

## Line by Line response to Food Standards Agency proposals for Regulations on Infant Formula and Follow-on Formula.

Prepared by Baby Milk Action, with support from the National Childbirth Trust and BFLG members.

The proposed Regulations are similar to the 1995 Regulations and the amending 1997 and 2003 Regulations except for the fact that some aspect of composition of products has been improved and advertising of infant formula is totally banned (the 1995 regulations allow advertising in the health care system). However new claims have been added and manufacturers are permitted to include new ingredients with no pre-market authorisation or listing in the regulations. The following recommended changes are in line with the position taken by the Baby Feeding Law Group, which it believes would lead to better information for parents making decisions about baby feeding, greater protection for breastfeeding and therefore a reduction in health inequalities for children in the UK.

<b>Draft Statutory Instrument arising from Commission Directive 2006/141/EC</b>	<b>BFLG suggested amendments in line with the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Resolutions</b>
<b>Title</b>	<b>Change to read:</b> Breastmilk Substitutes Regulations 2007
<b>Insert opening preambular paragraph</b>	<i>“The application and interpretation of these regulation <u>shall be in conformity with</u> the International Code of Marketing of Breast-Milk Substitutes and subsequent relevant World Health Assembly Resolutions and the Global Strategy for Infant and Young Child Feeding</i>
<b>Interpretation</b>  Definitions  Definitions are included for The Act, The Directive, Food Authority Health Care System	<p>The following Definitions should be made</p> <p><b>‘Designated products’</b>: means all are covered by the regulations even if their compositional requirements are not included – for example, complementary foods such as baby drinks and all foods which are promoted for babies and young children Bottles and teats which are included in the Scope of the International Code could be covered by this or separate legislation. This section can be updated as and when new products arrive on the market.</p> <p><b>“ Generally accepted”</b>: means having been subject to an independently funded systematic review which gives consideration to conflicts of interest and also requires a substantial proportion of independently funded research.</p> <p><b>“Systematic review”</b>: means a systematic review of all the available published or unpublished literature carried out by an independently-funded body.</p> <p><b>“Independent”</b>: means independent both from funding or other support from manufacturers and distributors of infant and young child feeding products.</p> <p><b>“Advertising”</b>: see response to RIA Page 12 – it is essential that this includes the label and packaging.</p> <p><b>“Presentation”</b>: see response to RIA page 22.</p> <p><b>“Idealise”</b>: means present in any way as ‘better than in reality’ or attempt to create an emotional response rather than providing factual information as provided for in the regulation. See Response to RIA Page 20</p> <p><i>The following definitions are taken from the International Code:</i></p> <p><b>“Healthy” means</b></p> <p><b>‘Health worker’</b>: means a person working in a component of such a health care system, whether professional or non-professional, including voluntary unpaid workers.</p> <p><b>"Breastmilk substitute"</b> means any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.</p>

	<p><b>"Complementary food"</b>: means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant.</p> <p><b>"Container"</b>: means any form of packaging of products for sale as a normal retail unit, including wrappers.</p> <p><b>"Distributor"</b>: means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.</p> <p><b>"Label"</b>: means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of any products within the scope of the Regulations.</p> <p><b>"Manufacturer"</b>: means a corporation or other entity in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code.</p> <p><b>"Marketing"</b>: means product promotion, distribution, selling, advertising, product public relations, and information services.</p> <p><b>"Marketing personnel"</b>: means any persons whose functions involve the marketing of a product or products coming within the scope of this Code.</p> <p><b>"Samples"</b>: means single or small quantities of a product provided without cost.</p> <p><b>"Supplies"</b>: means quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.</p>
Regulation 4	<p><b>Change "during the first months of life" to" during the first 6 months of life" and prohibit promotion of all designated products including specialised formulae.</b></p> <p>This is in line with the Global Strategy on Infant and Young Child Feeding which recommends that complementary feeding should not be started before 6 months.</p> <p>The BFLG has previously expressed concern that the marketing restrictions of the Directive apply only to foods for 'healthy infants' and there is no clear definition of the word 'healthy' The marketing of specialised foods for infants is covered in a separate Directive [xxx] and is much less strict . The marketing controls should be as strict if not stricter than for infant formula , whereas under the current and proposed Regulations, these products can be promoted and even sold at a reduced price. All babies, especially sick babies, need the protection of the International Code and Resolutions.</p>
<p><b>New ingredients and notification procedure.</b> Regulation 6 (1) <i>"Infant formulae shall be manufactured from protein sources defined in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data and</i></p>	<p><b>Change to:</b></p> <ul style="list-style-type: none"> <li>• <i>Infant formulae shall be manufactured from protein sources defined in point 2 of Annex I</i></li> <li>• <i>Optional ingredients should not be permitted in infant formulae and follow-on formulae.</i></li> <li>• <i>Prior to the introduction on the market, new ingredients should be required to go through a pre-authorisation procedure which includes an independent systematic review of all available evidence.</i></li> <li>• <i>Declarations of interests must be made for all research and the dossier must include a substantial proportion of independently-funded studies.</i></li> <li>• <i>If the ingredient is shown to be safe and essential with no</i></li> </ul>

