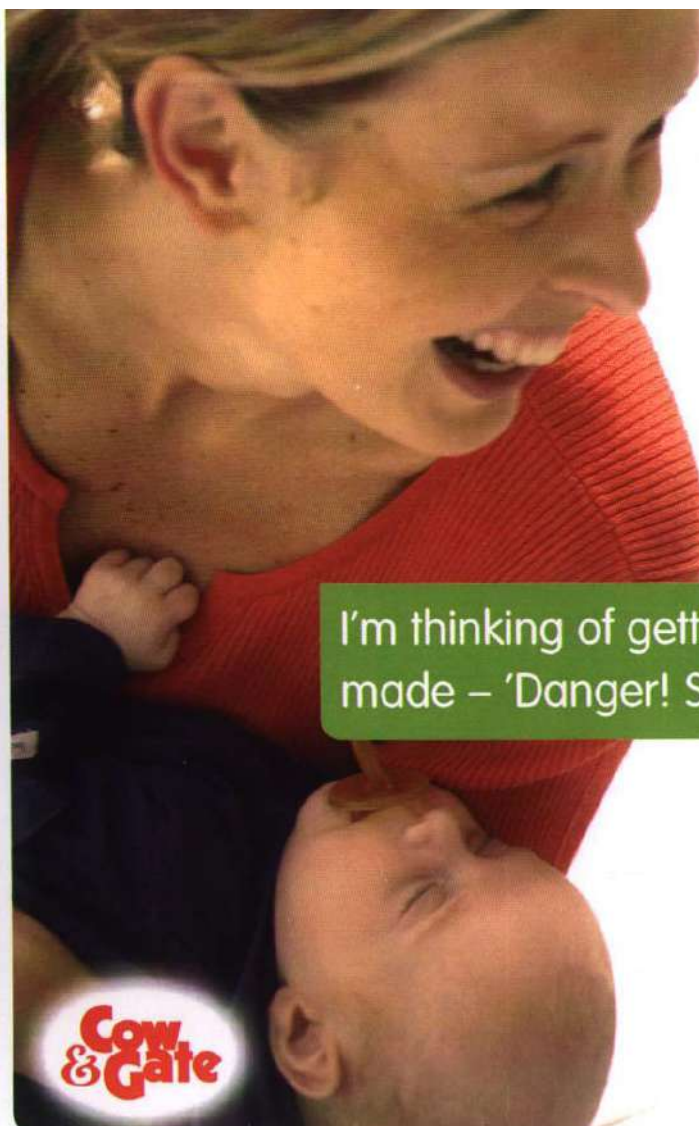


BRIEFING

BABY MILK
ACTION



**Briefing on EU and UK legislation on infant
formulas and follow-on formulas**

Baby Milk Action Briefing on EU and UK legislation on baby formulas and foods

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Baby Milk Action, 34 Trumpington Street, Cambridge, CB2 1QY

Tel : (UK) 01223 44620

Cover picture: Danone leaflet sent to mothers in the UK - perpetuating the notion that breastfeeding will always be painful . Because mothers believe this they don't ask for help and the problems continue.

For just five illnesses, moderate increases in breastfeeding would translate into cost savings for the NHS of £40 million and tens of thousands of fewer hospital admissions and GP consultations.

Preventing Disease and Saving resources, UNICEF UK, 2012

A 10% increase in breastfeeding rates would result in savings in the cost of treating gastroenteritis, asthma and otitis media. Total savings for just 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

NICE Costing report 2006

50-80% of the selling price of formula goes towards company promotion and profits. This means that a mother using formula for 12 months will contribute about £300 above the cost of the formula processing and distribution to the company's promotional budget, rising to £800 if ready to feed formula is used.

Baby Milk Action analysis 2012

"We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupportable. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods." The UK Government's Scientific Advisory Committee on Nutrition (SACN) 2007

"In this region alone [Asia Pacific] sales of infant formula have grown 15% per year for the last five years....but sadly it's the formula manufacturers who are capturing most of the value of our milk. Infant formula delivered to the back door of a supermarket is worth ten times as much as our milk powder exports at the border. "We blither on incessantly about the need to add value to our exports. Infant formula is a clear, no-brainer opportunity to add value...." Tim Morris, Coriolis Limited, New Zealand, 2011

"A kilo of infant formula is worth ten times the value of a kilo of milk powder, so it's obvious which product New Zealand should be selling."

Gerry Brownlee, Economic Development Minister, 2011

"The Irish Government and Danone Baby Nutrition.. today announced details of a €50 million investment programme at its manufacturing facility in Macroom, Co Cork Ireland.... The expansion will result in a trebling of capacity to 100,000 tonnes annually, .. 98% of the output from Macroom will be exported and commercialized in more than 60 countries worldwide....."

Enterprise Ireland Press release 4.12.10

"The industry is fighting a rearguard action against regulation on a country-by-country basis,"

Global Packaged Food: Market Opportunities for Baby Food to 2013 Euromonitor

"You have to understand - the big companies don't feel any national loyalty any more - we are beyond that - we're global - we move the money around, we can pay ourselves gargantuan compensation packages that are offensive to social norms in the host country because we don't feel part of the host country any more....."

Jeffrey Sachs, Economist, speaking on BBC Radio 4. 2011

Self-regulation does not work as a way to limit the extent and impact of marketing. Instead, self-regulatory systems promote trust in advertising among consumers and governments, undermining their resolve to bring in the legislation that is needed to protect health. Under these systems the volume of advertising increases"

Corinna Hawkes, Int. Food Policy Research Institute, Washington.

"Artificially fed infants consume 30,000 more calories than breastfed infants by 8 months of age" (equivalent to 120 Mars bars - 4 a week).

Student Study Guide KG Auerbach, J Riordan 1993

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1 Introduction

Infant formula has been described as a semi-medicinal food or 'nutritional medicine' which should only be used on the advice (and ideally under the supervision) of health workers.¹ It is a processed food, based on cow's milk or soya, intended for use when babies are not breastfed by their mothers and do not otherwise have access to breastmilk (from a donor milk bank, for example).

Infant formula is unlike other foods in that it is used as the sole source of nutrition during the first six months of life - a critical period of rapid growth and development. It can also continue to be used alongside complementary foods after 6 months for as long as needed. There is no benefit in moving onto follow-on formulas or other formulas for older babies. Processed formulas can only ever be an imperfect approximation of human breastmilk which is a living substance that changes as the baby grows. A mother's breastmilk contains antibodies and other protective factors that are tailored to her baby's needs. It is impossible to mimic a mother's breastmilk, which is delivered to her baby in a uniquely safe way. In every stage of the manufacture, storage and delivery of formulas, there are countless opportunities for contamination, human error and corruption.

In addition to these problems, minor modifications and omissions in the ingredients used in these products can have major effects on infant health. *The Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae*² identified some of the problems that have occurred with the introduction of modified infant formulae. Examples included reduced protein availability with impairment of growth; trace element deficiency with severe clinical disease; chloride deficiency with long-term neurological damage and thiamine deficiency with severe clinical disease, including neurological damage and several cases of infant death.

Breastmilk substitutes may be required when a child is orphaned, the mother is incapacitated or drug intake might be a contraindication to breastfeeding (though expert pharmacists should be consulted as breastfeeding is possible with many drugs, even when the standard information indicates otherwise as a routine recommendation - contact the Drugs in Breastmilk Helpline).

In the UK, a large proportion of mothers use formula with no medical need. Indeed, the preliminary results from the Infant Feeding Survey 2010 show that nearly a fifth (19%) of babies in the UK are never breastfed. The last full published survey (2005) found that the number of babies breastfed exclusively until 6 months, as recommended by the Departments of Health and the World Health Organisation, is insignificant; only 21% of babies are still being exclusively breastfed at 6 WEEKS of age in the UK.

Mothers (and carers when the mothers are absent) who are unable or unwilling to breastfeed and do not have access to breastmilk by other means will require access to breastmilk substitutes (infant formula).

¹ *Infant formula and related trade issues in the context of the international code of marketing of breast-milk substitutes, health implications of direct advertising of infant formula.*
www.who.int/nutrition/.../infant_formula_trade_issues_eng.pdf

² Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae SCF/CS/NUT/IF/65 Final 18 May 2003

2 KEY FACTS

2.1 Key facts about infant feeding:

- The UK Government, as a signatory to the *International Code of Marketing of Breastmilk Substitutes* and subsequent relevant World Health Assembly Resolutions, has obligations to implement them in their entirety, to protect breastfeeding, to ensure parents and carers are not misled and properly informed and that breastmilk substitutes are used safely if needed.
- The International Code was adopted in 1981 as a **minimum standard** to be **implemented in its entirety** in all countries.³ Leading health bodies and parliamentarians have called for its full implementation since 1981. (*The International Code and WHA Resolutions have equal status and should be read together.*)
- 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 months.
- Of 17 countries studied, Britain's rates of *any* breastfeeding at 6 months is position 16.⁴ Although the 2010 ONS survey shows that UK's initiation rates are starting to improve at 83%, our duration rates are almost the lowest in Europe with less than half of babies (48%) breastfed at 6 weeks.⁵
- In the 2005 ONS survey, the overwhelming reasons given by UK mothers for stopping breastfeeding were '*insufficient milk*' and other problems that can be overcome with good management. "*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.*"
- Breastfeeding has the effect of counteracting the effects of poverty for babies. Breastfeeding rates are lowest among young and poor mothers.⁶
- Higher breastfeeding rates in the UK would significantly improve the health of mothers and babies and reduce health service costs.⁷

³ 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;*

⁴ *Promotion of Breastfeeding in Europe, a Blueprint for Action.* EU Project Contract N. SPC 2002359

⁵ *Infant Feeding Survey 2005*, Office of National Statistics. Only initiation statistics are available for 2010.

⁶ *Infant feeding Survey 2005* ONS

⁷ <http://guidance.nice.org.uk/page.aspx?o=345136> A NICE costing report shows how the expected 10% increase in breastfeeding rates due to Baby Friendly Initiative accreditation (removing promotion of breastmilk substitutes, feeding bottles and tests from hospitals in line with the Code) would result in savings in the cost of treating gastroenteritis, asthma and otitis media. With a 10% improvement in breastfeeding 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

2.2 KEY FACTS ABOUT FORMULA COMPOSITION

- Any product sold as an infant formula must comply with the compositional criteria set out in legislation and the basic nutritional profile of the majority of formulas is very similar.
- There is no proven need for any baby to use follow-on formulas or formulas for older babies (Toddler milks) which were invented to get round the restrictions of the International Code. (See Section 3.5.)
- There is, as yet, no proven benefit from optional ingredients.
- “If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods.” SACN 2007
- Some babies have been shown to have adverse reactions to certain ingredients.
- Parents may have ethical issues about ingredients such as beef tallow, fish, egg, GM ingredients.

