advertising and others permit it. **Luxembourg** forbids follow-on milk samples and controls information on these products. In **Denmark, Sweden, Finland and Norway** follow-on milk promotion is not allowed by instructions to control authorities or voluntary measures. The UK's attempt to restrict infant formula advertising to the health care system was challenged by SMA but was overruled (see p10). There has been no other challenge to these differing implementations. Italy has new draft proposals which include a ban on follow-on milk promotion.

2. Variation in the composition

Articles 5 & 6 of the new Directive, proposed by the Commission, permit unlimited and controversial variation in composition of formulas. Most member states wanted pre-authorisation but the Commission said there is no legal basis for this in the overarching PARNUTS Directive. (See p10)

3. No clear lead from the Commission.

The Commission has so far been unable to give a final answer

on the question of harmonisation, apart from indicating that nothing is black and white and that ultimately, in case of challenge, it is for the European Court of Justice to decide whether harmonisation covers the whole field or whether it leaves room for national regulatory initiatives. It would be invalid to suggest that a Member State has misguided itself if it viewed the Directive as a Partial Harmonisation Measure (notwithstanding the fact that the International Code could still be implemented under a Total Harmonisation measure) when it can justifiably argue that it has fulfilled its due diligence obligations in seeking the view of the Commission before deciding its view of the Directive.

Danish Transfat ban: There are precedents for taking such action. For example, Denmark's successful action to limit Transfatty Acids in foods. The Commission's challenge to this was eventually dropped.

Conclusion

- The Government has an obligation to implement the Directive which explicitly gives its aim as the implementation of the International Code.
- The Government has obligations to implement the Code under the *United Nations Convention on the Rights of Child*.⁷ Governments can be legally held accountable for action or inaction which hinders the enjoyment of these rights.
- The Government should take this opportunity to implement the Code. It is its right and obligation to do so.

The Directives do not harmonise formula marketing in Europe

Member States have not only implemented the 1992 Directive in different ways, there are different infant feeding cultures and practices within Member States. Harmonisation could increase protection of health, but only if standards are raised in line with the *International Code*. Dropping them to meet the needs of industry is a risk to health. The lack of harmonisation in both regulations and cultures is demonstrated by the following:

The new Directive specifically permits the inclusion of insufficiently tested ingredients as composition can vary from country to country. *This is not harmony.*



Shown left is an advertisement for Aptamil 2 and 3 from a parenting magazine in **Germany** - both are follow-on formulas. Aptamil 2 is marketed for use from 4 months and Aptamil 3 from 8 months.

In the **UK** Aptamil 2 is an infant formula - not a follow-on milk - for use from birth for 'hungrier babies'. Aptamil 3, shown right, is a follow-on milk, and is marketed for use from 6 months of age. *This is not harmony.*

In the **UK** follow-on milk can be advertised to the general public but infant formula can only be advertised in specialist publications distributed through the health care system. In **Germany**, infant formula can be advertised in baby care magazines everywhere. In **Spain, France, Denmark, Luxembourg,**

Netherlands, Belgium and Ireland infant formula cannot be advertised anywhere. Scandinavian countries do not have a culture of using follow-on milks. Infant formula is intended from birth to one year of age. There is generally no advertising of infant formulas or follow-on formulas in Scandinavia. *This is not harmony.*



The Baby Feeding Law Group monitoring project

Throughout this report there are numbered boxes which present findings from the BFLG monitoring project to illustrate why implementing the International Code is essential.

The Baby Feeding Law Group monitoring project is coordinated by Baby Milk Action. This project provides information to BFLG members and the public to assist them in monitoring the International Code and the UK law and invites reports of violations. It also provides information on how to report violations to authorities such as Trading Standards and the Advertising Standards Authority.

Monitoring results are held in a database and are available for Trading Standards officers. Summary reports are published on the BFLG website. The 2007 pamphlet *Hard Sell Formula*¹ contains an overview of the strategies used to push products.

In 2004 BFLG received funding from the King's Fund to train a team of monitors for the project and has conducted training for health workers and development organisations on monitoring.

Monitoring results are used here to illustrate the demands of the BFLG. Examples were gathered in 2006/2007 unless otherwise stated.

Baby Milk Action would like to thank everyone who has contributed examples to the monitoring project.

For other examples and to make a report see: **www.babyfeedinglawgroup.org.uk**

Key to monitoring boxes

1. Advertising is not information - all formulas claim to be the best
2. Companies try to co-opt health workers - independence must be maintained
3. Targeting mothers before their babies are born - why the Code's prohibition on seeking direct and indirect contact is needed
4. Company logos are associated with formula for young babies
5. Company produced or sponsored 'information' materials idealise products and promote brand names, logos, teddy bears and ducks!
6. Point-of-sale promotion pushes brand names
7. Clearer legislation on claims is essential
8. The follow-on formula claims loophole should be closed
9. Adding new ingredients is used as a marketing strategy - the case of Long Chain Polyunsaturated Fatty Acids (LCPUFAs)
10. Companies suggest formula is better than in reality
11. Company promotion of specialised formulas can lead to mis-use
12. How company names have taken over labels to promote a range
13. The current and suggested approach to differentiating between infant and follow-on formula creates easily exploited loopholes
14. Company promotion of follow-on milks can lead to mis-use

Regulatory impact assessment

Full implementation of the International Code is essential

1. Doing so would help to satisfy governments' obligations under World Health Assembly Resolutions, the Codex Alimentarius Commission, the UN Convention on the Rights of the Child and the EU Directive.
2. Breastfeeding rates in the UK are the lowest to bottom in Europe¹ as promotion that does not take place in some of the other Member States (such as promotion of follow-on milks) is commonplace in the UK. Scandinavian countries and others, such as Brazil, have seen marked recovery of breastfeeding rates after implementing the International Code and taking other steps to promote and support breastfeeding². By contrast, in the UK duration rates are declining in some regions.
3. On a crude estimate based on a US study, a modest increase in breastfeeding rates could save the UK economy at least £360 million for each year of higher rates, including the contribution to the economy from babies who would otherwise have died³. The National Institute for Clinical Excellence (NICE) has calculated that a 10% increase in breastfeeding initiation would save £5.6 million on treatment costs for just three illnesses².
4. Effective controls on labelling and a prohibition on companies seeking direct and indirect contact with mothers and carers, coupled with better provision of independent information for them and health workers, will reduce social, environmental and health care costs for formula fed infants.

The need for BFLG's Option 3 - implementing the Code

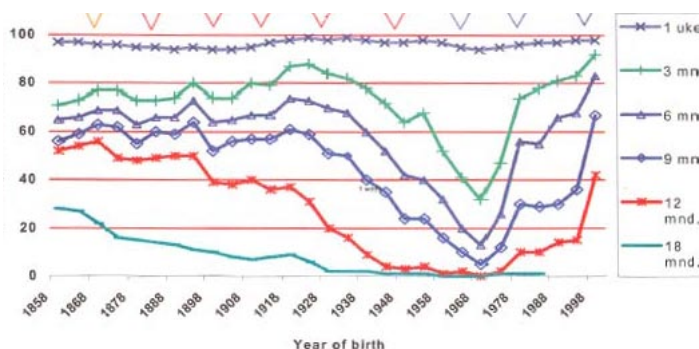
The Regulatory Impact Assessment (RIA) considers two options. Option 1: "Retain the Status Quo" and Option 2: "Implement the Regulations". This response proposes Option 3: "Implement the International Code" (meaning the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant Resolutions of the World Health Assembly). If legal considerations present obstacles, every effort should be made to bring the regulations as closely in line with the International Code as possible, while seeking to remove those obstacles for future improvements.

The Minister of Public Health said in a Parliamentary Answer regarding the consultation: "Any responses received, including those that suggest alternative options, will be considered as part of the consultation exercise." On this basis analysis in this section considers Option 3 "Implement the International Code" as well as the options proposed by the Food Standards Agency.

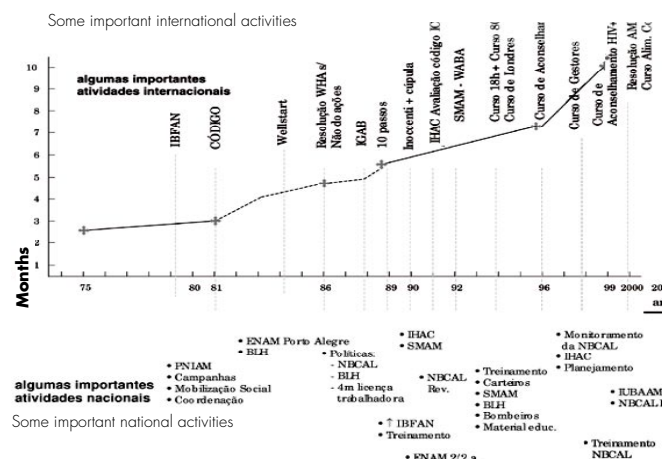
If the Government wishes to empower mothers to breastfeed as long as they wish it should undertake to implement the Code. Around nine in ten mothers who breastfed for less than six weeks said that they would have liked to continue longer, as did 40% of mothers who breastfed for at least six months⁴. Scandinavian countries do not allow advertising or company-sponsored information for parents and have far higher rates.

The two graphs on the right show how rates have recovered in Norway (breastfeeding at 6 months recovering from about 10% in the 1970s to over 80% in 1998) thanks in part to such steps. The median duration of breastfeeding increased in Brazil from 3 months to 10 months as a result of efforts to protect, promote and support breastfeeding⁵.

NORWAY 1858-1998⁶



BRAZIL 1975-2002⁵



RIA question: The Agency would welcome stakeholders views and supporting evidence on what should be considered as ‘advertising’ for the purposes of these Regulations.

BFLG position on advertising and promotion (regulations 21, 22, 23 and 24 in proposed text):

- ban all promotion of breastmilk substitutes (including follow-on formula, specialised formulas and other bottle-fed products),
- prohibit baby feeding companies from seeking direct or indirect contact with pregnant women and mothers and carers of infants and young children and other members of the public (including a clear ban on company ‘carelines’, pamphlets, mailshots, emails and promotional websites),
- prohibit company-produced or sponsored materials on pregnancy, maternity, infant feeding or care (the Government must provide objective information on infant feeding, avoiding conflicts of interest in funding infant feeding programmes),
- prohibit the promotion of names associated with breastmilk substitutes and their use on other products,
- restrict information for health professionals to scientific and factual matters with no idealising text or images,
- introduce regulations in line with the *International Code* covering the marketing of feeding equipment, feeding bottles, teats, dummies etc.

No advertising or promotion

“Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising”.

EU Directive 2006/141/EC

5.1 “There should be no advertising or other form of promotion to the general public of products within the scope of this Code.”

6.2 “No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code.”

International Code

The International Code is clear that there should be a prohibition of advertising and any type of promotion of products within its scope both inside and outside the health care system (breastmilk substitutes, feeding bottle and teats and other foods marketed as replacements for breastfeeding). This includes infant formula, follow-on formula and specialised formulas.

The Directive takes the position that some forms of advertising of infant formula are acceptable, but there is a specific clause which allows even these to be prohibited.