<p><i>demonstrated in accordance with paragraph (2)</i>  <i>(2) Such suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.”</i></p> <p><b>Regulation 7</b> is the same as 6 but for Follow-on formula</p> <p><b>Regulation 13</b>  <i>“No food business operator may place an infant formula on the market that has not yet been placed on the market in the UK unless he has given prior notice to the Agency by forwarding to it a model of the label used for the product.”</i></p> <p>There is no notification for follow-on formula</p>	<p><i>unintended side effects and achieves its intended effect, taking into account the levels present in human milk as appropriate, it should be listed as an essential ingredient in EU Directive 2006/141.</i></p> <ul style="list-style-type: none"> <li><i>The Directive should be revised at regular intervals and only those ingredients listed in Annex 1 should be permitted.</i></li> </ul> <p><b>Optional ingredients</b> The BFLG has submitted numerous comments to the FSA and the European Commission during the consultation on the Directive 2006/141/EC outlining our concerns about the lack of harmonization of ingredients in the products covered and its promotion of optional ingredients with little evidence of their efficacy or long-term safety. This is not only risky, but encourages the use of claims and inevitably creates double standards. All infants who are artificially fed should be assured the safest and most nutritious substitute possible and if an ingredient is demonstrated by independent systematic review of independently funded-scientific research it would be unethical to withhold it for commercial reasons: it should be made a mandatory ingredient in all formulas of that category (notwithstanding the particular composition requirements of specialized formulas) See also pages 18,19 of BFLG response to the RIA)</p> <p><b>Notification procedure:</b> The BFLG has submitted concerns about the notification procedure and the lack of pre-market approval for new ingredients. There seems to be unanimous agreement among scientific experts worldwide that the suitability and safety of new ingredients used in the production of infant or follow-on formulae must be evaluated by an independent scientific authority prior to introduction into the market. Regulations 6.1b and 6.2 and 7.b fail to include requirements for <i>independent</i> substantiation. It is a betrayal of public trust if systematic reviews are carried out by a body that is in any way funded by an interested party.</p> <p>The fragile argument put forward by the Commission that, because pre- authorisation is not specified in the Parnuts Framework Directive (89/398/EEC) it is not possible to permit it, does not seem credible. It must be possible for Member States to introduce a pre-market approval system for ingredients. If this is not considered possible, for this and other concerns regarding lack of transparency and accountability, the PARNUTS Directive must be revised at the earliest opportunity and the Directive 2006/141/EC reopened.</p> <p><b>Declarations of interest:</b> It is standard practice for UK professional bodies, professional journals and Government Committees to require Declarations of Interest. This is an essential requirement for any scientific data submitted to support the efficacy of ingredients used in designated products. WHA Resolution 58.32 (2005) calls on Member States: <i>“to ensure that research on infant and young-child feeding, which may form the basis for public policies, always contains a declaration relating to conflicts of interest and is subject to independent peer review.”</i></p> <p><b>History of safe use:</b>  In the 2005 Codex consultation on the composition of infant formulae the International Expert Group commented on consumer phone lines as evidence of safe use. <i>“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</i></p>
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*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. 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....”<sup>1</sup>*

#### **Global influence**

Improvements in the quality of breastmilk substitutes should be driven by public health, not commercial competition. In anticipation of the new EU Directive companies have already introduced ingredients illegally, such as *Immunofortis*, *Alphalactalbumin*, which have invented names. In New Zealand, fructo-oligosaccharides, (FOS) have not been subject to the required risk-based safety assessment for formulas and are not as yet permitted in NZ. Nutricia has nevertheless defied the government's requirements and has added these ingredients to formulas. The NZ authorities have referred to 7 years of use in the EU despite the fact that Oligosaccharides are not legally permitted until 2008 when the Directive comes into effect.<sup>2</sup>

**Soya:** BFLG has asked for the risks of soya in breastmilk substitutes to be considered. Reference is made in the footnote to the CMO's advice but no action is taken to label, warn or restrict sales of soya formulae which are on open sale alongside normal formulae and aggressively advertised in health professional journals and the internet. See Endnote on action taken in other countries.<sup>1</sup>