2.3 KEY FACTS ABOUT FORMULA MARKETING

- The *International Code* clearly intended to cover the marketing of products such as follow-on formulas and formulas for older babies. The *International Code* contains no definition for these products because they hardly existed at that time and only started to be aggressively promoted after the International Code was adopted.⁸
- The UK Government, and all EU member states, as signatories the International Code and the Convention of the Rights of the Child to implement it.
- There is no definition of follow-on milks in the International Code because they were not promoted or commonly used before the 1981.
- 9 UNICEF clarified its opinion on follow-on formulas and the scope of the Code in its statement to the *European Parliament Development and Co-operation Committee in Nov 2000*.⁹
- Six nutrition claims (Lactose only, Lactose free, Added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid, Taurine, fructo-oligosaccharides and galacto-oligosaccharides, nucleotide) and one disease risk reduction claim (Reduction of risk to allergy to milk proteins) are specifically permitted for infant formulas.¹⁰

⁸ The definition of 'breastmilk substitute' in the *International Code* refers to “any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.” so covers far more than infant formula: “The Code applies to the marketing, and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.”

⁹ “The Code applies to ALL BREASTMILK SUBSTITUTES and related products, which include feeding bottles and teats. The Code is not limited to basic infant formula intended for healthy babies born after nine months of gestation and with adequate weight and length for age as many companies would argue. The Code covers special formulae such as those for premature infants, hypoallergenic formulae, lactose free formulae and follow-on formulae (ref 4). It also covers waters, juices, teas, and foods if marketed or in any other way represented as a partial or total replacement for breastmilk. These two principles, universality and the scope including all breastmilk substitutes, cannot be over emphasised given the tendency of the infant feeding industry to attempt to limit the application of the Code.”

<http://www.babymilkaction.org/press/press23nov00unicef.html>

¹⁰ *The Infant Formula and Follow-on Formula (England) Regulations 2007*.

- Claims for follow-on formulas and formulas and foods for older babies must be first be authorised according the EU Nutrition and Health Claims claims legislation.¹¹ To date, although several claims for children's foods and foods for pregnant women have been authorised, only one health claim for follow-on formulas has been permitted:
*"Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age."*¹²
- Before being authorised in 2011, the DHA claim was challenged by Members of the European Parliament.
- The DHA claim is not permitted for infant formulas, but since they share the same brand name as follow-on formulas, the DHA health message crosses over to the permitted DHA nutrition claim.¹³
- The EU Commission has clarified that a brand name cannot be an implied health or nutrition claim unless that claim is legally permitted.¹⁴
- The EU Commission has clarified that 'Prebiotic' and 'Probiotic' claims are health claims so are not permitted on infant formulas.¹⁵
- Formulas for Special Medical Purposes are covered by separate more lax legislation which permits a description that could imply a health claim.¹⁶ See Section 9.
- Manufacturers have the legal right to market products in the UK provided they meet EU Requirements. Regulations in EU member states vary considerably so products that do not meet UK standards can be legally marketed in the UK.¹⁷
- The detailed rules laid down in the Infant Formula and follow-on formula Regulations 2007, have precedence over general food labelling rules in the UK.
- A Department of Health Survey in 2004 found that over a third (34%) of women in the UK believe that infant formulas are very similar or the same as breast milk.
- The ONS infant Feeding Survey 2005 and others commissioned by UNICEF, Save the Children and the National Childbirth Trust in 2005 and 2007 show a profound lack of understanding about the risks of artificial feeding especially amongst younger and less educated parents. In one study around a third of the respondents said advertising gave the impression that infant formula milk was 'as good as' or 'better than' breastmilk

¹¹ REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 on nutrition and health claims made on foods

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF>

¹² <http://ec.europa.eu/nuhclaims/>

¹³ Claims for follow-on formulas and formulas and foods for older babies must be first be authorised according the EU Nutrition and Health Claims claims legislation. To date, although several claims for children's foods and foods for pregnant women have been authorised, only one health claim for follow-on formulas has been permitted:

"Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age."

¹⁴ Summary Report of The Standing Committee on the Food Chain and Animal Health (SCoFCAH), 22 June 2011

¹⁵ Letter from Basil Mathioudakis, European Commission to Mark Toal, UK FSA, 4.10.2007: *"The use of the claim "contains prebiotics", as you correctly mentioned in your letter, is a claim describing a function and therefore has to be considered as a health claim which is currently not foreseen in Directive 2006/141/EC and consequently is not permitted for use for infant formula."*

¹⁶ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.

3 LEGISLATION AND MARKETING CODES

3.1 UK Legislation:

- The Infant Formula and Follow-on Formula (England) Regulations 2007¹⁸
- Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended) Revision 2, March 2009¹⁹

3.2 UK Self Regulatory Codes:

- The UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code)
- The UK Code of Broadcast Advertising (BCAP Code)
- IDACE/IFM and company codes of Practice

3.3 EU Legislation:

- Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC²⁰
- COMMISSION DIRECTIVE 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children
- Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.²¹ (which in turn refers to the Council Directive 18.12.1978 on the approximation of the laws of Member states relating to the labeling, presentation and advertising of foodstuffs for sale to the ultimate consumer.²²
- Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.
- Nutrition and Health Claims Regulation 1924/2006 on nutrition and health claims made on foods.
- EU Register On Nutrition & Health Claims providing an updated list of all the permitted health and nutrition claims.²³
- *Food Safety Regulation 178/2002/EC of the European Parliament and of the Council* (OJ No. L31, 1.2.2002, p.1) lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Food Labelling Directive 2000/13/EC on the approximation of the laws of Member States relating to the labelling, presentation and advertising of food, OJ No. L 109, 6.5.2000, p.29, as amended
- *Novel Foods Regulation* (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredient laying out detailed rules for the authorisation of novel foods, ingredients and processes.
- GM Foods Commission Regulation (EC) No. 1829/2003
- *Pesticides Regulation* (EC) No. 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin *OJ L 158, 21.6.2005, p. 6–9*
- *Lisbon Treaty*: http://europa.eu/lisbon_treaty/index_en.htm
- Council Directive 92/52/EEC of 18 June 1992 lays down harmonised rules with respect to infant formulae and follow-on formulae intended for export to third countries.

¹⁸ <http://www.legislation.gov.uk/uksi/2007/3521/contents/made>

¹⁹ <http://www.food.gov.uk/multimedia/pdfs/guidancenotes2008amendmar09.pdf>

²⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:401:0001:0001:EN:PDF>

²¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0021:EN:NOT>

²² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1979:033:0001:0014:EN:PDF>

²³ <http://ec.europa.eu/nuhclaims/>

- Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive').²⁴

3.4 LEGISLATION AND GUIDANCE ON CONTAMINANTS:

- Joint FAO/WHO Workshop on Enterobacter Sakazakii and Other Microorganisms in Powdered Infant Formula, Geneva, 2-5 February 2004
- COMMISSION DIRECTIVE 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles²⁵
- COMMISSION REGULATION (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.²⁶

3.5 RELEVANT CODEX STANDARDS ²⁷

- Codex Standard for Infant Formula and Formulas for Special Medical Purposes Codex STAN 72-1981 Formerly CAC/RS 72-1972. Adopted as a world-wide Standard 1981. Amended 1983, 1985, 1987. Revision 2007
- Codex Guidelines for Use of Nutrition and Health Claims cac/gl 23-1997, Rev. 1-2004
- Codex Standard for Canned Baby Foods 1 Codex Stan 73-1981 (amended 1985, 1987, 1989)
- Codex Standard for follow-up formula codex stan 156-1987 (amended 1989)
- Codex General Standard for the Labelling of Prepackaged Foods (Codex Stan 1-1985)
- Standard for Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991)
- Codex Standard for Cereal-based Foods [Codex Stan 74-1981]
- The Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP 66-2008
- Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991) (currently under review)
- Code of Ethics for International Trade in Food Including Concessional and Food Aid Transactions (Adopted 1979; revised 1985 and 2010)

²⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:149:0022:0039:EN:PDF>

²⁵ <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/229&format=HTML&aged=0&language=EN&guiLanguage=en>

BPA is widely used in the production of plastic baby bottles. The ban which also covers the placing on the market and import into the EU of baby bottles containing BPA. Meanwhile, the industry announced that they would voluntarily withdraw baby bottles containing BPA by mid 2011. Canada has officially declared BPA a toxic substance because of its adverse effects on human health and the environment. Six US manufacturers are removing BPA from bottles sold in the US, but not from other markets.

²⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:322:0012:0029:EN:PDF>

The BIOHAZ Panel of EFSA issued an opinion on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs on 26 and 27 January 2005. It concluded that one of the major control measures is to control temperature and to establish a system based on hazard analysis and critical control point principles. Dehydrated foods, in which the presence of spores of pathogenic *Bacillus* spp. is frequent, might permit the growth of *Bacillus cereus* once rehydrated in warm water. Some dehydrated foods, including dried infant formulae and dried dietary foods, are consumed by potentially fragile consumers. In line with the EFSA opinion, the numbers of *Bacillus cereus* spores in dried infant formulae and dried dietary foods should be as low as possible during processing and a process hygiene criterion should be laid down in addition to good practices designed to reduce delay between preparation and consumption.