Therefore, the UK Government can and should prohibit all advertising and promotion of infant formula and follow-on

formula. In other countries, such as in Scandinavia¹ (where follow-on formula hardly exist - infant formula is marketed for use until 12 months) and Brazil², this has been done, helping to achieve the recovery of breastfeeding rates as already described.

The Government should bring feeding bottles and teats and specialised formulas within the scope of the legislation or introduce separate legislation prohibiting the advertising and promotion of these products

Advertising should be considered to include any form of promotion of products, including in a publication directed at any target, on the internet, as a product placement, on a telephone careline or on product labelling.

Scientific information for health workers and independent information for parents

A prohibition on advertising and promotion will not prevent companies from providing scientific and factual or product-recall information to health workers or prevent them from submitting studies for peer-review and publication in scientific journals.

Under the Code and Directive governments and health organisations have a responsibility to provide accurate, independent information to parents. BFLG looks to these bodies to analyse the differences between products and make this available to those that require it.

“WHO has concluded that a decision on whether to use infant formula and, if so, which product and how, should not depend upon the effectiveness of commercial advertising. Proper use of infant formula should rather be the result of informed decision-making based on objective and consistent advice, and appropriate supervision. This message is implicit in the final paragraph of the preamble to the International Code of Marketing of Breast-milk Substitutes, which states:

“Believing that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products.”

WHO, 2001³

Scientific evidence for the impact of advertising and promotion

Promotion of breastfeeding initiation and duration: Evidence into practice briefing. Add Dyson L, Renfrew M, McFadden A, et al. London: National Institute for Health and Clinical Excellence; 2006. Evidence-based action 4 states: *“In order to increase the duration of any and exclusive breastfeeding among all women, routine policy and practice for clinical care in hospital and community settings should abandon or continue to abandon... the provision of hospital discharge packs and any informational material given to mothers which contain promotion for formula feeding including the advertising of ‘follow on’ formula milks to mothers of new babies.”*

Office prenatal formula advertising and its effect on breast-feeding patterns. Howard C et al. *Obstetrics and Gynaecology* Vol 5, No 2, Feb 2000 p296-303 This study of 547 pregnant women, compares the effect of formula company-produced materials about infant feeding to breast-feeding promotion materials without formula advertising on breast-feeding initiation and duration. Although breast-feeding initiation and long-term duration were not affected, exposure to formula promotion materials increased significantly breast-feeding cessation in the first 2 weeks. Additionally, among women with uncertain goals or breast-feeding goals of 12 weeks or less, exclusive, full, and overall breastfeeding duration were shortened. The study concludes that formula promotion products should be eliminated from prenatal settings.

Evidence for the 10 Steps to successful breastfeeding. Tables 1.1, and 6.4 and 6.5. WHO Geneva 1998.

A Social Science Perspective on Gifts to Physicians from industry, Dana J et al, *JAMA*, July 9, 2003 - Vol 290, no 2: 252-255.

Breastfeeding in Norway – where did they go right? A Gerrard, *British Journal of Midwifery*, 2001 May, vol. 9, no. 5, p: 294-5, 297-300, (21 This comparative paper between Scotland and Norway, analyses the historical, social and cultural factors that influence the prevalence of breast-feeding. It concludes that the strong cultural norm to breast-feed in Norway is partly because strategies to reverse the effects of commercial promotion of formula milk, and inconsistent advice by health professionals were implemented at an early stage of the declining trends.

Do consumer infant feeding publications and products available in physicians’ offices protect, promote, and support breastfeeding? Valaitis RK, Sheeshka JD, O’Brien MF. School of Nursing, McMaster University, Hamilton, ON, Canada. *J Hum Lact.* 1997 Sep;13(3):203-8.

Commercial hospital discharge packs for breastfeeding women (Cochrane review). Donnelly A., Snowden HM, Renfrew MJ, Woolridge MW. In: *The Cochrane Library*, Issue 2, 2002 Oxford: Update Software.

The U.S. infant formula industry: is direct-to-consumer advertising unethical or inevitable? Cutler BD, Wright RF. *Health Mark Q.* 2002;19(3):39-55. This article provides a historical background of infant feeding in the United States and looks at how mothers’ make their infant formula selection.

Violations of the international code of marketing of breastmilk substitutes: prevalence in four countries. Taylor, A *BMJ* 1998;316:1117-1122. Based on interviews of 3050 women and 466 health professionals in 165 health facilities in Bangladesh, Poland, South Africa, and Thailand.

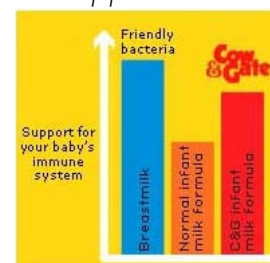
1. Advertising is not information - all formulas claim to be the best

Parents, carers and health workers have a right to accurate, independent information. Company advertising, promotional materials, websites and telephone carelines do not provide accurate information. Companies have a statutory duty to put the interests of their shareholders first, subject to the restrictions of legislation, which invariably means trying to increase profits and sales. It is not surprising, therefore, that they all claim their infant formula is the best.



Milupa Aptamil infant formula labels (detail left) claim that 'prebiotics support natural defences' and that it is 'The closest to breastmilk'.

However, the graph shown right was taken from the Cow & Gate website and suggests that Cow & Gate formula is closest to breastmilk, again citing its prebiotics.



But then again, Heinz has distributed fliers to health workers encouraging them to recommend its Farley's formula as the best infant formula, again with a graph claiming to show it has far more nutrients that are contained in breastmilk than competing brands.

Wyeth has launched a major promotional campaign in 2007 aimed at creating an emotional connection with its milks. Its marketing slogan is 'Love the milk you give'. A 60-second television advertisement shows a man making various promises to the mother of his child, including making up night feeds. As the brief packshot is for follow-on milk the authorities are unlikely to do anything under the current or proposed legislation. Wyeth claims on formula labels that it has 'new improved protein balance'. Wyeth claims in materials for health workers and parents this makes its formula the closest to breastmilk and on its careline claims it is closer than its competitors.

The information companies provide is not objective. Better regulations than those proposed are needed if those who use formula are to understand the differences between brands with different ingredients.

2. Companies try to co-opt health workers - independence must be maintained

Companies offer gifts to health workers, encourage them to provide company materials to mothers or even allow company staff to run parenting classes and target them with advertising that is overwhelmingly promotional. Below, Cow & Gate asks health workers to pass these cards onto parents, directing them to the company careline. They are offered the chance to win £250 if they give the careline a call themselves.



Currently the Advertising Standards

Authority refuses to investigate complaints about advertising in professional journals, arguing it is the responsibility of health workers to decide whether the claims are true or not.

3. Targeting mothers before their babies are born - why the Code's prohibition on seeking direct and indirect contact is needed



Companies advertise in parenting magazines and, more recently, fashion magazines. Left: NUMICO promotes its Cow & Gate brand name with a postcard attached to the advertisement for pregnant women to return, including a tick box for receiving information on infant milks. They are offered £90 of vouchers as an inducement for signing up.

The International Code of Marketing of Breastmilk Substitutes states that companies: *"should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children."* Companies ignore the World Health Assembly's call to comply independently of government measures.

The purpose of the advertising is to persuade mothers to visit company websites, sign up to receive company materials and call company carelines. They are branded with the names and logos of infant and follow-on formula. In the example, right, Wyeth states: *"SMA Nutrition has some new arrivals of its own to help ease you into parenthood..."*

The website people are referred to promotes 'new, improved' formulas. The Advertising Standards Authority takes no action over such advertisements as they do not explicitly refer to infant formula and it ignores the websites, which are an extension of the advertisements, arguing these are 'editorial'. Trading Standards are also hampered from acting by the current legislation and will have similar problems with the new legislation unless there is clear prohibition on seeking direct and indirect contact. This does not stop companies displaying their address and contact details for customers who have an unprompted need to contact them.



Left: a Wyeth SMA-branded email to mothers stating they receive hundreds of calls from parents every week. The email features one of the 'frequently asked questions' and the company's response. The question: *"How does infant formula support my baby's development?"* The answer includes idealising claims about the formula. Breast is the best it says, but for mothers who don't breastfeed: *"They can still provide all the necessary goodness by choosing an infant milk with a balance of nutrients as close to breast milk as possible, like SMA Gold."*

close to breast milk as possible, like SMA Gold."

The Directive's *"requirement for objective and consistent information"* can and should be provided by NHS Direct, NHS 24, health professionals and other independent sources such as mother-support groups. The company carelines are both promotional and unnecessary.

Right: Registry offices have even been recruited by Hipp in some cities to distribute a sticker booklet on 'Baby's first year' - which promotes its formula brand, website and careline telephone number.



“Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose”.

EU Directive 2006/141/EC

Member States should: *“ensure that financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest.”*

WHA 58.32 (2005)

Sponsored materials

The government should, as clear policy, neither request nor accept donations of materials from companies that manufacture products within the scope of the legislation, nor permit them to produce materials for pregnant women or mothers or other carers of infant and young children.

Brand names and logos used for formula

The restrictions on advertising and promotion should encompass brand names and logos used for infant formula and follow-on formula as well as the products themselves. This should not prohibit use of parent company names and logos where these are not associated with infant formula or follow-on formula.

4. Company logos are associated with formula for young babies

In a MORI survey¹ carried out in July 2007, with a nationally representative sample of women of childbearing age, there was a high recognition of formula manufacturer's logos and a very high association between the logo and infant formula or milk used for young babies. For SMA's logo, 89% of women who had any association of the logo with a product, linked it to infant formula or milk used for young babies. The table shows the proportion of women who associated the company logo with infant formula or milk used for young babies:

	SMA	Cow & Gate	Farleys	Milupa
All women in sample	71%	63%	34%	32%
All women who associated the logo with a product	89%	79%	45%	69%
Mothers of children under 16yrs	78%	71%	43%	43%
No product association	20%	21%	25%	53%

In the last 15 years, some brand names have changed and logos have become more prominent, so that SMA, for instance, is the logo and brand name used on infant formula and follow on formula, rather than the overall company name, Wyeth, and the logo is more prominent than the product name: Gold, White or Progress.

Milupa is owned by Nutricia, as is Cow & Gate. They are now using the name Aptamil for the whole range of breastmilk substitutes. Previously it was Aptamil – the whey based infant formula, Milumil – the casein based infant formula and Milupa Forward for the Follow on milk. Now there are: Aptamil First, Aptamil Extra Hungry, Aptamil Easy Digest, Aptamil Follow on, all of which have the brand name: Aptamil as the largest word on the carton.

The larger number of 'Don't know's to the Milupa name logo may be because the company have moved to the Aptamil name instead, and as the screen shot of the Aptamil website shows, the Aptamil brand name dominates labels.

Advertising the brand name – which is widespread in pregnancy magazines, for instance, to attract pregnant women to the brand, actually has the effect of advertising the formula milk.

Coming soon! We're updating our look, so you'll soon notice the same great Aptamil formulas are available in brand new packaging.