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

2 [http://www.nzfsa.govt.nz/publications/media-releases/2007/fos.htm#P27\\_3203](http://www.nzfsa.govt.nz/publications/media-releases/2007/fos.htm#P27_3203) **Infant Formula does not meet New Zealand Standards** DIRECTOR GENERAL STATEMENT 16 July 2007 NZFSA has been notified that Karicare Nutriprem [that its products] are non-compliant under the joint Australia New Zealand Food Standards Code. The Acting Chief Executive, Director-General of the New Zealand Food Safety Authority (NZFSA) for purpose of section 37 of the Food Act 1981, is advising parents and caregivers that Nutricia Karicare Gold Plus Infant Formula and Follow-On Formula both contain added substances called fructo-oligosaccharides, (FOS). FOS has not been subject to the required risk-based safety assessment for the purposes of permitting their addition to infant formula products for sale in New Zealand. In the absence of such a safety assessment, NZFSA is taking a cautionary approach to this situation, particularly, for New Zealand infants who may consume them as their total dietary intake.

<p><b>Regulations 8 and 12 Compositional and Purity criteria</b></p>	<p><b><u>Insert the following text:</u></b></p> <p><i>All ingredients of designated products shall be as free from chemical and microbial contamination as possible, of good quality, safe and suitable for ingestion by infants. They shall conform to optimal quality requirements, such as colour, flavour and odour.</i></p> <p><i>Designated products shall not contain commercially produced hydrogenated oils and fats, shall not have been treated by ionizing radiation and shall not contain ingredients modified through genetic engineering. Thickening agents, emulsifiers and antioxidants are not needed in infant formulas. These non-nutritive chemicals expose infants to needless additives when the infant is already exposed to a large number of foreign substances present in infant formulas. As well formula fed infants are in an immunologically deprived status and less able to handle unnecessary chemicals.</i></p> <p>Cosmetic ingredients are frequently used to make the products more attractive to parents rather than providing for the infant’s needs.</p> <p>Designated products shall be free from residues of hormones, antibiotics, N-nitrosamines, nitrates, heavy metals, mycotoxins, as determined by agreed analysis, and free from other contaminants, especially pharmacologically active substances such as phytoestrogens. The use of soya should be reviewed.</p> <p>The product shall comply with any microbiological criteria established in accordance with the principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997) and shall be free from pathogenic microorganisms, parasites and any other hazardous or deleterious substances</p>
<p><b>Naming of infant formula Regulation 15</b> ( a) Infant formula may not be sold unless it is sold under the name - In the case of a product which is not manufactured entirely from cows’ milk proteins, the name ‘infant formula’ or (b) in the case of a product which is manufactured entirely from cows’ milk proteins, the name ‘infant milk’ Naming of follow-on formula Regulation 16 follows the same format.</p>	<p><b>INSERT THIS NEW TEXT:</b></p> <p><i>The Brand name of designated products should be no bigger than the Name of the Product and nor should it contain or imply anything which indicates or may be understood by the purchaser to be a claim of any kind or to imply a health advantage. The name should not imply that the product is like human milk.</i></p> <p><b><u>The name of the food should not be, or contain, anything which indicates or may be understood by the purchaser to be a claim of any kind or to imply a health advantage. The name should not imply that the product is like human milk.</u></b></p> <p><i>A product which contains milk or any milk derivative shall be labelled “contains cows’ milk”</i></p> <p><i>If the product is soy-based it must be labelled “Formula Based on Soya”.</i></p> <p>Rationale: <b>HA</b> or <b>Hypollergenic</b> (indicating possible reduction of allergy risk), <b>AR, Staydown,</b> (indicating anti-reflux properties), <b>Organic, Prebiotic, Probiotic</b> or <b>Humana</b>. All these claims promote the product and should not be permitted. Particular properties of products are more safely conveyed through clear nutrition labelling, or independent certification stamps, alongside clear instructions which indicate the intended use of the product. No claim implying a health advantage or regarding the efficacy of the product</p>