²⁷ Baby Milk Action/ IBFAN Briefing on Codex. Revised April 2012

Codex items currently in discussion with relevance for baby food marketing :

- Proposed Draft Revision Of The Guidelines On Formulated Supplementary Foods For Older Infants And Young Children
- Proposed Draft Amendment Of The Standard For Processed Cereal-Based Foods For Infants And Young Children (Codex Stan 74-1981) To Include A New Part B For Underweight Children
- Proposal To Review The Codex Standard For Follow-Up Formula (Codex stan 156-1987)

The following Codex Committees are relevant:

- **Nutrition and Foods for Special Dietary Uses (CCNFSDU)**
- **General Principles (CCGP)** The Code Of Ethics was under review. IBFAN managed maintain a reference to the International Code and Resolutions.
- **Food Labelling (CCFL)**
- **Food Additives and Contaminants (CCFAC)**
- **Food Hygiene (CCFH)**
- **Codex Alimentarius Commission (CAC)**

3.6 IBFAN's concerns about CODEX – the rise of follow-on milks

IBFAN first worked on Codex issues in 1987 when the follow-on milk standard was passed. WHO was involved in this controversial move and asked for information about the Baby Milk Action and Health Visitors' Association campaign to follow-on formulas being promoted for babies of 4 months. There was much concern that their high solute load was unsuitable for young babies (HVs reported newborns being fed them). An analysis by Prof Michael Crawford at London Zoo, had shown that these milks were closer to rhinoceros milk than human milk. Although the Codex Standard stated that follow-up formula are "*suitable for infants from the 6th month on and for young children*" the fact that a Codex standard was adopted at all served to legitimize them. The World Health Assembly had already, in 1986, described them as 'not necessary'.²⁸

The establishment of the World Trade Organisation (WTO) in 1995 gave Codex a new status and importance since WTO is mandated to refer to Codex Standards in trade disputes and governments use Codex as a basis for legislation. At the same time IBFAN started work on the revision of the 1981 Codex infant formula standard and later, the Cereal-Based baby food standard. If the standards could be brought into line with World Health Assembly Resolutions, Member States would be able to implement them without fear of challenge.

The deliberations on these two standards took place mainly in Germany in the industry-dominated Nutrition Committee (CCFSNDU) The bad chairing of this committee helped the baby food industry in its efforts to lower the standards so that as many products as possible could be exempt from the Code's restrictions. The Food Labelling Committee (CCFL) in Canada, in contrast, was much fairer, and there IBFAN, with the support of the Netherlands, succeeded in getting strong wording banning claims on all foods for infants and young children into the Codex Guidelines for Health and Nutrition claims (stronger wording than the WHA Resolutions at that time). The Guidelines fed into the deliberations on nutrition and by the time the two standards were adopted in 2007 many key provisions of the International Code and WHA Resolutions had been included and most claims prohibited. The industry and EU Commission's move to have a separate standard for formulas for special medical purposes was blocked but sugar levels in

²⁸ WHA Res 39.28.

baby foods remain far too high²⁹ and there continue to be problems over transparency, the independence of the advisory panels and the lack of distinction between different types of NGO observers.

Many of these issues, including the relevance of the WHA resolutions continue to be contentious.³⁰ At the November 2011 Nutrition meeting (CCNFSDU) the **US** and the **EU** opposed the inclusion of references to the WHA Resolutions, WHO clarified that it was indeed appropriate to cite them: *“While the WHA Resolutions are not legally binding under the constitution – it doesn’t mean that the Resolutions are just paper and devoid of effect. [They] constitute the international practice and a consensus language that is also used in other international fora, for instance they are used customarily in [WTO](#) litigations.*

²⁹ **EU and US block Thailand’s proposal to reduce sugar in baby foods** FAO/WHO Codex Nutrition Committee (CCFSNDU) Chiang Mai, Thailand, 3rd November 2006, http://www.ibfan.org/news-2006-eu_us.html.

³⁰ **The Business of malnutrition: breaking down trade rules to profit from the poor.** *“The extensive food industry presence – the norm for Codex meetings. 40% of the 268 delegates were food industry, with 59 attending as members of Business Interest NGOs (BINGOS) and 49 included on government delegations – some even heading these delegations. For example, the Mexican delegation, which made many industry-friendly interventions, was 100% industry, with US baby food companies **Mead Johnson** and **Abbott** alongside **Kellogg’s** and **Coca Cola**. **Germany** hosted the meeting and 12 of its 15 delegates were industry, including baby food giants, **Milupa (Danone)** and **Nestlé**, alongside **Coca Cola**, **Kraft**, **Merk**, and others.”* <http://info.babymilkaction.org/pressrelease/pressrelease24nov110>

4 PARNUTS - historical background

Article 152(1) EC : "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."

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 the EU Treaty states: "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities" and there have been repeated calls from the European Council of Ministers and Parliamentarians that the EU should act to protect health and address food related illnesses.

Since the early 1980s there has been an ongoing struggle between the European Parliament and the European Commission regarding the status and importance of the recommendations adopted by the World Health Assembly. All 10 members of the EU at that time had endorsed the *International Code of Marketing of Breastmilk Substitutes* and in 1986 the European Parliament voted with a sweeping majority to implement the *International Code of Marketing of Breast-milk Substitutes* as a European Directive. In the run up to this vote, three EP committees rejected the Commission's proposals, with the Consumer Committee specifically questioning the scientific basis of including follow-on formulas. The Codex follow-on milk standard (see section 3.5) and 'paediatric experts' were used as a justification by the EU Commission.³¹

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." Unless carefully applied, health can easily take second place to the interests of trade.

The marketing of formulas in the UK is covered by horizontal EC legislation that is, in turn governed by a *Framework Directive on Foods for Particular Nutritional Uses*.³² The legal terms 'Dietetic' and 'Dietary' were established in 1967³³ and the power to initiate and finalize legislation on these Foodstuffs was essentially transferred to the European Commission with limited requirement to consult Parliament. This was way before the Lisbon Treaty in 2009 introduced articles that allowed the EU Member States and European Parliament to delegate power to the European Commission to adopt delegated acts and implementing acts.

³¹ In 1985 the Consumer Committee of the EU Parliament questioned the scientific basis for including compositional requirements for follow-on milks in the proposed Directives: "The need of follow-up milks is extremely dubious (page 14) and there is no need whatsoever for a new specially manufactured product." The European baby food industry (IDACE) responded: "No scientific references are given to support these statements. In the opinion of the paediatric experts of the SCF a standard is necessary. There are many papers which support this scientific opinion..... it should also be noted that FAO/WHO is also developing a Codex standard for follow-up foods."

³² Directive 89/398/EEC

³³ 69/414/EEC: Council Decision of 13 November 1969 setting up a Standing Committee for Foodstuffs. The Council delegates powers to the Commission in respect of foodstuffs and sets up a Committee made up of the Member States with the EU Commission as Chair

74/234/EEC: Commission Decision of 16 April 1974 relating to the institution of a Scientific Committee for Food
Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for nutritional uses. Establishes the legal use of the term 'Dietetic' or 'Dietary', specifies labelling requirements/

After a long campaign involving hundreds of NGOs and professional groups, the Directive was adopted. Although some gains had been made, the Directive did go as far as banning advertising outright and follow-on milk advertising was permitted.³⁴ (see also Chronology Page xxx) However the Commission agreed to an important amendment in the final stages – namely Article 14 that: “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.” This meant that Member States could fulfil their obligations under the Code if they wished.

In subsequent years, although some improvements were made to EU Legislation regarding levels of pesticides, under the oversight of the Commission, many of the gains in relation to marketing were gradually eroded.³⁵ At the *Eurodiet* Conference in May 2000 the Commission argued that implementing the WHA requirements in full would pose constitutional problems for several countries. In fact advertising restrictions *would* have been admissible provided they were based on considerations of public welfare and provided the restrictions were in line with the basic principle of proportion.³⁶

Perhaps most importantly, in 1999, despite the opposition of 900 health and development NGOs, the European Commission pressed ahead with the adoption of the *Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes. (FSMP)* This essentially allowed a whole new range of products to be marketed with minimal restrictions.

The Commission now acknowledges that the market has ‘evolved’ since the FSMP Directive was passed and that industry has been exploiting its loopholes. The Commission’s excuse for inaction in 1999 was that: “labelling, advertising and promotional restrictions, as those applicable to infant formula, were not considered appropriate at the time” (See Section 10) Because PARNUTs has been such a serious fault line running through the policy-making process in Europe, we have been calling for it to be scrapped in favour of a more transparent and accountable process. PARNUTs discussions have taken place in closed sessions of Experts from Member States and the *Standing Committee on the Food Chain and Animal Health (SCFCAH)*, with inadequate and partial summary records.

Because mandatory pre-authorisation of ingredients is not specified in PARNUTs, the Commission has refused allow it – despite requests from Member States and unanimous scientific agreement that the suitability and safety of new should be evaluated by an independent scientific authority prior to introduction into the market.³⁷

The EU Commission’s role was such a major problem that in 2008 Baby Milk Action made a complaint of maladministration to the European Ombudsman. We alleged that the Commission had failed to protect public health and had ignored Member States’ obligations to implement the *International Code*. After a 20-month investigation, the

³⁴ “Protecting breastfeeding- protecting babies fed on formula. BFLG response to the consultation on the revised Infant Formula and Follow-on Formula regulations. Pages 8-11. 2007

³⁵ IBFAN State of the Code by Country Charts

³⁶ *The constitutional relevance of advertising restrictions for Breastmilk Substitutes in Germany*, presented to Eurodiet by Andreas Adelberger, AGB, May 2000

Implementation of the International Code of Marketing of Breastmilk Substitutes in CEE countries: Can the countries of Central and Eastern Europe (CEE) adopt the International Code of Marketing of Breastmilk Substitutes and Subsequent Relevant World Health Assembly Resolutions (the Code) as a minimum requirement, without affecting any existing legal commitments or prejudicing eligibility to join the European Union(EU)? *Paper commissioned by UNICEF.*

³⁷ See IBFAN PARNUTS Comments: 2012:

<http://info.babymilkaction.org/sites/info.babymilkaction.org/files/IBFAN%20PARNUTS%20PbyP4.pdf>

IBFAN comments 2010: <http://info.babymilkaction.org/node/141>

European Ombudsman decided not to uphold our complaint, focussing only on whether the Commission carried out “its tasks” adequately. He failed to question the Commission’s analysis of the status of the [International Code](#) or its importance saying: “*In any case, although the Code was only a recommendation, not an international agreement or convention, and was, therefore, not binding, Directive 2006/141 and other relevant EC legislation have endorsed most of its guiding principles.*”³⁸

4.1 New developments – the revision of PARNUTs

The Ombudsman decision, although disappointing, seemed to prompt a slight improvement in the Commission’s responses on marketing questions and discussions have now started on the revision PARNUTs Framework Directive.