Aptamil First
Click to view



Aptamil Extra Hungry
Click to view



Easy Digest
Click to view

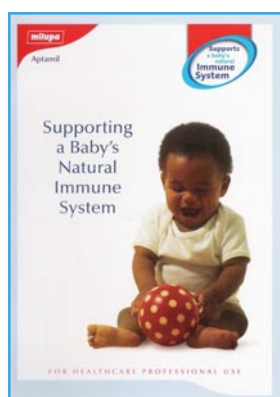
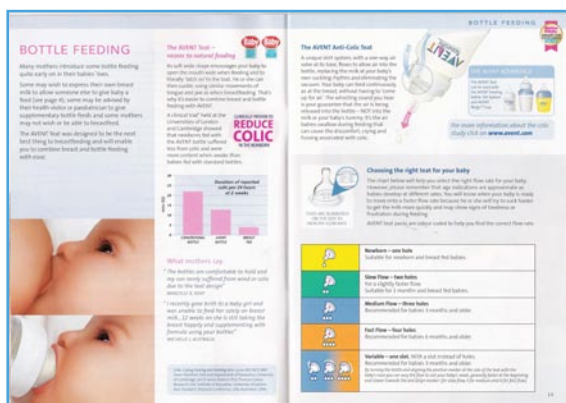
Closest to breast milk

Aptamil has led the way in the understanding of breastmilk for over 50 years. That's why we've developed **IMMUNOFORTIS**, a patented mix of special prebiotics, inspired by those found naturally in breastmilk.

5. Company produced or sponsored 'information' materials idealise products and promote brand names, logos, teddy bears and ducks!



This selection of company materials for parents and health workers on infant feeding shows some of the techniques used for undermining breastfeeding and idealising products. The Farley's bear and SMA duck are used to build association with these images on formula labels.



6. Point-of-sale promotion pushes brand names

Promotion of formula in supermarkets and pharmacies is commonplace, including illegal promotion of infant formula (Trading Standards officers have not pursued cases as companies try to argue they exercised 'due diligence' in restricting promotions to follow-on formula, but 'accidentally' included infant formula - demonstrating the need for the clarity of a ban on all promotion). The example right was in Boots in 2005.



The example left was in ASDA and other supermarkets in 2005. While the product displayed is the follow-on formula, it is the Cow & Gate brand that is being promoted, which 79% of women who recognise the brand associate with a milk for young babies. When it was challenged about this promotion, Tesco revealed that the company representatives do also promote the formula 1 and 2 (which are infant formulas), giving the confused and unjustifiable explanation¹: "If the supplier is also drawing attention to the first and second milk products they should be re-iterating government guidelines that they don't recommend a diet of sole Baby Milk formula to a Baby less than 6 months old".

RIA Question: Stakeholders are invited to comment on the proposed notification procedure and on the format of the proposed notification form in Appendix III. Stakeholders may wish to propose alternative notification methods which still fulfil the requirements of the Directive.

Safety and suitability must be demonstrated

The BFLG position is that:

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. The Government should pursue the possibility of pre-authorisation of ingredients.

Before new ingredients can be introduced manufacturers or researchers should submit a dossier of evidence which should include a substantial proportion of independently funded and conducted research to the notification procedure. This dossier should undergo an independent systematic review and only if the ingredient is shown to be safe and essential should permission be given for it to be included. The ingredient should then be added to the composition requirements for all formulas. Depriving formula-fed infants of an essential ingredient would be unethical.

The FSA's proposed notification procedure only requires manufacturers to submit a form and a model of the label, so does not even satisfy the requirement in the Directive that the suitability of any product marketed as an infant formula or follow-on formula be demonstrated.

"Article 5: Infant formulae shall be manufactured from protein sources defined in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data.

"Such suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies."

EU Directive 2006/141/EC (Art 6 sets out the same requirement for follow-on formulae)

*"the extent of potential additional scientific data that may be necessary, should be determined by an **independent** scientific body prior to the commercialization of the modified product.... a full description of the new ingredient(s) should be provided, such as the chemical name ...synonyms, trade names and abbreviations, molecular and structural formulae, molecular weight, purity and impurities....."*

The Opinion of the Scientific Committee for Food

Mass uncontrolled trial?

Allowing manufacturers to add optional new ingredients as they wish, is potentially hazardous and amounts to a mass uncontrolled trial on the general population. Optional ingredients open the door for claims on a nutrient by nutrient basis and are especially misleading in the context of breastmilk substitutes.

"The problem with nutrient by nutrient nutrition science is it takes the nutrient out of the context of food, the food out of the context of diet and the diet out of the context of lifestyle." Marion Nestlé, New York University¹

"The history of infant formula has shown that virtually all similar examples have led to wide-scale introduction of such additives into infant formula, even if there was no evidence that the additives were important. Infant formula is currently a commodity market with all products being almost identical and marketers competing intensely to differentiate their product."

Market analysts Hambrecht and Quist commenting on Formulaid, an additive for infant formulas (also see box 9)

Reporting Problems

The notification system, whatever form it takes, should include provision for health workers and others to report to the authority any concerns they may have about the health impact of the new ingredients and products. Manufacturers should not be relied upon to carry out this monitoring function.

"ESPGHAN wishes to emphasize that there is no evidence available to show that the evaluation of consumer phone line services is sensitive enough to detect adverse effects of infant formulae. On the contrary, for example the very severe adverse effects recently induced by an infant formula with inadequate contents of vitamin B1 (thiamine), which resulted in failure to thrive, severe neurological damage, severe lactic acidosis and even infant deaths (2-4), were not detected by the distributor's consumer phone line services...."

European Society of Paediatric Gastroenterology, Hepatology and Nutrition Comments on the Circular Letter CL 2005/53-NFSDU.

Independent information

Accurate, independent information on new ingredients and products should be prepared for communication to health workers by the Food Standards Agency, or other authority to equip them to advise parents.

7. Clearer legislation on claims is essential

Current legislation states that claims can only be used on infant formula labels if they are amongst the 7 listed in the law. Yet after the Food Standards Agency reminded the companies of this provision they launched new labels with idealising claims not on the list, such as those on the Milupa *Aptamil* infant formula shown right.

The label carries the claims : “*Immunofortis*” (a new unauthorised ingredient), “*Inspired by breastmilk*” and “*Best infant milk*” as well as an idealising image of a bear that conveys no information and has the sole purpose of giving a positive emotional response to the product.

While guidance accompanying the current legislation states explicitly that ‘closer to breastmilk’ claims are non-compliant no action has yet been taken and on occasion Trading Standards officers have even initially responded clearing the use of the phrase as they were unaware of the guidance notes.



8. The follow-on formula claims loophole should be closed

Cow & Gate removed the non-compliant claim ‘*Prebiotics supporting baby’s natural defences*’ from its infant formula labels after being contacted by the Food Standards Agency. It also has a ruling against it from the Advertising Standards Authority for claiming in a follow-on formula advertisement that the prebiotics in its formula ‘help build natural defences’.

Neither of these actions dissuaded the company from launching a shelf-talker promotion with the claim ‘support your baby’s natural immune system’ because the products pictured were follow-on milks - even if the shelf talker was with the infant formula (right).

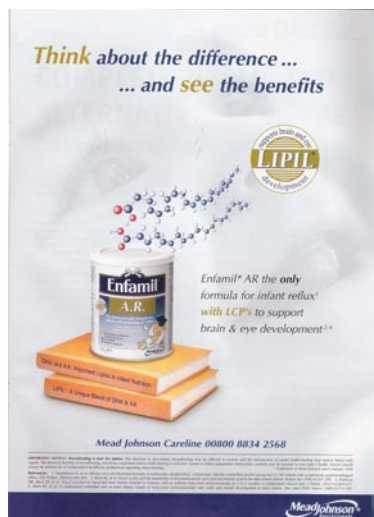
Company representatives were reported approaching mothers and offering money-off coupons for the follow-on milk, which promotes the brand and the immune protection claim. These were also displayed with the products to draw attention to them.



9. Adding new ingredients is used as a marketing strategy - the case of Long Chain Polyunsaturated Fatty Acids (LCPUFAs)

The Cochrane Library has conducted a systematic review of studies on LCPUFAs (also known as LCPs) and infant formula and concluded¹ : *"At present there is little evidence from randomised trials of LCPUFA supplementation to support the hypothesis that LCPUFA supplementation confers a benefit for visual or general development of term infants."*

The European Union Scientific Committee has also investigated the claims for LCPs and concluded² : *"Having reviewed the available literature the Committee sees the evidence insufficient to set an obligatory minimum level of LCPUFA."* In other words, no benefit has been proven from adding LCPs so it is not compulsory.



Yet for years companies have claimed LCPUFA supplementation gives benefits as shown in this example for Mead Johnson *Enfamil Lipil* formula in a health worker journal. It states : *"Enfamil AR the only formula for infant reflux with LCP's to support brain & eye development."* The advertisement is dominated by the promotional claims, rather than anything scientific. References are given, but these require critical appraisal. For example, in a study used to claim improved intelligence and visual acuity there are substantial conflicts of interest. Mead Johnson donated the formula used in the study, part-funded it and provided the randomization schedule of study participants to the researchers, who worked for a foundation receiving financial support from the company.

World Health Assembly Resolution 58.32 calls on Member States: *"to ensure that financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest."*

Market analysts Hambrecht & Quist advised people to invest in the company, Martek, which provides LCPs to Mead Johnson and most other companies, with its product Formulaid. They stated³ : *"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.'"*

Independent analysis of the safety and need for new ingredients should be required in the law.

Current legislation states that claims are only allowed on infant formula labels if they are on a permitted list and required conditions are satisfied⁴. The claim has to be given using the specified wording. LCPUFA claims are not on the permitted list, but Trading Standards officers have been reluctant to take action as they have found the law lacked clarity. This will remain a problem if the proposed legislation is not improved.

The Directive will allow a claim on infant formula saying it contains LCPs. Although the Directive has not yet been implemented in UK legislation companies are adding LCP claims already in breach of the current law. An example of Heinz/Farley's infant formula is pictured. This shows how claims, permitted or not, are used for promotional purposes. There is a prominent banner stating: *"With omega 3 LCPs"* and the claim : *"our most advanced formula ever"*.



RIA Question: The Agency would welcome stakeholders views and supporting evidence on the interpretation of the term 'idealise' for the purposes of these Regulations.

The only information required on formula labels is:

- Brand name and formula generic name (with the brand name no bigger than the generic name and not incorporating a claim e.g. Advanced, Humana, HA).
- Warnings and preparation instructions (in accordance with FSA and WHO guidance to parents).
- Ingredients.
- Permitted nutritional claims (which should be with the list of ingredients on back of pack).
- Batch number, use by date, manufacturers details.
- Specific independent certification on kosher/organic etc. (using the independent authorities' stamp or wording).

Any other information is unnecessary and likely to be

promotional and so should be prohibited. Images should only be allowed in the preparation instructions. Brazilian law stipulates not only no humanized images, but no animals, vegetables, fruits or any other type.

Specialised formulas are outside the scope of this Directive and their promotion is not properly regulated. Companies encourage parents to self-diagnose illnesses through websites information materials and to either buy directly themselves (for conditions such as 'reflux') or to ask their health worker to prescribe it (for example SMA Wysoy formula for 'milk intolerance, which the Food Standards Agency says is rarely the most appropriate response - see box 11). Specialised formulas should come within the prohibition on advertising and promotion.