	<p>should be made or implied. (see also comments on Regulation 17.4)  The names infant formula, infant milk, follow on formula and follow-on milk are of concern to BFLG members. Some BFLG members propose ‘artificial milk drink’</p>
<p><b>Warnings about intrinsic contamination</b>  <b>Regulations 17 (1)(d) and 18 (1)(d)</b>  <i>“instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.”</i>  Appendix 4 of the RIA indicates that the FSA is considering asking the formula industry to agree a voluntary approach to warning parents and health professionals about the risks of pathogenic contamination of formula powders.</p>	<p><b>Recommendation:</b>  <i>The label should contain an explicit warning on the front of the package that the product (powdered infant formulae, specialised formulae and follow-on formulae) is not sterile and may contain harmful bacteria <b>that can cause serious illness and that correct preparation and handling reduces the risk of illness.</b></i></p> <p><i><b>The warning must be clear, conspicuous, easy to read, explicit and understandable. Clear preparation instructions in line with FSA, WHO and WHA Res 58.32 recommendations regarding the steps that need to be taken to decontaminate powdered formulas in order to minimize the risk of harm related to the lack of sterility should also be included.</b></i><sup>3</sup></p> <p><b>RATONALE:</b></p> <p>The Food Standards Agency meeting in January 2007 discussed its research on public understanding of the term 'non-sterile' and attitudes to labelling, concluding that parents do need to be made aware of the reasons for any change in advice.</p> <p><sup>4</sup> It seems that few parents are aware of this problem and not all health professionals have received up to date information. Unless parents are made aware of that the product may be intrinsically contaminated (not just contaminated DURING preparation) they are unlikely to comply with recommendations since this involves extra cost and preparation.</p> <p>In April, WHO published its Guidelines for the safe preparation, storage and handling of powdered infant formula and these should be followed carefully<sup>5</sup></p> <p><b>Appendix IV states that</b> voluntary labelling is to be agreed with industry concerning the information that powdered formula milks are not sterile. BFLG is sceptical that industry will voluntarily comply on this issue, which has such significant implications for infant health. The recent <i>Infant Feeding Survey</i> found that the majority of parents were not following the recommendations for making up feeds safely. Health professionals are not always able to brief parents when they decide to change to formula milk; this information needs to be clear, accessible and on the tin.</p>
<p><b>Regulation 17 (1) (e) (ii)</b>  <i>A statement recommending that the product be used only on the advice of independent persons having qualifications in</i></p>	<p><b>Change to:</b>  <i>A statement recommending that <b>Designated products</b> should be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy <b>ADD or nursing, midwifery or health visiting. DELETE: or other professional responsible for maternal and child care.</b></i></p>

<sup>3</sup> WHA 58.32 urges Member States (3) to ensure that clinicians and other health-care personnel, community health workers and families, parents and other caregivers, particularly of infants at high risk, are provided with enough information and training by health-care providers, in a timely manner on the preparation, use and handling of powdered infant formula in order to minimize health hazards; are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and, where applicable, **that this information is conveyed through an explicit warning on packaging;**

<sup>4</sup> [www.food.gov.uk/science/surveys/infantformula](http://www.food.gov.uk/science/surveys/infantformula)

<sup>5</sup> [www.who.int/foodsafety/publications/micro/pif2007/en/index.html](http://www.who.int/foodsafety/publications/micro/pif2007/en/index.html)

<p><i>medicine, nutrition or pharmacy, or other professional responsible for maternal and child care.</i></p>	
<p><b>Regulation 17 (3)</b> The labelling of infant formula shall not include – (a) any picture of an infant; or (b) 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.</p>	<p><b>Change to:</b> The labelling of infant formula shall not include – (b) any picture of an infant, <b>woman</b> or (b) any other picture, <b>symbol</b> or text which may idealise the use of the product,  but may <b>MUST</b> include graphic representations for easy identification of the product or for illustrating methods of preparation.</p>
<p>17 (4) The labelling of an infant formula may bear <b>Health and Nutrition claims</b> only when the claim is listed in the first column of Annex IV and is expressed in the terms set out there.</p>	<p><b>Recommendation:</b> 17 (4) The labelling of designated products may should bear no <b>Health and Nutrition or other claims, text or any symbols depicting a health advantage - except text which provides essential information for the correct use of the product.</b> <del>only when the claim is listed in the first column of Annex IV and is expressed in the terms set out there.</del> <b>Any permitted claims should be presented in a non-promotional way placed at the back of the package next to the ingredients list – ideally in the same typeface and text size. (See page 23 of the RIA response.)</b></p> <p>If it is legally possible for the UK to ban all health and nutrition claims on designated products ( infant formulae, follow-on formula and specialised formulae etc), it should do so. If this is not possible any permitted claims should be presented in a non-promotional way placed at the back of the package next to the ingredients list – ideally in the same typeface and text size. The regulations should make it clear that no claims other than those listed should be permitted for example, claims such as Prebiotic, Probiotic, HA, Hypoallergenic, for Hungry baby or made up names such as Immunofortis should not be permitted.</p> <p>The UK Government should as policy advocate that additional claims on Designated products (Infant formula, specialised formula and follow-on formula etc) proposed in future years should be opposed and that optional ingredients/ and variations in composition are kept to the absolute minimum necessary for health.</p> <p>Compositional information must be presented in a clear factual manner that is understood by purchasers and not in any way promotional or idealizing. Products based on cows’ milk should say this explicitly. Ingredients derived from fish, egg or other sources should be clearly stated.</p> <p>Health or nutrition claims on any breastmilk substitute are marketing tools which are inevitably misleading and deceptive. By highlighting one or other ingredient out of the context of the other ingredients a false message is conveyed that the whole product has a health advantage over breastfeeding and that for example, the product will make children cleverer and or protect them from infection. As stated below if an ingredient is essential or important for health it should be a mandatory requirement in all breastmilk substitutes. The BFLG strongly advise that all such promotional claims are</p>