Aware that PARNUTs has been used to promote all manner of targeted foods and to avoid the Regulations covering health and nutrition claims, the Commission now proposes to abolish the concept of “*foodstuffs for particular nutritional uses*” (and the terms ‘Dietetic’ and ‘Dietary’ Foods) and replace Directive 2009/39/EC with a new Regulation covering baby formulas and foods. The Commission has gone on record saying that PARNUTs “*undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators and while the risks of marketing abuse and distortion of competition cannot be ruled out.*”

The Commission states that its aim is to ensure a high level of health protection and the effective functioning of the internal market. It will also establish principles of risk analysis and require the European Food Safety Authority to be consulted ‘*on all matters likely to affect public health.*’³⁹ The Commission has brought links to the pieces of legislation that will be affected together on one link.⁴⁰

Following debates in the European Parliament’s *Environment, Public Health and Food Safety* Committee and full Plenary, the Council, and the Commission’s *Standing Committee on the Food Chain and Animal Health* (SCoFAH),⁴¹ there will now be three High Level Triologue meetings of MEPs, Commission and Council in September, October and November 2012, with the aim of agreeing new text and an early 2nd reading, possibly before the end of the year under the Cypriot Presidency.

³⁸ *Decision of the European Ombudsman closing his inquiry into complaint 97/2008/(BEH)JF against the European Commission* <http://www.ombudsman.europa.eu/cases/decision.faces/en/4265/html.bookmark>

We argued that the Official failed to chair the SCoFAH meetings in a fair and objective way because he: (i) produced misleading written statements regarding their proceedings and, as a consequence, misled Member States and others involved in the protection of child health; (ii) failed to consult with others regarding the content of notes for the files of certain “off the record” meetings; (iii) misrepresented the complainant’s views; (iv) failed to take into account Member States’ concerns about the need to protect public health in discussions concerning Directive 2006/141 within the SCoFAH; and (v) failed to follow the advice of SCF in certain areas covered by Directive 2006/141.

³⁹ “This Regulation should establish, among others, definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control, taking into account relevant provisions in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC and Commission Directive 1996/8/EC. (17) It is important that ingredients used in the manufacture of the categories of food covered by this Regulation are appropriate to satisfy the nutritional requirements of, and are suitable for the persons to whom they are intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

⁴⁰ http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm

⁴¹ On 14 June 2012, the European Parliament adopted its first reading position. The text adopted:

<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-255>

On 7 June, the Council of the European Union agreed its ‘general approach’, to give a mandate to the EU Presidency to negotiate with the European Parliament: <http://register.consilium.europa.eu/pdf/en/12/st10/st10086.en12.pdf>

During the first Parliamentary Reading on 14th June, there were many important amendments proposed, including two key ones by the Socialists and Greens. These called for EU legislation to specifically state that Member States are free to go further and ban the advertising of follow formula and baby foods. These amendments provoked the most debate with much support from the majority of speakers. While gaining strong backing, they were not passed. While **Commissioner Dalli**, did express willingness to look at an extension of advertising prohibitions to follow-on milks he said the amendment calling for the same for baby foods would affect the internal market too much. ⁴²

During the Triologue meetings the EU Commission is likely to insist on maintaining its control of the formation and application of the legislation, aware that this will be tempered by the new co-decision process. Parliament will insist on greater oversight. The Commission will be reluctant to accept other MEP amendments, including the reference to Precautionary Principle, which the Commission argues is already embedded in EU policy.

The new rules should toughen up the safeguards regarding ingredients including establishing a Union List of vitamins, minerals and other substances, however it is unclear whether this will mean mandatory pre-authorisation of all novel and existing ingredients, whether optional ingredients will still be permitted and if so who will approve them, and whether the evaluations for safety and efficacy will require independently funded research and independent systematic reviews of the totality of research.

The Commission wants to maintain control

Para 19 on Page 11 of the Council Opinion ⁴³ gives an indication of the level of control that the Commission would like and that the stimulation of innovation (growth of trade in new products) is its main concern:

*“Furthermore, in order to enable consumers to benefit rapidly from technical and scientific progress, especially in relation to innovative products, and **thus to stimulate innovation**, the power to adopt acts in accordance with Article 290 TFEU **should also be delegated to the Commission** for the purpose of a regular update of the requirements applying to infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, food for special medical purposes and total diet replacement for weight control, taking into account all relevant data, including data provided by interested parties. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, **should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.**”*

Once more, breastfeeding, the undisputed safest way to feed all infants, will have to compete with these highly profitable ‘innovative’ products, *“resulting from scientific and technological progress – the fruits of industry research.”*

⁴² **MEPs warn of sweet baby milks and call for stricter marketing rules** Baby Milk Action press release <http://info.babymilkaction.org/pressrelease/pressrelease15jun12>

Compromise Amendment by **Carl Schlyter**, on behalf of the Greens: “Advertising of infant formulae, follow-on formulae and of any other kind of food intended for infants or young children shall be prohibited. This includes advertisements in publications, point-of-sale advertising, giving samples or any other promotional device to induce sales directly to the consumer.”

⁴³ <http://register.consilium.europa.eu/pdf/en/12/st10/st10086.en12.pdf>

The European Parliament's agreed position ⁴⁴

The amendments adopted in the June 2011 Plenary vote addresses some – not all - of Baby Milk Action's concerns. MEPs are calling for:

- The safety of foods is stressed before the free movement of goods (Amendment 2)
 - The precautionary principle (amendments 9, 10 and 53)
 - Stricter safeguards on contaminants and pesticides in baby foods than on other foods (Amendments 15, 17, 62 and 63)
 - Slightly stricter controls on claims “ The labelling, presentation and advertising of food referred to in Article 1(1) shall be accurate, clear and easy to understand for consumers and must not be misleading. It shall not attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties.” (Amendment 58 -This could mean the end of the allergy claim)
 - Stricter controls on the labeling of follow-on milks – no baby pictures:
 - *“The labelling of infant formula and follow-on formula shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. Graphic representations for easy identification of the product and for illustrating methods of preparation shall, however, be permitted. Directive 2006/141/EC shall be amended accordingly.”(Amendment 59)*
 - *“The dissemination of any useful information or recommendations with reference to the categories of food referred to in points (a), (b), (c) and (ca) of Article 1 (1) may be made exclusively to persons having qualifications in medicine, nutrition or pharmacy. Additional information disseminated by healthcare professionals to the final consumer shall only be of a scientific and factual nature and shall not contain advertising.”*
 - More transparency (Amendment 76);
 - More oversight from the European Parliament and EFSA,
 - Post market surveillance (Amendments 54 and 68);
 - Controls on exports;
 - Caution on Nano technology;
 - EFSA review of formulas for older babies before deciding what to do (amendment 81)
 - Clearly defined Union List of vitamins, minerals and other substances (this is not the same as pre-authorisation of ingredients) Amendment 37.
 - Slightly stricter controls on evaluating new ingredients (Amendment 14, 57 and 88 - do not require independently funded evidence – referring the ‘generally accepted’ or independent reviews and independently evaluated science and medical opinion.)
 - *prohibition of the term “specialized nutrition’* (amendment 56) Amendments 30 and 31 ease the way for SMEs.
-
- **In addition to the above amendments**, which are for the most part welcome, one bad Amendment (no 13) was adopted on formulas for LBW babies. See section 8
 - **Amendment 91** allows the Commission freedom to authorize new foods “*resulting from scientific and technological progress – the fruits of industry research*” - on the market temporarily pending amendment of the delegated acts – but only after EFSA has been consulted.

⁴⁴ <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-255>

5 Optional Ingredients

“We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupported. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods.” The UK Government’s Scientific Advisory Committee on Nutrition (SACN) 2007 ⁴⁵

The UK Regulations state:

4. *No person shall market or otherwise represent a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula.*⁴⁶

The EU Directive requires that

“Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants” and that all products must contain the essential ingredients specified in annex I of the EU Directive.

Annexes to the law set out terms for the essential compositional requirements for infant formula and follow-on formula, which may be marketed for use from 6 months of age. Manufacturers are allowed to add other ingredients to both infant formulas and follow-on formulas on an optional basis as they see fit

“provided their suitability ‘for particular nutritional use by infants from birth has been established by generally accepted scientific data and demonstrated in accordance with paragraph (2)’ and that (2) Suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies”.

Some of these optional ingredients are specified in the legislation – others are not. When placing a new infant formula on the market, manufacturers must *“notify the competent authority”* in the particular country by forwarding a model of the label. They should also be ready to produce the required evidence, however Member States are not obligated to ask for this. There is no requirement for Manufacturers to notify follow-on formulas.

With no pre-market authorisation of ingredients, nor any requirement for efficacy or safety to be proven by independently-funded studies, manufacturers can add or withhold any ingredient they choose in order to gain competitive advantage. In effect European babies have been subjected to a mass uncontrolled trial. The commercial pressure to add ingredients to formulas and to contravene the International by promoting products as closer to breastmilk - the recognised ‘gold standard’ - is evident.

A new infant formula launched by Hipp in June 2012, uses claims not listed in Annex IV of the Infant Formula and Follow-on Formula Regulations (so contravening regulation 21). Hipp claims that its *“unique organic formula combines friendly bacteria with other important*

⁴⁵ http://www.sacn.gov.uk/pdfs/position_statement_2007_09_24.pdf

⁴⁶ The Infant Formula and Follow-on Formula (England) Regulations 2007, Section 4 Prohibition on the marketing of products other than infant formula for normal healthy infants
http://www.legislation.gov.uk/uksi/2007/3521/pdfs/uksi_20073521_en.pdf

*ingredients like LCPs and prebiotic oligosaccharides – we call it Combiotic.”*⁴⁷ For more examples see monitoring reports sent separately.

In 1996, Investment advisors Hambrecht & Quest famously advised investing in Martek, manufacturer of an LCP supplement called Formulaid on the grounds: *“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. 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.*

Currently all non-organic standard infant formulas on the UK market contain nucleotides, Long Chain Polyunsaturated Fatty Acids (LCPs, specifically DHA and AA) and structured tryglycerides even though there is no proven benefit. Oligosaccharides are added to some formulas

6 History of safe use

The *European Society of Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN)* made comments in the conclusion of the Codex International Expert Group report on the composition of infant formulae questioning the industry’s use of the term ‘history of safe use’.⁴⁸ ESPGHAN, a body that takes funding from the baby food industry and often supports its position, in this instance usefully pointed out that problems with infant formulas are not always disclosed, and one should certainly not assume that evidence from industry sponsored consumer phone lines constitute a ‘*history of safe use.*’

“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....”