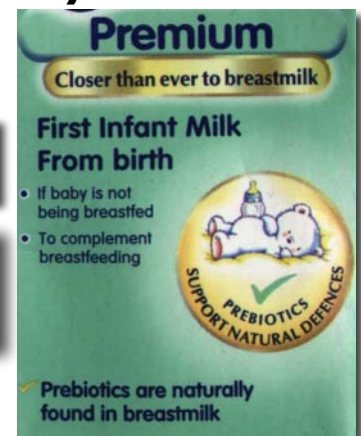
10. Companies suggest formula is better than in reality

Breastfed babies are less likely to develop (Department of Health¹):

- gastric, respiratory and urinary tract infections
- obesity in later childhood
- juvenile-onset insulin-dependent diabetes
- atopic disease

love the milk you give

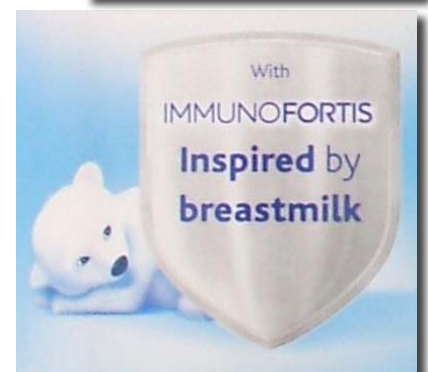
closer than ever to breast-milk



idealize (also idealise) : **verb** regard or represent as perfect or **better than in reality**.

Oxford dictionary

This selection of images shows how companies change the 'breast is best' required notice on their products into an endorsement by suggesting their product is close to or inspired by breastmilk and try to invoke an emotional attachment to it with slogans and cute animal images. This is not a good basis for selecting what is to be the sole nutrition for a child at its most important development phase since leaving the womb.



Trading Standards officers have allowed idealising claims to remain on the market for years as they were unsure how to interpret the law. Even following action with the Food Standards Agency spelling out that 'closer to breastmilk' is a non-compliant claim, there continues to be debate about some other claims and no action has been taken over idealising images.

In Brazil the only images permitted are in preparation instructions. Formula there looks more like a nutritional medicine (example right).



11. Company promotion of specialised formulas can lead to mis-use

Companies have produced an increasing range of specialised formulas. Some are attempting to create a market by medicalising infant feeding issues, as with formulas for 'hungrier babies' or babies with reflux.

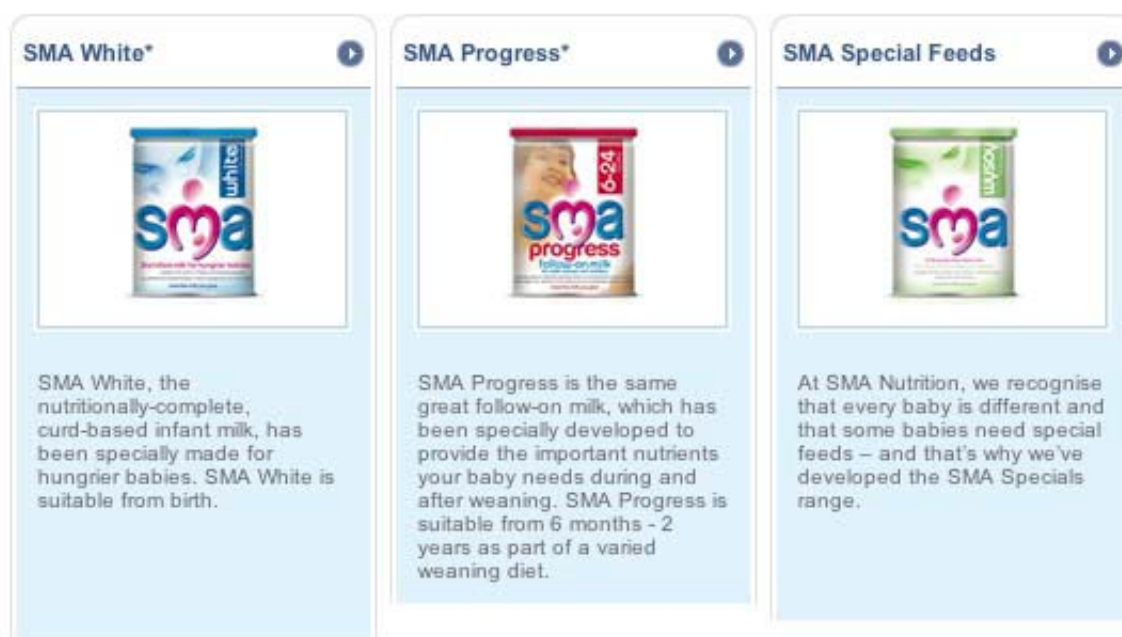
Mead Johnson and Nestlé focus on specialised formulas, both promoting 'hypoallergenic' formula, a health claim which is prohibited in the US after infants fed on it suffered allergic reaction. The BFLG has written to the Minister of Health twice (2005 and 2006) with concerns over the use of the HA claim, which it believes to be non-compliant. The Mead Johnson advertisement in a health worker journal (right) has no scientific or factual information at all and encourages use of the formula for cases of milk allergy.



Under current legislation no action has ever been taken by Trading Standards against a company for producing information for health workers that is not restricted to scientific and factual information. The Advertising Standards Authority refuses to even investigate advertisements in health journals.

Nor will the ASA investigate websites and Trading Standards is hampered as these were not a major means of communication when the 1995 legislation was introduced so are not referred to.

The screen shot below is for Wyeth's widely advertised smannutrition website. It shows how infant formula, follow-on formula and specialised formulas have little to distinguish them. The 'specialised feeds' promoted to parents are soya, high energy, lactose free and 'staydown'. Parents are encouraged to self-diagnose and ask doctors to prescribe products such as Wysoy soya formula. Yet the Food Standards Agency advice on soya formula and milk intolerance is¹: *"In almost all cases, breastfeeding or another type of formula will be a better choice."* The Chief Medical Officer has stated (January 2004)²: *"should not be used as the first choice for the management of infants with proven cow's milk sensitivity, lactose intolerance, galactokinase deficiency and galactosaemia. Soy formulas have a high phytoestrogen content, which could pose a risk to the long-term reproductive health of infants."*



RIA Question: The Agency would welcome suggestions about how manufacturers can ensure that infant formula and follow on formula are packaged, presented and advertised in a way which avoids any risk of confusion between them. These suggestions will be considered by the Agency when the guidance on this regulation is drafted.

“On the basis of the experience gained in other EU countries on the marketing of follow-on formulae the National Food Agency of Finland recommends that the regulations on the sale and marketing of infant formulae as well as these control instructions are also applied to the sale and marketing of follow-on formulae.”

Sale and Marketing of Infant Formulae
Instructions for control authorities and operators
National Food Agency of Finland, 15 June 2005

foods when these are promoted for use as a partial or total replacement of breastmilk. As breastfeeding is recommended into the second year of life and beyond and milk that replaces it is a breastmilk substitute.

Follow-on milks are not necessary

“the practice being introduced in some countries of providing infants with specially formulated milks (so-called “follow-up milks”) is not necessary.”

World Health Assembly Resolution 39.28

Follow-on milks created in an attempt to circumvent regulations

Follow-on milks did not exist as a separate classification of products when the International Code of Marketing of Breastmilk Substitutes was adopted in 1981. They were introduced in an attempt to escape the provisions of the International Code, yet they come within the scope of the Code as this covers all breastmilk substitutes. The Code explicitly states it covers other products, including complementary

The Consumer Committee of the EU Parliament questioned the scientific basis for them in 1985, calling them ‘extremely dubious’.

Follow-on milks compositionally can be identical to infant formula. If a mother is not breastfeeding, she can continue using infant formula for the first year of her babies life as recommended by the Department of Health (see Birth to 5¹).

12 How company names have taken over labels to promote a range



As with other brands, the Farley's name has progressively increased in prominence of its formula on formula labels, while the size of the age of use information has been reduced.

In 1988 (top left) it removed its baby images, replacing them with a humanized bear image (which was still prohibited by the Code). In 1995 (above) when media advertising of infant formula was banned, the company name increased again and took over as the brand - the type of milk is hardly visible - a trend that continued (left).

The higher levels of iron, which are the advertised benefits of follow-on milks, can be adequately provided through complementary foods. There are risks of adding high levels of iron to milk, particularly as research has shown some mothers use them for younger babies².

Stronger regulations on branding and logos are essential if follow-on milks continue

Companies have made the labelling and presentation of follow-on milks progressively closer to infant formulas to make them cross promotional. As described in box 14 this leads to confusion and mis-use of follow-on milks.

Follow-on milks should not be presented as one in a range of formulas.

They should not have the same brand names and logos as infant formula.

Where a company name is associated with formula, this should not be used as a brand name for follow-on milk, nor displayed prominently on the label.

There should be a notification for follow-on formulas the same as those the BFLG proposes for infant formula.

13. The current and suggested approach to differentiating between infant and follow-on formula creates easily exploited loopholes



This advertisement for Milupa Aptamil appeared in The Independent newspaper during National Breastfeeding Awareness Week in May 2005. It draws equivalence between Milupa Aptamil and breastmilk. No action was taken by the authorities, though the newspaper raised the issue with the company after receiving complaints. The only action necessary to escape the prohibition on infant formula advertising was to insert the word 'Forward' after Aptamil so the company could claim it was a follow-on formula advertisement. Nothing else was changed.

No action was taken over this Heinz/Farley's advertisement on Discovery Health Channel for the simple reason that



it is purple. Hillingdon Environmental Health (the home authority for Heinz) admitted in an email to Ofcom¹: *"I was unable to work out the precise product pictured in the video footage."* Ofcom's investigator agreed: *"I don't know what product appears in the credits as no information is given on the pack shot. Discovery have told us that the product was follow-on formula."* They - and viewers - didn't know that Farley's provides 'clear distinction' by using yellow or green for infant formula.

14. Company promotion of follow-on milks can lead to mis-use

Companies try to escape the prohibition on infant formula advertising by advertising follow-on milks. The advertisements are misleading. A survey of 1,000 women commissioned by UNICEF and the National Childbirth Trust¹ in 2005 found that 60% believed they had seen an advertisement for infant formula, when most likely it would have been for follow-on milk. Around a third said the advertising gave the impression that infant formula milk was 'as good as' or 'better than' breastmilk.

The UNICEF/NCT survey found that nearly one in five mothers (17%) who used follow-on milk said they started before their baby was three months old – even though it's unsuitable for children of this age.

RIA Question: The Agency would welcome stakeholders views on the proposal to further restrict the advertising of infant formula.

The BFLG position has been presented already.

There should be no advertising of infant formula or follow-on formula anywhere. The current and proposed exceptions to this prohibition should be removed.

Companies should provide data and studies on their products to the Food Standards Agency or other authority for it to

evaluate and provide accurate, independent information to health workers. Companies should also be permitted to provide studies for consideration by peer-reviewed journals.

Health professional bodies have made it clear they do not view company advertising as a reliable source of information. BFLG member, The Royal College of Midwives, is producing an independent review of formulas and their ingredients.