	<p>not permitted. If the nutritional panel is clear following QUID guidelines then all the information will be available.<sup>6</sup></p> <p><i>“The problem with nutrient-by-nutrient nutrition science is that it takes the nutrient out of the context of food, the food out of the context of diet and the diet out of the context of lifestyle”</i> Marion Nestle, New York University.</p> <p>It is a matter of considerable regret that Annex IV of the Directive permits certain claims and that some of these claims are highly controversial and lucrative. If claims must be allowed on UK packaging it should be made crystal clear that ONLY those claims listed in Annex 4 should be permitted and then, as the regulation state, <i>“in the terms set out there.”</i> For example, <i>‘contains fructo-oligosaccharides’</i> should not be changed to <i>“contains pre-biotics”</i></p> <p>See Response to RIA Page 20 which lists the essential information needed on packaging of breastmilk substitutes. Companies may argue that the phrases used on packaging, such as “for hungry babies” are not ‘nutrition or health claims’ so it is important that any loopholes are closed.</p> <p>The Directive makes no reference to claims on follow-on formula or other designated products , so they should not be permitted.</p> <p>Any permitted claims – even those listed in Annex IV should also be supported by a dossier of evidence which includes a substantial number of independent studies carried out in conformance with the COMA guidelines</p>
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<sup>6</sup> Claims for LCPUFA imply that it enhances intellectual outcome. Yet ISDI says in CX/NFSU 03/6 page 27 on LCPUFA “however it is not known if increases occur in neural tissues. Some studies do show a positive effect, where others were unable to measure such effects”

The Report of the Scientific Committee for Food also said: “Babies fed with breastmilk may have more mature sight skills and a higher IQ (Intelligence Quotient) than babies fed formula. It has been suggested that low levels of longchain polyunsaturated fatty acids (LCPUFA) found in formula may contribute to lower IQ levels and sight skills. Some formulas are available with added LCPUFA. This review of trials found that there was not enough evidence to show a longterm benefit of LCPUFA supplementation but that LCPUFA supplementation was safe. More research is needed to assess whether LCPUFA supplementation results in mild improvements in problem solving ability.

The author of the independent Cochrane review examined nine randomised controlled trials and concluded: “At present there is little evidence from randomised trials of LCPUFA supplementation to support the hypothesis that LCPUFA supplementation confers a benefit for visual or general development of term infants. Minor effects on VEP acuity have been suggested but appear unlikely when all studies are reviewed. A beneficial effect on information processing is possible but larger studies over longer periods are required to conclude that LCPUFA supplementation provides a benefit when compared with standard formula.”<sup>6</sup>

The Hambricht and Quist Spot Report on pharmaceuticals recommendation for Martek Biosciences, (manufacturers and distributors of *Formulaid*, an artificial source of DHA and ARA ) referred to *Formulaid* as a ‘strong buy’ on the following basis: *“Infant formula is currently a commodity market, with all products being almost identical and marketers competing intensely to differentiate their product. Even if Formulaid has no benefit, we think it would be widely incorporated into formulas, as a marketing tool and to allow companies to promote their formula as “closest to human milk”.*

Nutrition claims about Fructo-oligosaccharides and galacto-oligosaccharides imply that these ingredients protect babies from infection, despite the lack of evidence of the health benefits of these ingredients. The SCF report Para 3.2.2 also questioned the Health benefits of FOS and GOS in children.



	<p>and which demonstrate incontrovertibly that the ingredient used is safe in the short and long term and that it achieves the expected purpose.<sup>7</sup></p> <p><b>Future claims:</b> In the RIA reference is made to minutes of a SCoFCAH meeting where the Commission's 'expectation' that EFSA would be consulted on new claims on infant formula if they were likely to have an impact on public health. Claims considered 'simple' and which would be submitted to the SCoFCAH for discussion/possible vote. Even if EFSA gives a negative opinion on a claim, according to Annex A, it is only 'unlikely' that the Commission would draft an amendment. Given that the Commission has already included several highly controversial claims which will have an impact on public health in the revised Directive, this safeguard does not really inspire confidence in the process.</p> <p>An explanation is needed of the legal status of the assurances given by the Commission. Once more we ask that the proceedings of the SCoFCAH be more transparent .</p> <p>There is no clarity regarding the addition of new ingredients to Follow-on milks, which can be done without having to notify authorities. Under the Health Claims regulations these claims may first be approved by EFSA but this is not certain.</p> <p><b>HA and Hypoallergenic claims</b> The Baby Feeding Law Group has written several times to the Minister of Health expressing concerns about the evidence base for claims relating to allergy and the industry's use of the term "HA" and "Hypoallergenic" which we believe is illegal. This particular claim is extremely controversial and was refused by the US FDA in 2006 on the grounds that there is no credible evidence to support it<sup>8</sup></p> <p>Allergenicity claims are particularly problematic and would be more safely handled with a nutrition statement such as, 'contains hydrolysed proteins' alongside generic product descriptions and warnings that the product should be used only on the advice and under the guidance of an independent health professional.</p> <p>Manufacturers using the HA claim have been required to voluntarily include a warning that the product 'may cause an allergic reaction if given to an infant with diagnosed allergy to cow's milk' Although perhaps better than</p>
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<sup>7</sup> Working Group on the Nutritional Assessment of Infant Formulas of the Committee on Medical Aspects of Food and Nutrition Policy (COMA). *Guidelines on the Nutritional Assessment of Infant Formulas*. Stationery Office. 1996.