⁴⁷ hipp4hcps.co.uk

⁴⁸ ESPGHAN Comments on the Circular Letter CL 2005/53-NFSDU and on the Synopsis of comments received until 30.4.05 (prepared by Germany) *“The question arises whether the ranges of nutrient levels in infant formulae that are reported by ISDI, without documented occurrence of side effects, suffice to establish a “history of safe use”, or even of adequacy of such nutrient levels for infant formulae. ISDI suggests that a history of apparently safe use of products might be based on the use of commercially produced infant formula and the monitoring of spontaneous consumer reports of observations that may indicate a problem with a specific batch of formula. In some areas, such as Europe, Israel and the USA, there are consumer phone line services have been established where parents may call in, usually free of charge, to place questions or complaints to the manufacturer or distributor of an infant formula. ISDI explains that such customer reports are monitored and should provide a tool for post-marketing surveillance of infant formula safety. Based on the evaluation of these consumer phone line services and the absence of detected serious side effects, ISDI implies that a history of safe use has been established for the nutrient levels reported in their compilation. 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.”*

7 Health and nutrition Claims – key points

- The UK Regulations currently permit the following for infant formulas:
 - *six nutrition claims (Lactose only, Lactose free, added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid, Taurine, fructo-oligosaccharides and galacto-oligosaccharides, nucleotide)*
 - *one disease risk reduction claim (Reduction of risk to allergy to milk proteins).*⁴⁹
- Claims for follow-on formula, formulas and foods for older babies must be first be authorised according the EU Nutrition and Health Claims legislation.⁵⁰
- To date, although several claims for children’s foods and foods for pregnant women have been authorised, only one health claim for follow-on formulas has been permitted: *“Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age.”*⁵¹
- Although the infant formula regulations do not permit a DHA ‘health’ claim on infant formulas, they do allow a ‘nutrition’ claim. Because products share the same branding and similar packaging, ‘health’ claim messages on products for older infants and young children are transferred.
- Parents assume that claims and ingredients undergo strict evaluation.
- The packaging and information materials idealise the products in other ways, in addition to health and nutrition claims. For example claims that the product is good for ‘hungry babies’ or may make babies sleep better. Images of hearts, shields, encircling arms etc also signify care, love and safety.
- The EU Commission has clarified that a brand name or trademark cannot be an implied health or nutrition claim unless that claim is legally permitted.⁵²
- The EU Commission has clarified that ‘Prebiotic’ and ‘Probiotic’ claims are health claims so are not permitted on infant formulas.⁵³
- Formulas for Special Medical Purposes are covered by separate more lax legislation which permits a description that could imply a health claim.⁵⁴ There is ongoing discussion about this. (See also Section 9).

Infant formula trademark that could be construed as a health claim One delegate asked whether it was permissible for an infant formula to bear a trademark that could be construed as a health claim. MS were reminded that this was discussed at Standing Committee in June 2009 when the conclusion was that, in the case of infant formula, a trademark constituting a nutrition or health claim may only be used where it is accompanied by a specific claim listed in annex IV to Directive 2006/141/EC⁵⁵

⁴⁹ *The Infant Formula and Follow-on Formula (England) Regulations 2007.*

⁵⁰ *Regulation (Ec) No 1924/2006 Of The European Parliament And Of The Council of 20 December 2006 on nutrition and health claims made on foods*

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF>

⁵¹ <http://ec.europa.eu/nuhclaims/>

⁵² “Infant formula trademark that could be construed as a health claim *One delegate asked whether it was permissible for an infant formula to bear a trademark that could be construed as a health claim. MS were reminded that this was discussed at Standing Committee in June 2009 when the conclusion was that, in the case of infant formula, a trademark constituting a nutrition or health claim may only be used where it is accompanied by a specific claim listed in annex IV to Directive 2006/141/EC.* Summary Report of The Standing Committee on the Food Chain and Animal Health (SCoFCaH), 22 June 2011

⁵³ Letter from Basil Mathioudakis, European Commission to Mark Toal, UK FSA, 4.10.2007: *“The use of the claim “contains prebiotics”, as you correctly mentioned in your letter, is a claim describing a function and therefore has to be considered as a health claim which is currently not foreseen in Directive 2006/141/EC and consequently is not permitted for use for infant formula.”*

⁵⁴ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.

⁵⁵ Taken from DH Update from the European Commission’s Working Group meeting on nutrition and health claims, 18 June and informal meeting about flexibility

The majority if not all the studies that show benefits of the optional ingredients commonly used in formulas are conducted or funded by baby food companies. While the potential for bias is present in all research, and ‘independence’ from commercial interest does not ensure quality, misleading findings and unintended consequences are reduced if research is commissioned and funded by a disinterested party rather than one active in the market and when academic rigor can be demonstrated in the research process. Problems are compounded by publication bias where trials with negative outcomes are less likely to be published. Infant feeding studies are often considered ‘proprietary’ and many are not published in peer reviewed journals.

7.1 The DHA claim

In 2009 the European Food Safety Authority (EFSA) gave a positive opinion on a DHA health claim for visual acuity. EFSA stated that it could not have reached its conclusion “*without considering the studies claimed by the applicant as proprietary.*”⁵⁶ In this case the research was eventually published.

Despite the absence of consistent peer-reviewed independent evidence of a causal relationship between DHA-fortified formulas and better visual acuity in term babies, and in conflict with of many leading health bodies, the DHA claim was approved and can now be used on all EU baby formulas and foods.^{57, 58}

In April 2011 the European Parliament voted against the DHA health claim - but not by a large enough majority to stop the Commission authorising it.⁵⁹

7.2 Assessing the risk of the DHA claim

EU Health Claims regulations require EFSA to assess only the ‘efficacy’ of the claim not the risk. The risk is considered by the Commission and SCoFCAH. However, on 25th March 2011, 10 days before the European Parliament was to vote on the DHA claim, EFSA’s Director of Risk Assessment, Riitta Maijala, stepped into the debate by writing to the Commission, saying “*We are unaware of any factor in breast milk which is needed for DHA to exert its “optimal” effect.*”⁶⁰

IBFAN takes a different view. Synthesised DHA added to formulas are in a different biological environment to breastmilk, which is a species-specific, living substance. Formula contains no co-enzymes or co-factors to enable the fats to work optimally as they do in breastmilk. Indeed the

of wording of health claims, 19 June

⁵⁶ EFSA published three opinions on DHA and ARA in January and March 2009:

www.efsa.europa.eu/en/efsajournal/doc/941.pdf www.efsa.europa.eu/en/efsajournal/doc/1003.pdf

www.efsa.europa.eu/en/efsajournal/doc/1004.pdf

⁵⁷ “*WHO does not have a recommendation about the addition of docosahexaenoic acid (DHA) to formula milk.....to date no solid evidence exists to be able to say that adding DHA to infant formula will have important clinical benefits. Were WHO to give such a recommendation, it would have to follow a strict guideline development process based on grading of all available evidence collected through systematic reviews by expert panels free from conflict of interest.*” WHO to Glenis Willmott MEP 6.4.11: http://info.babymilkaction.org/sites/info.babymilkaction.org/files/WHO%20DHA_0.PDF The 2007 Cochrane Library concluded: “*This review found that feeding term infants with milk formula enriched with LCPUFA had no proven benefit regarding vision, cognition or physical growth.*”

⁵⁸ EFSA to EU Commission 3.9.09. In a letter to the European Commission in September 2009, EFSA said: “*The evidence, however, does not establish that starting DHA supplementation at 4-6 months in infants who had received a control (DHA-free) formula in the first months of life would have an effect on the visual development of those children... There are no data from specific randomised control trials supporting a benefit of DHA supplementation starting at 6 months of life in infants fed a DHA-free formula in the first 6 months of life....*”

⁵⁹ *European Parliament votes to block DHA health claim - but not by a large enough majority to guarantee action by the Commission* <http://info.babymilkaction.org/pressrelease/pressrelease06apr11>

⁶⁰ [Riitta Maijala to Eric Pondelet](http://info.babymilkaction.org/pressrelease/pressrelease06apr11), EU Commission. 25.3.11

US FDA, commented to Martek (the DHA manufacturer) in 2001: “The bioactive fatty acids ARA and DHA when consumed in mature human milk are part of a complex matrix that includes, for example, linoleic acid, alpha-linolenic acid, and other polyunsaturated fatty acids ...important physiologic considerations relative to the matrix are not accounted for by the simple addition of LCPUFAs to infant formula.”⁶¹

The Cornucopia Institute in Wisconsin, has followed the DHA issue carefully for many years. It used US Freedom of Information legislation to obtain information on concerns registered with the Food and Drug Administration (FDA) about adverse reactions to DHA/ARA-supplemented formulae. The FDA questioned the adequacy of information to determine safety and efficacy of the clinical trials required for pre-market approval of these LCPs. Cornucopia and the National Alliance for Breastfeeding Advocacy (NABA) petitioned the FDA for labels to warn of the possibility of an adverse reaction to DHA/ARA-supplemented formula.⁶²

The sources of LCPs in Cow & Gate and Aptamil products are vegetable and fish oils, whilst the sources of LCPs in SMA products are fungal and algal oils. The use of fish oils means that many milks are not suitable for vegetarians. Hipp Organic is the most recent company to have added LCPs to their products. A representative of the company told us that clinical trials using their product are currently underway in Europe. The decision to market the product in advance of clinical trials was based on a history of safe usage of LCPs, at the same level, in infant milks produced by other manufacturers. The source of LCPs in Hipp powdered formula milk is fish oils, whilst LCPs in the ready-to-feed formula are algal. Supplementation of formula with LCP can increase the retail price by 5%-25% and single cell oils produced by micro-organisms are likely to be the oils of choice commercially in future (Chávez-Servín et al, 2008). There are therefore considerable cost implications for welfare food schemes and families if these fats are considered essential ingredients in all infant formula.

For a full analysis see Infant Milks in the UK - A practical guide for health professionals, May 2012. First Steps Nutrition Trust).

Possible research question:

Do parents who want to breastfeed and fail choose a product that they think is closer to breastmilk and are they likely to go on using these products much longer?