RIA Question: The Agency would welcome stakeholders comments on any other aspect of the proposed provisions of these draft Regulations.

Line-by-line analysis is given in the annexed document prepared by Baby Milk Action with support of the National Childbirth Trust and other BFLG members.

In addition to the points already made, BFLG stresses the importance of setting out the following clearly in the legislation:

- prohibit baby feeding companies from offering sales incentives and bonuses or setting sales quotas linked to breastmilk substitutes for personnel employed by or on behalf of the company,
- prohibit all idealising text and images from all breastmilk substitutes,
- where possible prohibit all health and nutrition claims on foods for infants and young children. Require any permitted claims to be placed at the back of the package near the nutrition panel,
- require clear warnings about the fact that powdered formula is not a sterile product and may contain harmful bacteria, alongside clear instructions on how to reduce risks from possible contamination,
- prohibit promotion in healthcare facilities and gifts to health workers (allowing only single samples for evaluation),
- prohibit the promotion of any product in a way that could lead to it being used for babies under 6 months (complementary foods should not be marketed in ways that undermine breastfeeding).

Companies don't tell parents how to reduce risks of formula feeding

In November 2005 the Food Standards Agency issued new guidance for parents and health workers on reconstituting powdered infant formula because of concerns over intrinsic contamination with pathogens such as *Enterobacter Sakazakii* and *Salmonella*. This followed public attention brought to the issue following deaths of infants in Belgium and France linked to *Enterobacter Sakazakii* contamination. The FSA¹ warns that powdered infant formula is not sterile and that simple steps can be taken to reduce the risks, such as ensuring that water used to mix up formula is at least 70°C.

No company has given the information for parents as set out by the FSA, despite all launching new labels onto the market at the beginning of 2007, and some directly contradict it. Only one company includes the information that powdered infant formula is not sterile on its new labels (Hipp), but it instructs parents to use water at 50-60°C.

A spot survey of company carelines² found that some advisors claim powdered infant formula is sterile until opened, which is not the case. Some advise parents they can keep pre-boiled water in a sterile bottle for 24 hours at room temperature to mix up the formula, which will not provide the critical high temperature step needed to kill any bacteria intrinsic to the formula. Hipp advisors have said openly they disagree with the FSA position.

WHO recommend that caregivers should be informed through an explicit warning on the packaging that powdered infant formula may contain pathogenic micro-organisms³. In fact the WHA urged Member States:

(3) to ensure that clinicians and other health-care personnel, community health workers and families, parents and other caregivers, particularly of infants at high risk, are provided with enough information and training by health-care providers, in a timely manner on the preparation, use and handling of powdered infant formula in order to minimize health hazards; are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and, where applicable, that this information is conveyed through an explicit warning on packaging;

Appendix IV of the RIA states that voluntary labelling is to be agreed with industry concerning the information that powdered formula milks are not sterile. Given the paucity of accurate information on labels since the WHO, Codex and European meetings on this topic, it should not be left to voluntary labelling to convey this essential information to consumers.

The recent Infant Feeding Survey found that the majority of parents were not following the recommendations for making up feeds safely. Health professionals are not always able to brief parents if they decide to change to formula milk; this information needs to be clear, accessible and on the tin.

Relying on guidelines is insufficient - the legislation must provide clarity

As has been noted several times, experience has shown that companies and Trading Standards officers take most notice of what is in legislation, sometimes ignoring or being unaware of provisions in guidelines.

Therefore, it is essential that the legislation includes the clarity needed to avoid inaction due to questions of interpretation.

Legislation will give the authorities the power they need to require changes from companies and pursue actions through the courts, if necessary. The UK is an extremely competitive market and as the monitoring results show, companies push things to the limit and beyond unless the legislation is clear and action may be brought against them.

Where necessary, the legislation can reference separate documents, as is being done with the list of permitted claims (no longer included in a schedule to the law).

So for example, the legislation could include a requirement that instructions on labels be in accordance with the guidance to parents provided by the FSA or World Health Organisation.

RIA Question: The Agency would welcome views from stakeholders on their preferred option.

The Agency offers only two options:

Option 1: Retain the Status Quo.

Option 2: Implement the Regulations.

The BFLG advocates Option 3, implementation of the International Code as stated earlier in this report. The Minister for Public Health gave an assurance in a Parliamentary Answer that this will be considered.

RIA Question: The Agency would welcome views and evidence from stakeholders to help quantify costs associated with not implementing the Directive.

The proposed regulations are unlikely to have health or cost benefits above doing nothing

The marketing practices described in this document and other BFLG monitoring reports will continue with few exceptions whether the FSA's Option 1 or Option 2 is followed.

Hence, there are likely to be few health or cost benefits through the proposed implementation of the Directive. Indeed, the inclusion of new claims and the possibility of ingredients being added without adequate safeguards is likely to further undermine breastfeeding so harming health and incurring costs.

The RIA contains no estimate of the cost benefits of breastfeeding rates through taking effective action to implement the International Code (BFLG's Option 3). Savings could be considerable and it is recommended that such a calculation be carried out. As described on page 30, a US study estimated that US\$3.6 billion could be saved through modest increases in breastfeeding, in itself a figure described as an under estimate.

that amount promoting their products, while attempting to co-opt health workers to recommend them and distribute company materials.

The advertising spend for baby foods in 2006/07 was £7,626,847 according to Nielsen Research Multimedia, an increase of 36.6% on the previous year.

The government for promoting breastfeeding was £729,011 in 2006/07, a decrease on the 2004/05 figure of £747,000.

Attempting to out spend the baby food industry is unlikely to be effective and will be expensive
Figures published by Save the Children¹.

Countries such as Brazil and Norway have achieved significant gains in breastfeeding rates, including exclusive breastfeeding rates, thanks to coupling breastfeeding promotion and support with protection.

The proposed approach could cost the UK economy at least £360 million every year of inaction

As the proposed regulations are unlikely to improve breastfeeding rates and could increase illness due to unnecessary and unsafe formula feeding, the suggested approach would cost the economy the sums that could otherwise be saved and invested elsewhere in health programmes.

A crude pro rata calculation based on populations using the US figure suggests at least £360 million could be saved for each year of higher breastfeeding rates if a more effective approach were taken.

Promotion without protection does not work and can make things worse

When the US Department of Health (HSS) broadcast advertisements promoting breastfeeding in the period 2003-5, the industry brought in powerful lobbyists who succeeded in getting the ads toned down. At the same time, the industry substantially increased its own advertising as soon as the Government campaign was launched. According to a 2006 report by the Government Accountability Office, formula companies spent about \$30 million in 2000 to advertise their products. In 2003 and 2004, when the campaign was underway, infant formula advertising increased to nearly \$50 million.: The result was a fall in breastfeeding rates: *"the proportion of mothers who breast-fed in the hospital after their babies were born dropped from 70 percent in 2002 to 63.6 percent in 2006, according to statistics collected in Abbott Nutrition's Ross Mothers Survey, an industry-backed effort that has been measuring breast-feeding rates for more than 30 years."* ²

Implementing the International Code (referenced in the Directive) could have a significant impact

The Government's own Infant Feeding Survey finds that efforts to promote breastfeeding have had little impact on anything other than breastfeeding initiation rates. Indeed, the latest survey, based on figures gathered in 2005, found that breastfeeding duration is actually falling in some parts of the country.

Relying on breastfeeding promotion alone is unlikely to make much of an impact when baby food companies spend 10 times

If the Government has the political will to put infant health and mothers' rights first it could reverse the situation where 90% of mothers who stop breastfeeding by 6 weeks say they wish to breastfeed for longer. 40% of mothers still breastfeeding at 6 months also said they wanted to breastfeed for longer.

As well as reduced sickness and hence reduced costs to the NHS and fewer lost working hours as parents attend their children, the measures proposed by BFLG are likely to reduce sickness in formula-fed infants.

It has not yet been quantified how much illness is attributable to intrinsic contamination of powdered infant formula with pathogens such as *Enterobacter Sakazakii* and *Salmonella*, but the risks are sufficient for both the Food Standards Agency and World Health Organisation to prepare guidance for parents on how to reduce the risks of intrinsic contamination of powdered formula. This has not been reflected on the labels of formula and some companies are openly disagreeing with the position taken by independent health experts. The proposed regulations will not address this issue and guidelines to companies and Trading Standards will not have sufficient legal force to ensure action is taken.

If a legal requirement to give instructions in accordance with that of the FSA and WHO is included as an explicit requirement in the legislation, we may expect to see a reduction of illness amongst formula-fed infants.

Large savings could be made through reduction of illnesses and deaths

A US study³ examined the cost saving from modest increases in breastfeeding rates:

Scaling this saving by population, suggests the UK could save £360 million for every year of higher breastfeeding rates. This would be made up of annual savings in treatment costs and lifetime contribution to the economy from infants who would otherwise have died prematurely.

The US study found a minimum of \$3.6 billion would be saved if breastfeeding was increased from current levels (64 percent in-hospital, 29 percent at 6 months) to those recommended by the U.S. Surgeon General (75 and 50 percent), for each year at the higher rate. This figure is likely to be an underestimation of the total savings because it represents cost savings from the treatment of only three childhood illnesses: otitis media, gastroenteritis, and necrotizing enterocolitis. These savings would result from reducing both direct costs (such as formula costs and physician, clinic, hospital, laboratory, and procedural fees) and indirect costs (such as time and wages lost by parents attending to an ill child). Moreover, it does not count the savings of the cost of formula.

One comparative study in the US and UK, found that after adjusting for confounders, there were 2033 excess office visits, 212 excess days of hospitalisation, and 609 excess prescriptions for three illnesses (lower respiratory tract illnesses, otitis media, and gastrointestinal illness) per 1000 never-breastfed infants compared with 1000 infants exclusively breastfed for at least 3 months. These additional health care services cost the managed care health system between US\$331 and US\$475 per formula-fed baby during the first year of life⁴.

Compared with formula-feeding, breastfeeding each infant enrolled in WIC saved US\$478 in WIC costs and Medicaid expenditures (the US welfare schemes) during the first 6 months of the infant's life⁵. If women breastfed each child for at least 6 months, the total projected savings over a 7.5-year period ranges from US\$3,442 to US\$6,096 per family. This translates into estimated yearly savings of between US\$459 and US\$808 per family. Savings were calculated based on

estimates of the resulting decrease in infant morbidity, maternal fertility, and formula purchases⁶.

In the UK, a NICE costing report⁷ shows how the expected 10% increase in breastfeeding rates due to Baby Friendly Initiative accreditation would result in savings in the cost of treating gastroenteritis⁸, asthma⁹ and otitis media⁸ (this accreditation removes promotion of breastmilk substitutes, feeding bottles and tests from hospitals in line with the Code). On the basis of an annual birth rate of 605,634 a 10% improvement in breastfeeding would mean that 60,563 additional babies would be breastfed. Total savings for just these three illnesses and the formula, bottles and teats, would therefore be:

- about 17,000 cases of otitis media avoided at a saving of £509,000.
- almost 3900 cases of gastroenteritis being avoided, at a saving of £2.6 million
- over 1500 cases of asthma being avoided, at a saving of £2.6 million.
- a reduction in the cost of teats and formula of £102,000

According to a US study, the risk of post-neonatal (29–365 days of age) mortality is about 27% higher among babies who were never breastfed compared to babies who were ever

According to NICE, therefore, a 10% increase in breastfeeding would mean a saving for just the health service costs for these three illnesses of approximately £5.6 million.