<sup>8</sup> Friday 12th May 2006 the Food and Drug Administration in the USA rejected an attempt by Nestle USA to carry a reduced risk to allergy claim on its infant formulas saying there was no credible evidence to support the company's claim. 'Hypoallergenic' claims have not been permitted on infant formula labels in the US since 1989 when nine US authorities took legal action to stop Nestle Carnation making these claims. Several infants had suffered anaphylactic shock after being fed Nestlé formula which had been advertised as 'hypoallergenic.' Earlier this year Canadian Television carried an exposé on three consecutive nights about the falsified research of Canadian scientist, Dr Ranjit Chandra, which had been used by Nestlé and other companies to support their claims. [www.babymilkaction.org/press/press3feb06.html](http://www.babymilkaction.org/press/press3feb06.html). The Commission's advisory body – the Scientific Committee for Food in its report on the Composition of Infant formula recommended the removal of all the nutrition claims in the original Directive, apart from one - a lactose free claim. The report deliberately avoided the use of the word CLAIM, recommending instead NUTRITION LABELLING for ingredients such as long-chain fatty acids. The Commission seems to have ignored this advice in its drafting of the Directive. The Report of the Scientific Committee for Food found "no scientific foundation to base a claim that a formula induces "reduction of risk of allergy to milk proteins" or is "hypoallergenic" on a content of immunoreactive protein of less than 1% of nitrogen-containing substances, as is presently the case."

	<p>nothing, this strategy is inadequate to contradict the powerful promotional message contained in the HA claim.<sup>9</sup> The UK Food Standards Authority has also warned against using partially hydrolysed formula with allergic infants because of the risk of a reaction.</p> <p><i>HA or Hypoallergenic claims are not permitted in North America following Nestlé/Carnation's launch of Good Start HA in the US in 1988, when several allergic babies suffered from anaphylactic shock. Nine US States and the Food and Drug Administration investigated and forced Nestlé to stop using 'hypoallergenic' claims which they said were: "Misleading and deceptive...Those babies who had severe reactions to Carnation Good Start have paid a high price for the company's irresponsible conduct."</i></p> <p>The claims for hydrolysed proteins and the development of the market for infant formulae containing partially hydrolysed proteins was underpinned by the work of Dr R.K.Chandra, a Canadian researcher who has in recent years been discredited and whose entire body of work is now under investigation. Leading Swedish allergy specialist, Prof Bengt Bjorksten, questioned the European ESPGHAN support for hypoallergenic milks in 1993: "<i>The conclusion drawn by the Committee [ESPGHAN]...differ substantially from what most American and European researchers suggest, and they are almost identical to those suggested by the company marketing the partially hydrolysed product direct to the public... Why did the Committee not properly address this important controversy but merely uncritically quote a review published in a company sponsored book by an employee of the company?</i>" (Acta Paediatrica,1993)</p> <p>The Scientific Committee for Food <i>Report on the Revisions of Essential requirements of Infant formulae and Follow-on Formulae</i> also expressed concern about the validity of the claims and on Page 48 states:</p> <p><i>"it has been shown for some products that they were nutritionally inadequate. It is unknown if such products were removed from the market. The inherent claim that hydrolysates result in less allergic diseases cannot be deduced from technical data alone and needs substantiation in clinical trials. Surprising is the total lack of clinical studies published on follow-on formulae based on partially hydrolysed proteins."</i></p> <p>and on pages 50 &amp; 51: "<i>To our knowledge there are no systematic studies to assess growth and biological parameters of infant formulae with partially hydrolysed protein to determine the minimal safe protein content."</i></p> <p>and Page 161: "<i>The Committee concludes that there is no scientific foundation to base a claim that a formula induces 'reduction of risk of allergy to milk proteins' or is 'hypoallergenic' on a content of immuno-reactive protein of less than 1% of nitrogen-containing substances, as is presently the case."</i></p> <p>The properties of the product – for example, that it contains hydrolysed proteins,- can be conveyed through clear nutrition labelling alongside clear instructions which indicate its intended use. No claim regarding the efficacy of the product should be made or implied.</p> <p><b>CLAIMS ON SPECIALISED FORMULAE</b></p> <p>It is important to recall the labeling provision in the Codex Infant formula standard which reiterates that the Codex Guidelines on Nutrition Labelling</p>
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<sup>9</sup> Nestlé reported to UK Advertising Standards Authority over marketing of 'hypoallergenic' infant formula <http://www.babymilkaction.org/press/press28july04.html>