⁶¹ FDA Agency Response Letter GRAS Notice No. GRN 000041 CFSAN/Office of Premarket Approval <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm154126.htm>

⁶² *Replacing Mother, Imitating Human Breast Milk in the Laboratory* (Jan 08) www.cornucopia.org

8 Formulas for LBW infants

WHO on Feeding of low-birth-weight infants⁶³

WHO recommends that low-birth-weight (LBW) infants, including those with very low birth weight (VLBW), should be fed mother's own milk. If these infants cannot be fed mother's own milk, they should be fed donor human milk (in settings where safe and affordable milk banking facilities are available or can be set up) or standard infant formula. Very-low-birth-weight infants who cannot be fed mother's own milk or donor human milk should be given preterm infant formula if they fail to gain weight despite adequate feeding with standard infant formula. Low-birth-weight infants who are able to breastfeed should be put to the breast as soon as possible after birth when they are clinically stable, and should be exclusively breastfed until six months of age. Low-birth-weight infants who need to be fed by an alternative oral feeding method should be fed by cup or spoon and should be fed based on the infants' hunger cues, except when the infant remains asleep beyond three hours of the last feed. Implementation of these recommendations will help to reduce mortality and severe morbidity among these infants while helping in their growth and neurodevelopment.

Formulas for low-birth weight infants are currently marketed in line with Directive 1999/21/EC on foods for special medical purposes (FSMP) rather than the more stringent Directive 2006/141/EC on infant formulae and follow-on formulae. (see Section 10)

Although some breastfed infants require supplements of vitamins and minerals, occasionally protein, in order to thrive, the need for LBW formulas is very limited. Supplements can be administered within the definition of "exclusive breastfeeding" if medically indicated for the very small proportion of preterm and low birth weight babies (1% of UK births <1500g)

Of the 7% of LBW infants >1500g - almost all thrive very well when fed exclusively on breast milk. Indeed the protection of breastfeeding in this vulnerable group is particularly important. Randomised trials show that infants who are not breastfed are at approximately 5 times greater risk of a condition called necrotising enterocolitis. This has a mortality of approximately 20% and a significant long-term morbidity. The global consequences for the whole population of low birth weight infants in third countries are even more serious. As with formulas for special medical purposes, it is in the manufacturers interest to have numerous categories of products under the Medical Foods Directive umbrella – especially if they all share brand names and packaging.

During the Parliament's First reading in June 2012 the last minute proposal put forward by UK MEP Julie Girling was adopted. This distorted WHO's position on LBW formulas saying: "*Nonetheless, low birth-weight infants and pre-term infants often have special nutritional requirements which cannot be met by mother's own milk or standard infant formula*".

Thankfully, the general approach agreed by the Permanent Representatives and the Council has slightly better text: (16a) The nutritional requirements of low birth weight and/or preterm infants depend on the medical condition of the infant, in particular on his weight in comparison with that of an infant in good health, and on the number of weeks the infant is premature. It is to be decided on a case by case basis whether the infant's condition requires the consumption under medical supervision of a formula adapted for the dietary management of his specific condition.

⁶³ http://www.who.int/elena/titles/supplementary_feeding/en/index.html

9 Foods for Special Medical Purposes

The majority of the world's sick babies urgently require breastfeeding for survival. All babies, and especially sick babies, need the protection of the *International Code* and subsequent WHA Resolutions.⁶⁴

In 1999, despite the concern of over 900 NGOs, the European Commission pushed through the adoption of a Directive on Medical Foods (1999/21/EC) (FSMP Directive) – at the same time as the entire [Santer Commission](#) was forced to resign by the Parliament as result of fraud and corruption scandal. This the first time a Commission had been forced to resign *en masse* and represented a shift of power towards the Parliament.^[24] In response to the scandal the [European Anti-fraud Office](#) (OLAF) was created.

The FSMP Directive contained none of the safeguards of the *International Code* and WHA Resolutions and opened the door to widespread abuse. The only safeguard is a requirement that the label states that the product must be used under medical supervision. (See section 3.5 for the impact of this Directive on Codex.)

Since 2000 the market for 'specialised formulas', of no proven value has grown with formulas claiming to 'cure' or 'solve' all manner of normal feeding occurrences such as regurgitation and slow growth. The Directive does not curtail advertising or promotional strategies such as free and low-cost samples and supplies, promotional 'educational' literature for parents or health claims.⁶⁵

The baby food industry claims that the mandatory breastfeeding statement is inappropriate for many products and that it would "*undermine the confidence of parents in the special diet necessary for their infant.*" IBFAN contest this saying that the only products for which the '*breastfeeding is best*' statement may appropriate, are the formulas for the less than 1000 babies where breastfeeding is totally contraindicated, such as formulas for babies with Maple Syrup Disease (0.0005% of 129 million).⁶⁶

As more countries are clamping down on follow-on milk advertising, companies are building new markets for formulas for 1-5 year—olds. EU policy makers are in a quandry - aware that this is a marketing scam and that there is no evidence that fortified formulas for older babies are needed, but unable or perhaps unwilling to ban them. Young children need to eat real foods ideally alongside continued breastfeeding. Infant formula can go on being used after 6 months.

⁶⁴ The number of infants with autosomal, recessive, genetically-transferred metabolic disorders that need full or partial feeding with specialised formulas is extremely small Even though the conditions are under-reported because screening for/and diagnosis of these very specialised conditions is not universally accessible, the total global number is probably less than 25,000 babies. In Germany, where screening for such conditions is more common,⁶⁴ the incidence of **PKU** 1 in 10,000⁶⁴, **Galactosaemia** 1 in 35,000 and **Maple Syrup Urine Disease** 1 in 200,000. Extrapolating from these figures to the whole world, it is likely that **18,428** babies are born with PKU, **3,685** with Galactosaemia and **645** with Maple Syrup Disease – a total of **22,758** each year. There may be other even rarer conditions where breastfeeding could be contraindicated.

⁶⁵ The Medical Food Directive allows implied health claims and disease risk reduction claims:4. *The labelling shall also include:(a) the statement "For the dietary management of..." where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended.(c) a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;*

⁶⁶ Galactosaemic babies who cannot tolerate breastmilk are usually fed on lactose-free formulas. These formulas normally carry a '*breastfeeding is best*' notice because they are used by vegans and others avoiding dairy products. Other conditions such as **PKU require** formulas formula without *phenylalanine* but these infants benefit from the addition of partial, carefully managed breastfeeding, so the '*breastfeeding is best*' statement would not cause a problem.

The new formulas invariably share brands and logos with infant formulas, so promote the whole range. They are also expensive and with high levels of sugar, increase the risk of obesity. But the alluring claims trigger fears in parents that real foods miss essential nutrients.

Summary Report of the Standing Committee on the Food Chain and Animal Health 22 June 2012.

Exchange of views of the Committee on the interaction between Directive 1999/21/EC on foods for special medical purposes and Directive 2006/141/EC on infant formulae and follow-on formulae

Ireland calls for confirmation that 'special' formulas currently covered by the Medical Foods Directive will not be covered by the Directive for standard formulas. France called for confirmation that they would be.

In the exchange the Commission acknowledged that the market has 'evolved' since the FSMP Directive was passed and that industry is now exploiting its loopholes. The Commission's excuse for inaction in 1999 was that: "*labelling, advertising and promotional restrictions, as those applicable to infant formula, were not considered appropriate at the time*"

"It has to be admitted that the market situation has evolved since. Differing interpretation and enforcement of the definition of FSMPs by national authorities has contributed to a proliferation of these products in the market (the examples of products based on rice protein, not allowed for infant and follow-on formula, and of some anti-regurgitation products were mentioned). This in turn led to the use of wider and often similar distribution channels as those for infant formula and inevitably to labelling, advertising and marketing practices that were taking advantage of the absence of relevant rules for these products. The Commission stressed the important role of the competent authorities in verifying the compliance of the products presented as FSMP with the relevant definition as laid down in Article 1 of Directive 1999/21/EC in order to avoid any abuse of the legislation. On the basis of the discussion, and taking into consideration the letter of the law and the intention of the legislator when those measures were adopted, the Committee concluded the following:

Foods for special medical purposes intended specifically for infants, covered by the definition of Article 1 of Directive 1999/21/EC, are specific products and are distinct from infant formulae and follow-on formula. Therefore, foods for special medical purposes intended specifically for infants do not fall under the scope of Directive 2006/141/EC and are not subject to the provisions of that Directive except when specifically mentioned in Directive 1999/21/EC (see point 4 of the Annex of Directive 1999/21/EC).

Specific labelling requirements have been laid down in Directive 1999/21/EC taking into account the specificity of the product covered by that Directive (e.g. the medical conditions for which the product is intended, the mandatory statement on the label that the product must be used under medical supervision etc.). It is therefore not appropriate to apply the same labelling and advertising provisions as established in Directive 2006/141/EC to those products.

However, the Committee took note of the evolution in the market and considered that in the of the revision of the framework legislation on foods for particular nutritional uses and acts thereof, further consideration should be given to the inclusion of certain relevant specific provisions for FSMPs

10 Formulas for older babies – Growing up, toddler milks

- A report by the [German Federal Institute for Risk Assessment](#) (BfR) (16.08.2011) found that ‘toddler’ milk does not offer any advantage compared to reduced fat cow milk. *“From a nutritional and physiological point of view these special toddler milks are not necessary”,* says BfR President, Professor Dr. Andreas Hensel. *“The manufacturers of toddler milk drinks often refer to high consumption amounts on the packaging of their products. According to these recommended consumptions children would consume through children’s milk alone high amounts of macronutrients and micronutrients. Within the framework of the overall diet this would favour in the long-term an oversupply with all nutrients. From a nutritional physiological and health point of view this is problematic.”*
- The Italian Consumer Association **Altroconsumo** analysed these products and published a statement very similar to the German one in 2009.
- [A survey in 2010 by the Hong Kong Department of Health](#) (HKSAR) found that *“children who drank more milk (mainly formula milk) than the recommended volume generally consumed smaller amounts of grains, vegetables and fruits. Use of the bottle and parents’ misconceptions about the nutritional benefits of formula milk might have contributed to the high milk intake and the choice of milk.”*
- Prolonged Bottle Use and Obesity at 5.5 Years of Age in US Children, Gooze et al, J Pediatrics 2011, Sept; 159 (3):431-6
- A survey by the **German consumer centres** on the products being sold as “Kindermilch” (“milk for children”) targeting the age from 12 months found that Kindermilch was up to four times more expensive than normal milk, costing parents up to 245 euros more each year.⁶⁷
- For more information see *Infant Milks in the UK* which has a wealth of information about infant milks in the UK including on Page 61 (Table 17) a chart showing the amount of sugar in Growing Up milks.⁶⁸