Obviously, this a very conservative estimate as the report does not take into account cost savings that would be achieved in other disease areas, for example urinary¹¹ and respiratory tract infections, eczema¹² and diabetes¹³, ovarian¹⁴ and breast cancer¹⁵ and diabetes in mothers¹⁶. In addition, breastfed babies have at least 15% fewer GP consultations during their first 6 months of life than babies fed on artificial formula¹⁷.

breastfed. On this basis, about 720 infant deaths in the US would be averted each year if all infants were breastfed¹⁷. This estimate may be understated for several reasons. One consideration is that the study excluded neonatal deaths (0–28 days), when the risk of potentially fatal necrotising enterocolitis, is higher in babies who are formula-fed (these deaths contribute to the US\$3.6 billion figure in the first study cited). Second, many babies in the study were breastfed for a very brief period.

Through its efforts to protect, promote and support breastfeeding, including implementing the International Code, Brazil has increased median breastfeeding duration from about 3 months to over 10 months¹⁹.

The low breastfeeding rates in the UK do not have to be a permanent feature of the culture. Mothers can be empowered to breastfeed for as long as they wish saving a fortune for families and the economy.

RIA Question: The Agency would welcome comments from charities and the voluntary sector about the impact that implementing the Regulations may have on their work

The proposed regulations are unlikely to have any positive benefit - and could further harm infant health

As noted in response to previous questions, the marketing practices described in this document and other BFLG monitoring reports will continue with few exceptions with the FSA's proposed regulations.

Hence, there are likely to be few health or cost benefits with the proposed regulation. While improvements to composition of formulas in the regulations is welcome, the fact that companies can add insufficiently-tested new ingredients presents an unacceptable risk to health. These risks could outweigh the improvements in the essential composition required in the Directive.

Mother support groups will find mothers suffering the same misconceptions about breastfeeding, the differences between formulas and how to reduce risks of formula feeding.

If anything, workloads will increase as the regulations legitimise additional health and nutrition claims and, as they stand, do not prevent companies from using these in a promotional way. These claims will undermine the efforts to warn parents of the risks of formula feeding. Providing accurate, independent information to counter these misleading messages will be an extra drain on voluntary sector resources.

The Directive does not clarify when and if new claims may be made on infant formulas or the authorisation process which claims will undergo. The door is also wide open for new claims to be made on follow-on milks - although under the

EU Health and Nutrition Claims regulations these will have to first be vetted by EFSA. However, the work involved in keeping track of these claims and ensuring that the appropriate authorities are kept aware of health concerns and new developments is considerable, and will depend in part on the contribution of concerned health professionals and NGOs. The Scientific Committee for Food examination of Partially Hydrolysed Proteins in 1996 failed to consider the impact of HA claims in the USA.

Implementing the International Code (BFLG's Option 3) could have a significant impact

Again as noted in response to the last question, implementing the International Code would mean efforts to promote and support breastfeeding are more likely to succeed, giving a consequent reduction in workload for mother support groups.

The BFLG monitoring project and others who report aggressive marketing practices to the authorities would find this far easier and more effective. Presently there are often protracted discussions with Trading Standards and the Advertising Standards Authority over interpretation of the regulations, something that is unlikely to change with the FSA's proposed regulations. Clear regulations implementing the International Code will be far easier to interpret and enforce. The clarity provided to the industry would also mean violations are less likely. The type of violations of the International Code found in the UK do not occur in countries that have independently monitored and enforced regulations implementing the Code, such as Brazil. Companies can comply if given a clear lead by legislation.

RIA Question: The Agency requests comments and evidence from industry about the policy and administrative costs of its proposals.

In considering the BFLG proposal of a complete ban on the promotion of breastmilk substitutes the following is worth bearing in mind:

The majority of costs associated with generating income from formula sales are costs of advertising and promotion. Costs of production are a small proportion of the total costs associated with the product.

An industry wide promotion ban would have the effect of holding each company's market share steady relative to the

other but taking a very large part of their costs away, making the formula brands much more profitable.

Over time lack of promotion will lead to a decline in use of formula but on a timescale which will allow companies to painlessly switch their efforts into other areas, using the excess profits generated by the cut in advertising.

Any costs to industry are more than outweighed by the savings in health, social and environmental costs.

RIA Question: The Agency would welcome comments from stakeholders on the social and environmental costs and benefits of options 1 and 2 so that a sustainability assessment can be completed

The regulations proposed in Option 2 are unlikely to make a difference to social and environmental costs

It is significant that the government's own National Infant Feeding Survey has found a DECREASE in breastfeeding duration in some parts of the country, despite the present legislation and efforts to promote and support breastfeeding.

As noted in response to previous questions, the marketing practices described in this document and other BFLG monitoring reports will continue with few exceptions with the proposed regulations.

Implementing the International Code (BFLG's Option 3) could have a significant impact on social and environmental costs

Again as noted in response to the last question, implementing the International Code would mean efforts to promote and support breastfeeding are more likely to succeed, giving potential cost savings of hundreds of millions of pounds and additional savings from reduction in risk to infants who are fed on formula.

Increasing breastfeeding rates is recognised as an effective way to reduce health inequalities.

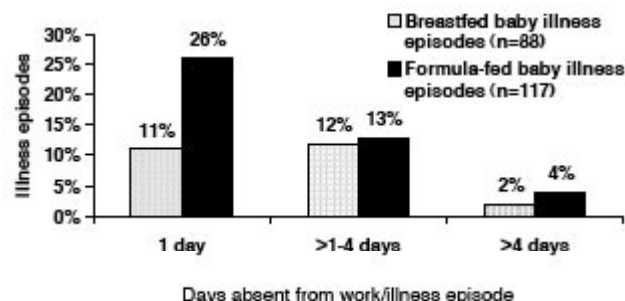
"Breastfeeding initiation is a good proxy indicator for infant health, but is much less prevalent amongst more disadvantaged groups. In general, mothers who do not initiate breastfeeding tend to be younger, less well educated and from lower income groups. Infants who are not breastfed are five times more likely to be admitted to hospital with infections in their first year of life. NHS staff should be following best practice in increasing initiation and duration of breastfeeding."

Infant health & inequalities: breastfeeding initiation rates
Healthcare Commission, 2007¹.

Implementing the International Code may help to reduce maternal absenteeism from work

The graph below is based on a US study and shows that mothers who were breastfeeding were less likely to have incidence of absence from work. Mothers in the study were self-selected and further research in the UK context is needed.

Distribution of illness episodes and maternal absenteeism by feeding practice



Adapted from: Cohen et al. Comparison of maternal absenteeism and illness rates among breastfeeding and formula-feeding women in two corporations. AJHP, 1995, 10(2):148-153. Transparency 6.25

Graph from BFHI course for decision makers².

"Approximately 28% of the infants in the study had no illnesses; 86% of these were breast-fed and 14% were formula-fed. 25% of all 1-day maternal absences were among breast-fed babies and 75% were among the formula-fed group."

"Conclusions. In this study fewer and less severe infant illnesses and less maternal absenteeism was found in the breast-feeding group. This was not an experimental study. Participants were self-selected, and a comparison group was used rather than a true control group."

Cohen et al. Comparison of maternal absenteeism and illness rates among breastfeeding and formula-feeding women in two corporations. AJHP, 1995, 10(2):148-153.

Implementing the International Code will help to achieve carbon reduction targets

There is no food more locally produced, more sustainable or more environmentally friendly than a mother's breastmilk. It is a naturally renewable resource that requires no packaging or transport and results in no wastage.

There environmental benefits from increasing breastfeeding rates are likely to be significant since the production, transportation, promotion and preparation of formula are energy and resource intensive. The Regulatory Impact Assessment must include a calculation of the possible impact on implementing the Code on carbon emissions and water consumption.

As the proposed regulations are unlikely to have any impact in improving breastfeeding initiation and duration, there will be no environmental benefit from Option 2 over Option 1.

Implementing the International Code will help to reduce obesity

Breastfeeding provides an ideal window of opportunity for obesity prevention. Exclusive breastfeeding protects against rapid weight gain during infancy and may also help in the development of taste receptors and appetite control.

Systematic reviews, meta-analyses and large cohort studies demonstrate an association between not breastfeeding and an increased risk of obesity in childhood. Several studies which compare longer durations of breastfeeding, demonstrate a dose dependent effect, that is, babies who were exclusively breastfed for longer were less likely to develop obesity.

Harder T, Bergmann R, Kallischnigg G, Plagemann A. *Duration of breastfeeding and risk of overweight: A meta-analysis*. Am J Epidemiol. 2005;162:397-403. These findings strongly support a dose-dependent and significant association between longer duration of breastfeeding and decrease in risk of overweight.

Kalies H, Heinrich J, Borte N, et al and LISA Study Group. *The effect of breastfeeding on weight gain in infants: results of a birth cohort study*. Eur J Med Res, January 28, 2005; 10(1): 36-42. In this prospective cohort study healthy term neonates were followed up to age 2 years in Germany. Duration of exclusive breastfeeding was inversely associated with the risk of elevated weight gain in a strongly duration-dependent way.

Akobeng AK, Heller RF. *Assessing the population impact of low rates of breast feeding on asthma, coeliac disease and obesity: the use of a new statistical method*. Archives of Disease in Childhood 2007;92:483-485. In the population of the 596,122 babies born in England and Wales in 2002, the number of cases of asthma, coeliac disease and obesity that could be prevented over 7-9 years if all babies were breastfed was 33 100 (95% CI 17 710 to 47 543), 2655 (95% CI 1937 to 3343) and 13639 (95% CI 7838 to 19308), respectively. [Further supporting references on obesity:]

Bergmann KE, Bergmann RL, Von Kries R, Böhm O, Richter R, Dudenhausen JW, Wahn U. Early determinants of childhood overweight and adiposity in a birth cohort study: role of breastfeeding. Int J Obes Relat Metab Disord. 2003 Feb;27(2):162-72.

Gillman MW, Rifas-Shiman SL, Berkey CS, et al. *Breast-feeding and overweight in adolescence: within-family analysis* [corrected] Epidemiology. 2006 Jan;17(1):112-4.

Gillman MW, Rifas-Shiman SL, Camargo CA Jr, Berkey C, Frazier AL, Rockett HRH, et al. *Risk of overweight among adolescents who had been breast fed as infants*. JAMA 2001;285:2461-7.

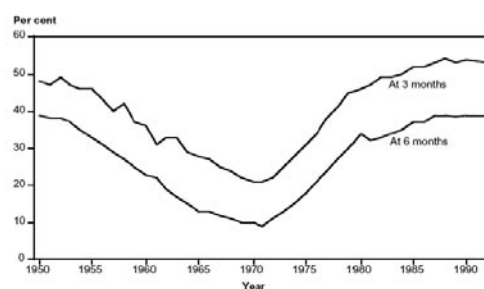
Hediger ML, Overpeck MD, Kuczmarski RJ, Ruan WJ. *Association between infant breastfeeding and overweight in young children*. JAMA 2001;285:2453-60.

von Kries R, Koletzko B, Sauerwald T, Von Mutius E, Barnert D, Grunert V, et al. *Breast feeding and obesity: cross sectional study*. BMJ 1999;319:147-50.