	<p>(CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims apply to infant formula and formula for special medical purposes for infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.</p> <p>Claims relating to ‘organic’ or ‘kosher’ should be independently authorised and limited to that authorisation.</p> <p>IBFAN’s monitoring report from 69 countries, <i>Breaking the Rules Stretching the Rules 2004</i>, found that 11 out of the 16 companies studies were promoting DHA and AHA with claims that it boosted intelligence.</p>
<p>Regulation 18 (1) a (iv) <i>The decision to begin complementary feeding, including any decision as to making an exception to the principle of not using follow-on formula before six months of age, should only be made on the advice of independent persons having qualifications in medicine, nutrition or pharmacy or other professional responsible for maternal and child care, based on the individual infant’s specific growth and development needs</i></p>	<p><b>Change to:</b> <i>The decision to begin complementary feeding, including any decision as to making an exception to the principle of not using follow-on formula before six months of age, should only be made on the advice of independent persons having qualifications in medicine, nutrition or pharmacy</i> <del><i>DELETE: or other professional responsible for maternal and child care, based on the individual infant’s specific growth and development needs.</i></del></p>
<p><b>Regulation 19</b> <b>infant formula and follow-on formula should be labelled in such a way as to avoid any risk of confusion between infant formulae and follow-on Formulae a</b> Regulation 20 (2) <b>The provisions...apply in relation to the presentation of follow-on formulae</b> Regulation 20 (3) <b>For the purposes of this regulation ‘presentation’ includes the shape, appearance and packaging materials used, the way they are arranged and the setting in which they are displayed.</b></p>	<p><b>Change to:</b> Regulation 19 Designated products (Infant formula, <b>specialised formula</b> and follow-on formula etc) should be <i>labelled</i> in such a way as to avoid any risk of confusion between infant formulae, <b>specialised formulae</b> and follow-on Formulae Regulation 20 (2) <b>The provisions...apply in relation to the presentation of Designated products (follow-on formulae and specialised formulae</b> Regulation 20 (3) For the purposes of this regulation ‘presentation’ includes <b>the brand names, logos, shape, appearance and packaging materials used, the way they are arranged and the setting in which they are displayed.</b></p> <p>The aim of paragraphs 19 and 20 (3) can only be achieved if all Designated products are subject to the same advertising and other restrictions which apply to infant formula.</p>
<p><b>Restrictions on advertising infant formula</b></p>	<p><b>Change to:</b> No person shall advertise <b>Designated products (Infant formula, specialised formula and follow-on formula etc)</b> —</p>