11 EFSA and WHA recommendations on exclusive breastfeeding

Baby Milk Action issued a critique of an EFSA Working Group on Complementary Feeding report published in December 2009.⁶⁹ We considered illogical and contradictory for several reasons, including that it over-emphasised Coeliac Disease and undermined existing effective public health recommendations. Several Working Group members had unacceptable links to the infant feeding industry and some were co-authors of an ESPGHAN paper on Complementary Feeding which reintroduced the concept of complementary feeding from 4-6 months (rather than from 6 months which is WHO/Codex policy and already in place in the UK and many EU countries). There is no evidence that the present six-month recommendation is harmful. The UK National Infant Feeding Survey 2005 indicates that the policy has had a good impact so far, delaying the introduction of solids. See also the Lucas issue.⁷⁰

⁶⁷ <http://www.vzhh.de/ernaehrung/129727/kostenfalle-kindermilch.aspx>

⁶⁸ http://www.firststepsnutrition.org/children/eating-well_first-six-months.html

⁶⁹ <http://www.babymilkaction.org/press/press23dec09.html>

⁷⁰ <http://info.babymilkaction.org/news/policyblog140111>

12 Contaminants, BPA, Pathogens, Pesticides

For more information see IBFAN briefings on contaminants in baby foods.⁷¹

12.1. Pesticides

The Greens in Parliament are calling for stricter safeguards on pesticides for baby foods. The Commission disagreed saying that the safety standards for ordinary foods are sufficiently stringent.⁷²

The Commission says:

(17) It is important that ingredients used in the manufacture of the categories of food covered by this Regulation are appropriate to satisfy the nutritional requirements of, and are suitable for the persons to whom they are intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

(17a) The use of pesticides in products of plant and animal origin intended for infants and young children should be restricted as far as possible. A prohibition of their use in the production of such products would not necessarily guarantee that they are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned. Therefore, the maximum residues levels in the products concerned should be set at the lowest achievable level consistent with good agricultural practices for each pesticide with a view to protect those vulnerable groups of the population.

(17b) Limitations or bans of certain pesticides equivalent to those currently established by the annexes to the Directives 2006/141/EC and 2006/125/EC should be taken into account in delegated acts. Those limitations or bans should be updated regularly, with particular attention to be paid to pesticides containing active substances, safeners or synergists classified in accordance with Regulation (EC) 'o 1272/2008 as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, considered to have endocrine disrupting properties that may cause adverse effects in humans.

12.2 SOYA

Concerns have been raised over the potential allergenic effect of soy protein based milks in infants at high risk of atopy and over the effects that the phyto-oestrogens present in soy protein based milks might have on future reproductive health. The Chief Medical Officer has recommended that soy protein based milks should not be used for infants under 6 months of age who have cows' milk protein allergy or intolerance. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) concluded that the high levels of phyto-oestrogens present in soy protein based milks posed a potential risk to the future reproductive health of infants (Committee on Toxicity, 2003). (For more see *Infant Milks in the UK*⁷³)

⁷¹ http://www.ibfan.org/fact-contaminants-reports_recall.html

⁷² <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-255>

⁷³ http://www.firststepsnutrition.org/pdfs/FSNT_Infant_milks_WEB.pdf

12.3 Pathogens - **ENTEROBACTER SAKAZAKII** (now called *Cronobacter sakazakii*)

IBFAN has worked to raise awareness of inherent contamination of powdered infant formula since first being altered to the problem by the death of a Belgian baby in 2002. Since then the issue has been taken up by WHO, the World Health Assembly, Codex and numerous governments. A key issue is the independence of the scientific evidence.

Nestlé's *Baby Nes* bottle preparation machine, launched in Switzerland in 2011,⁷⁴ is now entering the EU⁷⁵ contravening WHO, UK and EU safety recommendations. It is being marketed as the State of the Art technology - while encouraging unsafe practices. Nestlé offers a 24-hour after sales service - assuring Nestlé contact with mothers - something that is totally forbidden by the World Health Assembly requirements. We have asked the Commission to offer guidance to Member States before this spreads further. There are no EU wide marketing rules for bottles and teats.

- INFOSAN Information Note No. 3/2008 - Food Safety and Nutrition During Pregnancy and Infant Feeding Food Safety and Nutrition During Pregnancy and Infant Feeding WHO Infosan Note 2008 <http://www.ibfan.org/art/85-21.pdf>
- Product recall List: http://www.ibfan.org/art/recalls_2010-2012-feb.pdf
- Examples of information on Food Safety and Pregnancy issued by national authorities
- *Revised guidance on powdered infant formula* Friday 1 December 2006 United Kingdom Food Standards Authority:
<http://www.eatwell.gov.uk/asksam/agesandstages/pregnancy/>
<http://www.food.gov.uk/news/newsarchive/2006/dec/infantform>
- The Department of Health and Food Standards Agency originally issued advice on preparing infant formula in November 2005 following an opinion from the European Food Safety Authority's Scientific Panel on Biological Hazards on the microbiological risks of infant and follow-on formulas. This advice was revised in February 2006 to mention liquid ready-to-feed formula.
- *EFSA Panel advises on how to avoid microbiological risks in infant formulae, at home and in hospital* <http://www.efsa.europa.eu/fr/press/news/biohaz041118.htm>
- Opinion of the Scientific Panel on biological hazards (BIOHAZ) related to the microbiological risks in infant formulae and follow-on formulae₁
- *Food Safety Authority of Ireland:*
http://www.fsai.ie/publications/guidance_notes/gn22.pdf,
http://www.fsai.ie/publications/factsheet/factsheet_enterobacter_sakazakii.pdf
- *Food Standards Australia New Zealand:*
<http://www.foodstandards.gov.au/foodmatters/pregnancyandfood.cfm>
- *New Zealand Food Safety Authority:* <http://www.nzfsa.govt.nz/consumers/low-immunity-child-pregnancy/pregnancy-food-safety/>
- *United States Food and Drug Administration:*
<http://www.cfsan.fda.gov/~pregnant/pregnant.html>
- *Swedish National Food Administration:*
http://www.slv.se/templates/SLV_Page.aspx?id=15787&epslanguage=EN-GB
- *New South Wales Food Authority (Australia):*
<http://www.foodauthority.nsw.gov.au/consumer/pregnancy.asp>

⁷⁴ <http://info.babymilkaction.org/sites/info.babymilkaction.org/files/NesBaby%20PR.pdf>

⁷⁵ Link to the BabyNes launch in France: <http://fr.finance.yahoo.com/actualites/babynes-nespresso-biberons-arrive-france-085700962--finance.html>

Update 44 summary following testing of the BabyNes powder capsules
<http://info.babymilkaction.org/update/update44page23>

12.4 Codex Food Hygiene Provisions

15. The Committee recalled that in the Standard for Infant Formula and Formulas for Special Medical

Purposes Intended for Infants and the Standard for Follow-up Formula (CODEX STAN 156-1987), reference was made to the Code of Hygienic Practice for Powdered Formulae for Infants and Young

Children (CAC/RCP 66 - 2008), which superseded the Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979) and considered how to update the reference to the superseded code in other texts. The Committee agreed to proceed as follows:

16. *Standard for Cereal-Based Foods for Infants and Young Children*: delete the reference to CAC/RCP 21-1979 and refer to the *General Principles of Food Hygiene*, which adequately cover the products concerned.
17. *Standard for Canned Baby Foods*: delete the reference to CAC/RCP 21-1979 refer to the *Code of*

Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979) and the Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods (CAC/RCP 40-1993)

18. *Guidelines for Formulated Supplementary Foods for Older Infants and Young Children*: revise the hygiene section while revising the Guidelines (see Agenda Item 6)

Issues not yet covered in this document:

Other contaminants and heavy metals, such as Aluminium, Melamine, Flouride, BPA.

Nano technology

13. UK formula marketing regulatory system analysis

13.1 Introduction

The *International Code of Marketing of Breastmilk Substitutes* was adopted under a Resolution of the World Health Assembly in 1981. The British Government supported the Code at the time and in adopting subsequent, relevant Resolutions. The Code and Resolutions are “*minimum requirements*” for all countries.

Article 11.3 of the Code states:

Independently of any other measures taken for implementation of this Code, manufacturers and distributors of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.

Unfortunately, manufacturers and distributors in the UK (as elsewhere) fail to respect this requirement unless compelled to do so through governments implementing and enforcing the Code and Resolutions in legislation. Governments have a responsibility under the Resolutions and the *Convention on the Rights of the Child* to implement and monitor the *International Code* and Resolutions.

The Committee on the Rights of the Child report on the UK in 2008 stated:

The Committee, while appreciating the progress made in recent years in the promotion and support of breastfeeding in the State party, is concerned that implementation of the International Code of Marketing of Breastmilk Substitutes continues to be inadequate and that aggressive promotion of breastmilk substitutes remains common. The Committee recommends that the State party implement fully the International Code of Marketing of Breastmilk Substitutes.

While companies systematically violate the Code and Resolutions and successive governments have failed to implement these measures, the narrower *European Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC* have been implemented as the *Infant Formula and Follow-on Formula Regulations (2007)* as equivalent texts in the four countries of the United Kingdom. At UK level, associated Guidance Notes have been adopted, which Parliament was told⁷⁶ show “*how the regulations should be interpreted*”

As well as calling on companies and retailers to respect the Code and Resolutions, the Regulations and the Guidance Notes, Baby Milk Action reports violations to the following regulatory bodies:

- The Food Standards Agency
- Advertising Standards Authority
- Trading Standards

Baby Milk Action’s experience shows that even the regulations that do exist are poorly enforced.

⁷⁶ Hansard:

<http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080116/halltext/80116h0005.htm>

13.2 The Food Standards Agency

In 2006, the Food Standards Agency wrote to baby food companies and the Trading Standards home authorities responsible for them pointing out that under the Infant Formula and Follow-on Formula Regulations (1995) (since updated, though not significantly strengthened) only the claims specified in Annex IV to the Regulations could be used on the labels of infant formula. Specifically the following terms, widely used, were not permitted:

- 'Now even closer to breast milk',
- 'Closer than ever to breastmilk',
- 'Prebiotics support natural defences',
- 'Helps brain and eye development'

This led to changes to labels, but other claims continued and continue to be used today.

The Guidance Notes for the current Regulations make it clear that the regulations prohibit infant formula labels including "any other picture or text which may idealise the use of the product, but may include graphic representations for easy identification of the product or for illustrating methods of preparation."