Toschke AM, Vignerova J, Lhotska L, Osancova K, Koletzko B, von Kries R. *Overweight and obesity in 6- to 14-year-old Czech children in 1991: protective effect of breast-feeding*. J Pediatr 2002;141:764-9.

Evidence presented to the Australian Parliament

This comprehensive Parliamentary enquiry into infant feeding contains much information that the FSA may find of use in completing the RIA. Breastfeeding rates in Australia began to decrease in the 1950s, reaching a low point in the early 1970s. The Report says there are complex reasons for this, including the increase in availability of infant formula and its promotion by the health system.



The graph shows mothers fully breastfeeding at 3 and 6 months 1950-1992.

The Best Start - Report on the inquiry into the health benefits of breastfeeding. Parliament of the Commonwealth of Australia: House of Representatives Standing Committee on Health and Ageing. August 2007. Canberra.

Completing the Regulatory Impact Assessment and implementing the regulations requires care over conflicts of interest

“Member States are urged to:

(4) to ensure that financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest;

(5) to ensure that research on infant and young-child feeding, which may form the basis for public policies, always contains a declaration relating to conflicts of interest and is subject to independent peer review;”

WHA 58.32

References

References to some studies are given in the body of the report. Others are given here, arranged by section. A bibliography of relevant studies has been prepared by Baby Feeding Law Group member MIDIRS. For further information or explanation and details of monitoring results featured in this report, contact Baby Milk Action, the secretariat of the Baby Feeding Law Group.

Contents - page 3

1. World Health Organisation. The International Code of Marketing of Breastmilk Substitutes. Geneva: WHO, 1981.
2. World Health Assembly Resolutions WHA35.26, WHA37.30, WHA39.28, WHA41.11, WHA43.3, WHA44.33, WHA47.5, WHA49.15, WHA54.2, WHA55.25, WHA58.32 and WHA59.21
3. World Health Organisation. The international code of marketing of breast-milk substitutes. Frequently asked questions. p6. Geneva: WHO, 2006.

Executive Summary - page 5

1. World Health Assembly Resolution 33.32: *“Stressing that the adoption of and adherence to the International Code of Marketing Breastmilk Substitutes is a minimum requirement and only one of several important actions required in order to protect healthy practices in respect of infant and young child feeding... URGES all Member States:*

(1) to give full and unanimous support to the implementation of the recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding and of the provisions of the International Code in its entirety as an expression of the collective will of the membership of the World Health Organization;

(2) to translate the International Code into national legislation, regulations or other suitable measures;

(3) to involve all concerned social and economic sectors and all other concerned parties in the implementation of the International Code and in the observance of the provisions thereof;

(4) to monitor the compliance with the Code...

2. Office of National Statistics. Infant Feeding Survey 2005 (page 211) *“Around nine in ten mothers who breastfed for less than six weeks said that they would have liked to continue longer, this proportion declining to 40% of mothers who breastfed for at least six months.”*

<http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles/infant-feeding/infant-feeding-survey-2005>

3. Promotion of Breastfeeding in Europe, a Blueprint for Action. EU Project Contract N. SPC 2002359
4. Commission Directive of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC).
Commission Directive of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries (92/52/EEC).
5. Commission Directive of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (2006/141/EC).

The Government can and should implement the International Code – page 6

1. WHO. The International Code of Marketing of Breastmilk Substitutes. 1981. Geneva, Switzerland.
2. House of Commons. Infant foods [written answer]. Hansard, vol 463, no 130, 25 July 2007, col 1222W.

Lynne Jones: *“To ask the Secretary of State for Health if he will make it his policy to extend the consultation on the partial regulatory impact assessment on the Infant Formula and Follow-on Formula (England) Regulations 2007 to obtain views on a third option of fully implementing the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions on the health, social and environmental aspects of marketing breastmilk substitutes, giving these precedence over trade considerations; and if he will make a statement.”* [152498]

Dawn Primarolo: “The Food Standards Agency launched, on 2 July, a 12-week public consultation on draft domestic regulations which will lay down rules about the composition, labelling and advertising of formulae requesting views from stakeholders on a range of issues. Any responses received, including those that suggest alternative options, will be considered as part of the consultation exercise. The agency will consider all responses to the consultation before finalising the regulations.”

<http://www.publications.parliament.uk/pa/cm200607/cmhansrd/cm070725/text/70725w0035.htm#07072628000036>

3. Committee on the Rights of the Child. Concluding Observations of the Committee on the Rights of the Child: United Kingdom of Great Britain & Northern Ireland. CRC/C/15/Add.188, 2002. Paragraph 40: “The Committee recommends that the State party takes all appropriate measures to reduce inequalities in health and access to health services; to promote breastfeeding and adopt of the International Code for Marketing of Breast-milk Substitutes...”

<http://www.everychildmatters.gov.uk/strategy/uncrc/process/?asset=document&id=43144>

4. Treaty Establishing the European Community as Amended by Subsequent Treaties, Rome 25 March 1957.

5. Department of Health. Policy and guidance: maternal and infant nutrition. London: DH

<http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Maternalandinfantnutrition/index.htm>

The Baby Feeding Law Group position – page 7

1. World Health Organisation. Global Strategy for Infant and Young Child Feeding. Geneva. WHO, 2005.

http://www.who.int/child-adolescent-health/publications/NUTRITION/IYCF_GS.htm

History of the Code in Europe – page 8

1. Referenced paper available from Baby Milk Action.

Legal arguments surrounding the UK’s ability to implement the International Code - pages 9 - 11

1. Council Conclusions of 2 December 2002 on Obesity (OJ C 11, 17.1.2003, p. 3), of 2 December 2003 on Healthy Lifestyles (OJ

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Nutrition and Physical Activity (Press release: 8980/05 (Presse 117); of 5 June 2006 on Promotion of Healthy Lifestyles and Prevention of Type II diabetes (OJ C 147, 23.6.2006, p. 1).

Treaty of Rome: Article 36. “The provisions of Arts. 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.”

Article 100a 4. “If, after the adoption of a harmonisation measure by the Council acting by a qualified majority, a Member State deems it necessary to apply national provisions on grounds of major needs referred to in Article 36, or relating to protection of the environment or the working environment, it shall notify the Commission of these provisions. The Commission shall confirm the provisions involved after having verified that they are not a means of arbitrary discrimination or a disguised restriction on trade between Member States. By way of derogation from the procedure laid down in Articles 169 and 170, the Commission or any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.”

2. Taken from correspondence between Baby Milk Action (IBFAN) and Robert Madelin, Director General of the European Commission Directorate of Health and Consumer Affairs (DG SANCO). He indicated: “Member States may only depart from the

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directive, however, can still be regulated by the Member State provided the provisions of the Treaty are respected.”

3. Article 95(4) of the EC Treaty refers to maintaining such provisions, so a State cannot invoke this provision to justify new national provisions which derogate from the harmonisation measure but can only use it to justify the retention of existing provisions. Article 95(5) however allows Member States to introduce national provisions after the adoption of a harmonisation measure under certain strict conditions. Under Article 95(5), the introduction of new national provisions must be based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure. It is for the Member State which invokes Article 95(5) to prove that all the conditions for application of that provision have been met.

4. The precautionary principle is a moral and political principle which states that if an action or policy might cause severe or

irreversible harm to the public, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action.

5. Risks of Formula Feeding, a brief annotated Bibliography, INFACT Canada, Evidence on the long-term effects of breastfeeding: systematic reviews and meta-analysis. 2005. Canada.

6. Office of National Statistics. Infant Feeding Survey 2005. London. ONS (page 23).

<http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles/infant-feeding/infant-feeding-survey-2005>

“Among mothers who did breastfeed initially the proportion still breastfeeding at six weeks and at six months was the same in 2005 compared to 2000. Only at nine months was the proportion of mothers still breastfeeding higher in 2005 compared with 2000. However, in Scotland the proportion of mothers still breastfeeding at six weeks and six months fell in 2005 compared with 2000.”

7. ESPGHAN Comments on the Circular Letter CL 2005/53-NFSDU and on the Synopsis of comments received until 30 April (prepared by Germany)

8. Obligations under the United Nations:

The UK has ratified the Convention on the Rights of the Child (CRC). Countries having ratified the CRC are legally bound by its provisions

rights and freedoms set forth in it. Therefore, both national and international mechanisms for monitoring CRC implementation should address the implementation of the Code in their activities. The CRC Committee has indicated that the International Code should be viewed as a tool which will help governments fulfil their obligations to Article 24 of the Convention. In 2002 the CRC Committee called on the UK to implement the Code and report back in 2008 (page 6, ref. 3).

The UN Special Rapporteur on the Right to Food called for the Directive to be strengthened, recalling government obligations contained in human rights measures relating to the right to food and children's rights (The Universal Declaration on Human Rights)

General Comment 12 of the Committee on Economic, Social and Cultural Rights).

The UK is also signatory to the Global Strategy on Infant and Young Child feeding, the Global Strategy on Diet, Physical Activity and Health, The European Charter on Counteracting Obesity, The Blueprint for Action to Protect, Promote and Support Breastfeeding, which all contain commitments to support, promote and protect breastfeeding.

The Baby Feeding Law Group monitoring project - page 12

1. Baby Milk Action. *Hard sell formula - strategies used by the baby food industry in the UK*. Cambridge: Baby Milk Action, 2007.

Full implementation of the International Code should be considered - page 13

1. A survey of 'any breastfeeding' at 6 months in 17 European Countries, the UK is position 16th. Promotion of Breastfeeding in Europe, a Blueprint for Action. EU Project Contract N. SPC 2002359

2. UNICEF. *Progress of Nations 1999*. UNICEF. New York.

More infants are gaining the irreplaceable benefits of exclusive breastfeeding during their first four months, according to data from 35 developing countries. Rates have increased in the 21 countries listed below [in the report].

Iran achieved the highest average annual increase in breastfeeding, 6 percentage points, followed by Brazil and Zambia. Breastfeeding rates have declined in Colombia, Jordan, Kenya, Kyrgyzstan, Morocco and Tunisia.

Breastfeeding gains stem from initiatives to publicise the benefits to both mother and child and to prohibit the advertising and promotion of breastmilk substitutes, feeding bottles and teats.

3. See page 30 of this report for details and references.

4. See reference 2 for page 5.

5. Rea, M. *A review of breastfeeding in Brazil and how the country has reached ten months' breastfeeding duration*. Cad. Saúde Pública v.19 supl.1 Rio de Janeiro 2003.

6. Helsing. Breastfeeding in Norway 1860-1998 and some landmarks in global infant feeding. The data series was originally published in: Liestol K, Rosenberg M, Walloe L. Breastfeeding practice in Norway 1860-1984. J Biosoc Sci 1988;20:45-58.