Claims continue to be used and idealising images such as shields, cuddly toys and hearts are commonplace. It would be welcome for the FSA or Department of Health to remind companies and Trading Standards of the requirements and call for all products with such labels to be removed from the market with immediate effect as they break the law.

The FSA or Department of Health could also play a useful role in acting on misleading claims about follow-on formula promotion, which suggests, for example, that follow-on formulas are necessary as a source of iron when a child is over 6 months old.

13.3 The Advertising Standards Authority

The Advertising Standards Authority (ASA) has upheld some of the complaints brought by Baby Milk Action and other organisations and members of the public regarding misleading claims.

However, the ASA refuses to investigate the majority of complaints reported. The ASA's own slogan suggests it ensures advertising is "*legal, decent, honest and truthful*". Yet, in practice it refuses to investigate complaints about formula advertising where the complaint cites:

- Violations of the provisions of the *Infant Formula and Follow-on Formula Regulations* (undermining the 'legal' aspect of the ASA's slogan),
- Violations of the provisions of the *International Code* and Resolutions, which companies are called on by the World Health Assembly to abide by (undermining the decent and honest' aspects of the slogan),
- Misleading advertising to health workers,
- Misleading information on websites.

For example, in a message to Baby Milk Action (30 March 2012) the ASA stated:

We will not be considering whether the ad breaches the Infant Formula and Follow-On Formula Regulations 2007, European Regulation (EC) No 1924/2006 on Nutrition and Health Claims made on Foods, the International Code on Marketing of Breast Milk Substitutes, Department of Health or WHO guidance. If they would like their complaints to be considered under those rules or legislation, they should contact the bodies which administer those rules or

legislation directly. The ASA is able to consider complaints about ads under the rules set out in the CAP Code only.

This refusal is troubling, not least because the CAP (Committee of Advertising Practice) Code, states:

“These rules must be read in conjunction with the relevant legislation including the Infant Formula and Follow-on Formula Regulations 2007 and the European Regulation (EC) No 1924/2006 nutrition and Health Claims made on Foods”.

With regard to websites the ASA has said (25 May 2012):

Please note that they will only be looking at the leaflet; the website content that you included in your email is not something that we can deal with. The lack of a common definition of what constitutes ‘advertising’ as far as the regulations and associated guidance means that this matter should be referred to the advertisers’ local Trading Standards department as the body responsible for enforcing FSA Guidance on the Infant Formula and Follow-on Formula Regulations 2007.

It is also a concern that in its response to complaints the ASA states that it may not investigate a complaint or forward a draft ruling to the ASA Council for approval at all if the company offers to change the advertising in a way that resolves the complaint. When advertising campaigns may involve national billboard, magazine and television advertising, a published ruling is too little, too late, but does at least put the fact the advertising was misleading on the record. If the ASA is prepared to accept an assurance from the company, there will not even be this record.

13.4 Trading Standards

In the past LACORS (Local Authorities Coordinators of Regulatory Services - the umbrella body for Trading Standards) formed a committee of the home authorities for the baby food manufacturers to coordinate regulatory action.

However, Baby Milk Action was informed by Local Government Regulation (the new name for LACORS) on 25 August 2010:

“Unfortunately due to reduced budgets, LG Regulation can no longer provide secretariat support for all the sector specific home authority groups such as the infant formula groups.”

Complaints now have to be sent via Consumers Direct (currently operated by Citizens Advice Bureau). The standard message received from this route generally states something along the lines of (received 13 March 2012):

the information you have provided will be passed to Cambridge Trading Standards for further consideration. The case details will also be placed on a central data base that can be accessed by all the other Trading Standards throughout the UK and the Office of Fair Trading. Trading Standards will only contact you if they need further information.

In only a few cases have Trading Standards made contact. These cases have related to violations in retail outlets, when our local Trading Standards office (Cambridge) has contacted us. However, Cambridge has informed us that we must always go through the Consumers Direct route to report cases.

Experience has shown that Trading Standards is reluctant to take legal action against companies, even when they repeatedly break the law. The only case ever taken to court was by Birmingham Trading Standards in 2003 (the court found that Wyeth had carried out a “*cynical and deliberate breach of the regulations*”).

For example, Tesco broke the provisions of the Regulations through idealising claims it made alongside formula in a catalogue. Tesco was neither prosecuted nor required to recall the catalogue. Tesco then broke the Regulations again in October 2011 by promoting infant formula with a national 'Big Price Drop' campaign. Tesco claimed this was a mistake and again was allowed to get away with simply apologising. Without any form of deterrence through imposition of fines the same cavalier attitude to the Regulations is likely to continue.

Trading Standards officers have also been dismissive of the Guidance Notes, which show how the Regulations should be interpreted.

For example, Trading Standards responded to Baby Milk Action regarding a complaint about a national advertising campaign (11 June 2012):

I can confirm that I have discussed this campaign with [the company]. I advised them of improvements that should be made to improve clarity in the future. It is a criminal offence to breach the regulations but not the guidance notes, and most of the issues breached the guidance notes. No further action is proposed to be taken by this authority regarding this campaign, although I am aware the ASA investigation is ongoing.

However, as noted above, the ASA refuses to investigate the legality of formula advertising and had already said to Baby Milk Action: "you may wish to contact Trading Standards to pursue this matter under the regulations".

In passing responsibility to each other, neither the ASA nor Trading Standards is taking effective action.

13.5 The Review of the Regulations and Guidance Notes

The previous government commissioned an Independent Review Panel (IRP) to review the operation of the *Infant Formula and Follow-on Formula Regulations (2007)* at a cost of £500,000.

The IRP's report acknowledged concerns raised by Trading Standards and other bodies over enforcing the measures and stated that there need to be "steps taken to address these."

LACORS, the umbrella body for Trading Standards, is cited as follows:

"One of the major problems for enforcement officers is the use of advertising and promotional material which blurs the distinction between follow-on formula and infant formula."

The terms of reference for the review were narrow, considering only the question of whether parents were confused between promotion for infant formula and follow-on formula.

The panel considered the risk of parents using follow-on formula from too early an age, commented: "any ban on the advertising of follow-on formula, is a decision for policy makers, who if sufficiently concerned could consider the precautionary principle."

No steps were taken following the review and the coalition government has not taken up this issue.

Promotion of follow-on formula is cross-promotional of infant formula, particularly as the provisions of the Guidance Notes are neither respected nor enforced:

"the specific terms 'infant formula' and 'follow-on formula' should be clearly featured on the packaging, in a font size no smaller than the brand name."

Advertising of follow-on formula appears to be on the increase. According to the World Health Assembly these products are "not necessary".

Further information on the shortcomings with the *Infant Formula and Follow-on Formula Regulations* can be found in the submission by the Baby Feeding Law Group to the government consultation on updating the *Infant Formula and Follow-on Formula Regulations (1995)*. BFLG

was convened by Baby Milk Action and consists of leading health professional bodies and mother support groups. Its recommendations were ignored in drafting the 2007 Regulations. For the submission and BFLG monitoring reports produced by Baby Milk Action (which were at one time quarterly when funding allowed) see:

<http://www.babymilkaction.org/shop/publications01.html#bflgreports>

Violations are now recorded in a more ad hoc manner on the BFLG website at:

<http://www.babyfeedinglawgroup.org.uk/reports/bflgreports>

13.6 Action against violations at international level

Although the *International Code of Marketing of Breastmilk Substitutes* was adopted as a minimum standard for all countries, there is no enforcement mechanism at international level when national governments have failed to implement it and the subsequent, relevant Resolutions of the World Health Assembly in legislation or fail to enforce the measures.

The World Health Organisation is called on by the Assembly to report on the state of implementation and produces reports in even years on government action. It relies on government submissions for these reports. It does not comment on company practices or censure companies in any way for systematically violating the Code and Resolutions.

The UN Committee on the Rights of the Child usually reports on the state of implementation of the Code and Resolutions in its five-yearly reports on the compliance of State Parties with the Convention on the Rights of the Child. The Committee accepts government and non-governmental organisation reports. In the case of the UK, the Committee has twice called on the UK Government to introduce legislation implementing the marketing requirements, which has not resulted in any action being taken. While the Committee does not comment on individual company practices, in its last report the Committee did comment that “*aggressive promotion of breastmilk substitutes remains common*” (full quote on page one).

In theory there is scope to bring complaints about violations of the Code and Resolutions under the *UN Global Compact* and the *OECD Guidelines for Multinational Enterprises*. However, Baby Milk Action has been pursuing cases against Nestlé malpractice around the world (not specifically the UK) and found both of these initiatives to be worse than useless.

The UN Global Compact is a voluntary corporate social responsibility initiative set up by Kofi Anan when Secretary General of the UN, jointly with the World Economic Forum. Baby Milk Action and a coalition of Nestlé Critics registered complaints of violations of the Global Compact Principles under so-called Integrity Measures. However, over the course of three years, the Global Compact has taken none of the actions set out in the Integrity Measures other than to forward Baby Milk Action’s letters to Nestlé, which had already received them directly. Full details of the complaints and subsequent developments are available via the Baby Milk Action website and the publication: “Nestlé’s UN Global Compact cover up”. See:

<http://www.babymilkaction.org/shop/publications01.html#globalcompact>

The *OECD Guidelines for Multinational Enterprises* are sometimes cited by policy makers as justification for not pursuing an international regulatory system for transnational corporations. Baby Milk Action registered complaints with the UK National Contact Point (NCP) for the Guidelines regarding Nestlé practices in 2009 as it was Nestlé (UK) generally responded to letters regarding violations. The UK NCP forwarded the complaints to the Swiss NCP as Switzerland is Nestlé’s home country. The Swiss NCP said its role was to “promote dialogue” to resolve concerns. As Nestlé denied violating the Code and Resolutions (and consequently the OECD Guidelines), Baby Milk Action suggested the Swiss NCP request from Nestlé examples of

its latest formula labels and marketing materials so these could be discussed with reference to the Code and Resolutions. The NCP refused to do so and closed the case.

Baby Milk Action was a member of the UN System Standing Committee on Nutrition Task Force on Global Obligations for the Right to food and contributed the chapter on holding corporations accountable to the resulting publication. This chapter made recommendations for an enforceable regulatory system at international level for when national measures fail. See:

<http://www.babymilkaction.org/shop/publications02.html#gorf>

Baby Milk Action Briefing on EU Legislation, August 2012

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.