Response to RIA question - page 14 - 15

1. See page 25 of this report.
2. Brazilian regulations: Portaria no 2.051/2001 Norma Brasileira de Comercialização de Alimentos para Lactentes e Crianças de Primeira Infância, Bicos, Chupetas e Mamadeiras (NBCAL). RDC no. 221/2002 Resolução da Diretoria Colegiada / ANVISA. RDC no. 222/2002 Resolução da Diretoria Colegiada / ANVISA. LEI 11.265/2006 Governo Federal. Available at: <http://www.ibfan.org.br/legislacao/index.php>
3. World Health Organization. Nutrition for health and development. Geneva: WHO, 2001.

Company logos are associated with formula for young babies - page 18

1. Data available on request.

Point-of-sale promotion pushes brand names - page 19

1. Tesco response published as an update to Baby Milk Action's Campaign for Ethical Marketing action sheet May 2005. Available at: <http://www.babymilkaction.org/CEMresponses/CEMRmay05.html#2>

Response to RIA question - page 20

1. Marion Nestlé quoted in New York Times, 28 January 2007. Available at: http://www.nytimes.com/2007/01/28/magazine/28nutritionism.t.html?pagewanted=3&_r=1

Adding new ingredients is used as a marketing strategy - the case of Long Chain Polyunsaturated Fatty Acids (LCPUFAs) - page 22

1. Simmer K. Longchain polyunsaturated fatty acid supplementation in infants born at term (Cochrane Review). The Cochrane Database of Systematic Reviews, issue 4, 2001.
2. European Commission, Scientific Committee on Food. Report of the Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae. Brussels: European Commission, 2003.
3. Hambrecht and Quiest website briefing on Martek - archive copy available from Baby Milk Action.
4. Article 13.3 of the The Infant Formula and Follow-on Formula Regulations 1995 states:

The labelling of an infant formula shall include a claim concerning the composition of the product only when —

- (a) the claim is listed in column 1 of Schedule 4, and is expressed in the terms there set out; and
- (b) the condition specified in column 2 of that Schedule in relation to the relevant claim made in column 1 is satisfied.

Companies suggest formula is better than in reality - page 23

1. Benefits as listed with references in Department of Health. Infant Feeding Recommendation. DH. Available at: http://www.breastfeeding.nhs.uk/en/docs/FINAL_QA.pdf

Company promotion of specialised formulas can lead to mis-use - page 24

1. Food Standards Agency. Eat well, be well: milk and dairy: babies and children. <http://www.eatwell.gov.uk/healthydiet/nutritionessentials/milkanddairy/>
2. Department of Health CMO's Update. Advice issued on soy-based infant formulas. January 2004, page 2

Response to RIA question - page 25 - 26

1. Department of Health. Birth to five: your complete guide to the first five years of being a parent. London: Central Office of Information, 2007.

2. Idjradinata P, Watkins WE, Pollitt E. Adverse effect of iron supplementation on weight gain of iron-replete young children. *Lancet*. 1994 May 21;343(8908):1252-4
- Majumdar I, Paul P, Talib VH, Ranga S. The effect of iron therapy on the growth of iron-replete and iron-deplete children. *J Trop Pediatr*. 2003 Apr;49(2):84-8.

The current and suggested approach to differentiating between infant and follow-on formula creates easily exploited loopholes - page 26

1. Correspondence obtained under the Freedom of Information Act and reported in Baby Milk Action's Update 37, December 2005. Available at:
<http://www.babymilkaction.org/update/update37.html#7a>

Company promotion of follow-on milks can lead to mis-use - page 26

1. Unicef, National Childbirth Trust. NCT/Unicef follow-on milk advertising survey topline results. Unicef, NCT, 2005.
http://www.babyfriendly.org.uk/pdfs/formula_promotion_mori_2005.pdf

Response to RIA Question - page 27 - 28

1. Food Standards Agency. Guidance on preparing infant formula. http://www.food.gov.uk/news/newsarchive/2005/nov/infantformula_statement_nov05 [statement amended in 2006]
2. Monitoring data held by Baby Milk Action.
3. World Health Organization. Safe preparation, storage and handling of powdered infant formula: guidelines. Geneva: World Health Organization, 2007.

Response to RIA Question - page 29 - 30

1. Save the Children. A Generation On: Baby milk marketing still putting children's lives at risk. London. 2007. Available at:
http://www.savethechildren.org.uk/en/41_955.htm
2. Marc Kaufman and Christopher Lee. HHS Toned Down Breast-Feeding Ads Formula Industry Urged Softer Campaign. *Washington Post*. 31 August 2007. Available at:
http://www.washingtonpost.com/wp-dyn/content/article/2007/08/30/AR2007083002198_pf.html
3. Weimer. The economic benefits of breastfeeding: A review and analysis, Food Assistance & Nutrition Research Report No. 13. Wash.D.C., USDA, 2001.
4. Ball TM, Wright AL. "Health care costs of formula-feeding in the first year of life." *Pediatrics* 1999 Apr;103(4 Pt 2):870-6.
5. Montgomery DL, Splett PL. "Economic benefit of breast-feeding infants enrolled in WIC." *J Am Diet Assoc* 1997 Apr;97(4):379-85
6. Tuttle CR, Dewey KG. "Potential cost savings for Medi-Cal, AFDC, food stamps, and WIC programs associated with increasing breast-feeding among low-income Hmong women in California." *J Am Diet Assoc* 1996 Sep;96(9):885-90
7. NICE. Postnatal care: routine postnatal care of women and their babies. Costing report: Implementing NICE guidance in England. London: National Institute for Health and Clinical Excellence; 2006. pp 36. www.nice.org.uk/page.aspx?o=345136
8. Howie PW, Forsyth JS, Ogston SA, et al. Protective effect of breast feeding against infection. *BMJ* 1990;300(6716):11-6.
9. Oddy, WH., Holt, PG., Sly, PD, et al. Association between breast feeding and asthma in 6 year old children: findings of a prospective birth cohort study. *BMJ*, 1999; 319(7213): 815-819.
10. Aniansson G, Alm B, Andersson B, et al. A prospective cohort study on breast-feeding and otitis media in Swedish infants. *Pediatric Infectious Disease Journal* 1994;13(3):183-8.
11. Pisacane A, Gready M, Mazzarella G, et al. Breast-feeding and urinary tract infection. *Journal of Pediatrics* 1992;120(1):87-9.
12. Kramer MS, Chalmers B, Hodnett ED, et al. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. *JAMA* 2001;285(4):413-20.

13. Owen CG et al. "Does influence risk of type 2 diabetes in later life? A quantitative analysis of published evidence." *Am J Clin Nutr.* 2006 Nov;84(5):1043-54.
- Sadauskaite-Kuehne-VS, Ludvigsson J, Padaiga Z, et al. "Longer breastfeeding is an independent protective factor against development of type 1 diabetes mellitus in childhood." *Diabetes Metabolism Research and Reviews.* Mar-Apr 2004; 20(2):150-157.
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15. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and breastfeeding: collaborative reanalysis of individual data from 47 epidemiological studies in 30 countries, including 50302 women with breast cancer and 96973 women without the disease. *Lancet* 2002;360(9328):187-95.
16. Stuebe AM, Rich-Edwards JW, Willett WC, et al. Duration of lactation and incidence of type 2 diabetes. *JAMA* 2005;294(20):2601-10.
17. McConnachie A et al. Modelling consultation rates in infancy: influence of maternal and infant characteristics, feeding type and consultation history. *Br J Gen Pract* 2004; 54: 598–603.
18. Chen A, Rogan WJ. Breastfeeding and the risk of postneonatal death in the United States. *Pediatrics.* 2004;113:e435–439. doi: 10.1542/peds.113.5.e435.
19. Rea, M. *A review of breastfeeding in Brazil and how the country has reached ten months' breastfeeding duration.* *Cad. Saúde Pública* v.19 supl.1 Rio de Janeiro 2003.

Response to RIA Question - page 32

1. Healthcare Commission. Infant health and inequalities: breastfeeding initiation rates. Health Care Commission, 2007. Available at:
<http://www.healthcarecommission.org.uk/nationaltargets2007-2008/newnationaltargets/primarycaretrusts/indicators/infanthealth&inequalities-breastfeedinginitiationrates.cfm>
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http://www.who.int/entity/nutrition/topics/BFHI_Revised_Section2.6_Slides.ppt
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Ecological Impact of Bottlefeeding, Andrew Radford, Baby Milk Action, 1991
Breastfeeding - Nature's Way WABA Fact sheet 1997
Breastfeeding & the Environment, Women's Environmental Network

A minimum requirement to be implemented in its entirety

The *International Code of Marketing of Breastmilk Substitutes* was adopted by the World Health Assembly in 1981 with the support of the UK Government under a Resolution calling for Member States to implement it in its entirety. The Government has supported subsequent Resolutions that reiterate the importance of the *International Code* and address changes in scientific knowledge and baby food company marketing practices. In 2002 the UN Committee on the Rights of the Child called on the UK Government to implement the Code in legislation.

Now, in 2007, the Government has both the opportunity and obligation to do so as it implements EU Directive 2006/141/EC which: “provides for Member States to give effect to principles and aims of the *International Code of Marketing of Breastmilk Substitutes* dealing with marketing, information and responsibilities of health authorities”.

This long-overdue action is pressing for three reasons:

1. According to a UK government survey 90% of mothers who stopped breastfeeding before 6 weeks said they wanted to breastfeed for longer, as did 40% of those who breastfed for at least 6 months.
2. In Sweden 98% of mothers initiate breastfeeding, compared to 76% in the UK. In the UK, rates decline rapidly with less than half of babies (48%) breastfed at 6 weeks. Our rates are almost the lowest in Europe. In Sweden over 70% of mothers are still breastfeeding at 6 months.
3. Formula companies do not provide accurate information on differences between brands and essential information on how to reduce risks. Those who use formula need protection and independent sources of information.

In this report to the Government’s consultation on implementing the Directive, the Baby Feeding Law Group presents its case for taking action to protect mothers, babies and their families.

BFLG Member organisations

Association of Breastfeeding Mothers (ABM)
Association for Improvements in the Maternity Services (AIMS)
Association of Radical Midwives (ARM)
Baby Milk Action (BFLG secretariat)
Best Beginnings
Breastfeeding Community
Breastfeeding Network (BfN)
Community Practitioners and Health Visitors Association (CPHVA)
Food Commission
Lactation Consultants Great Britain (LCGB)
La Leche League Great Britain (LLLGB)
Little Angels
Midwives Information and Resource Service (MIDIRS)
National Childbirth Trust (NCT)
Royal College of Nursing (RCN)
Royal College of Midwives (RCM)
Royal College of Paediatrics and Child Health (RCPCH)
The Baby Café
UK Association for Milk Banking (U.K.A.M.B)
UNICEF UK Baby Friendly Initiative (BFI)
UNISON
Women’s Environmental Network (WEN)

What is our aim?

We aim to protect babies’ health by ending marketing practices which commercialise infant feeding and threaten breastfeeding.

This aim can be achieved by bringing UK and European legislation into line with the International Code and subsequent relevant WHA Resolutions.* This will help parents base their decisions about infant feeding on truly independent evidence-based information.

Since 1997 health professional and mothers-support organisations in the UK have worked together as the Baby Feeding Law Group, convened by Baby Milk Action.