<p><b>21.</b>—(1) No person shall advertise infant formula—</p> <p>(a) except—</p> <p>(i) in a scientific publication, or</p> <p>(ii) for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public; or</p> <p>(b) where the advertisement contravenes or fails to comply with the provisions of regulation 17(1)(e), (2), (3) or (4), regulation 19 or paragraph (2) or (3).</p> <p>(2) Advertisements for infant formula shall only contain information of a scientific and factual nature.</p> <p>(3) Information in advertisements for infant formula shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.</p>	<p>Information for health professionals for <b>designated products (Infant formula, specialised formula and follow-on formula etc)</b> shall only contain information of a scientific and factual nature, shall contain no idealizing images or text, and shall not imply or create a belief that artificial feeding or bottle-feeding is equivalent or superior to breast feeding.</p> <p><b>Restrictions on advertising follow-on formula</b></p> <p><del>22. No person shall advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions of regulation 18(2) or 19.</del></p> <p><b>RATIONALE:</b> We welcome the restriction of infant formula advertising within paragraph 21 and the removal of the weak definition of advertising (which in the previous regulations excluded the label or wrapper, so opening an important loophole.) However this needs to be extended to all designated products. The International Code makes no exception for any type of advertising and in accordance with this principle the EU Directive specifically allows Member States to prohibit all advertising and promotion. See response to RIA page 12.</p>
<p><b>Regulation 33</b> <b>Restrictions on the promotion of infant formula</b></p>	<p>The same restrictions should also apply to follow-on formula, specialised formulas and the brand names and logos on these products.</p>
<p><b>Promotional Gifts</b> Regulation 23.2 <i>“No Manufacturer or distributor of any infant formula shall provide for promotional purposes any infant formula free or at a reduced rate or discounted price. Or any gift designed to promote the sale of an infant formula</i></p>	<p><b>Change to:</b> <i>“No Manufacturer or distributor of any designated product (infant formula, follow-on formula, specialised formula etc) shall provide for promotional purposes any designated product (infant formula, follow-on formula, specialised formula etc free or at a reduced rate or discounted price or any promotional gift <del>DESIGNED TO PROMOTE THE SALE OF AN INFANT FORMULA</del> to-</i> The proposed regulations allow manufacturers and distributors to give gifts to parents provided they do not promote the sale of an infant formula and do not comply with Article 14.3 of the Directive. The wording allows companies to give any number of gifts, materials, advice, etc provided it does not specifically promote a particular infant formula.</p>
<p><b>Information and education regarding infant and child feeding</b> <b>Regulation 24(4)</b> No manufacturer or distributor of an infant formula shall make a donation of any informational or educational equipment or materials except in accordance with the following conditions—</p> <p>(a) the donation shall be made following a request by the intended recipient;</p> <p>(b) the donation shall be made with the written authority of the Secretary of State or in accordance with</p>	<p><b>Change to:</b> (4) No manufacturer or distributor of <i>any designated product (infant formula, follow-on formula, specialised formula etc )</i> shall make a donation of any informational or educational equipment <b>INSERT Resources or materials , or provide training on its behalf <del>DELETE: except in accordance with the following conditions—</del></b></p> <p><b>(a) the donation shall be made following a request by the intended recipient;</b></p> <p><b>(b) the donation shall be made with the written authority of the Secretary of State or in accordance with guidelines drawn up by the Secretary of State;</b></p> <p><b>(c) the equipment and materials shall not be marked or labelled with the name of a proprietary brand of infant</b></p>

<p>guidelines drawn up by the Secretary of State;</p> <p>(c) the equipment and materials shall not be marked or labelled with the name of a proprietary brand of infant formula; and</p> <p>(d) the equipment or materials shall be distributed only through the health care system.</p>	<p><b>formula; and</b></p> <p><del>(d) the equipment or materials shall be distributed only through the health care system.</del></p> <p>Governments have a responsibility to provide parents with accurate, independent information and several WHA resolutions stress the need to avoid conflicts of interest in the funding of infant feeding.<sup>10</sup> programmes .See Response to RIA question on Advertising Page 14 - 19.</p>
<p><b>Regulation 25</b></p> <p>Provides for free or reduced rate infant formula for infants who have to be fed on infant formula and only for as long as required by those infants;</p>	<p>Strengthen in view of new rules to cover all <b>Designated products (Infant formula, specialised formula and follow-on formula etc).</b></p> <p>A Government Health Circular (HC89 (21) of 1989) calls on Health Authorities not to accept free and reduced price infant formula and in order to ensure that this safeguard continues this section should be amended to state that Free or reduced rate formula should not be available except in the course of research studies which comply with the guidelines laid out in the COMA report.</p>
<p><b>Regulation 26 Exports</b></p> <p><b>Export of infant formula to third countries 26.</b>—(1) No person shall export to a third country any infant formula which contravenes or fails to comply with — (a) regulation 5, 6, 8, 10, 11, 12, 14(1) to (3), 17 or 19; (b) the Codex Standard for Infant Formula established by the Codex Alimentarius(10); (c) The Food (Lot Marking) Regulations 1996(11). (10) Codex Stan 72-1981, volume 4, Codex Alimentarius, 1981. (11) S.I. 1996/1502.9</p> <p>(2) No person shall export to a third country a product represented as suitable for satisfying by itself the nutritional requirements of normal health infants during the first four to six months of life unless that product is infant formula.</p> <p><b>Export of follow-on formula to third countries 27.</b> No person shall export to a third country any follow-on formula which contravenes or fails to comply with — (a) regulation 5, 7, 9, 10, 12, 14(1) to (3), 18 or 19; (b) the Codex Standard for Follow-up Formula established by the Codex Alimentarius(12); (c) The Food (Lot</p>	<p>The Regulation should be extended to include all the safeguards relating to products sold in the UK, provided the amendments outlined in this submission are made.</p> <p><b>Change to:</b> (2) No person shall export to a third country a product represented as suitable for satisfying by itself the nutritional requirements of normal health infants during <del>the first four to</del> six months of life unless that product is infant formula.</p> <p>The footnote references the Codex Stan 72-1981. Since a new infant formula standard covering infant formula and specialised formulas together was passed in July 2007 it will be important to update this reference in due course when the new reference is available. This is an important point which should not be forgotten.</p> <p>The exports provisions should also apply to specialised formulas and follow-on formulas. Compositional criteria for follow-on milks are not included.</p>

<sup>10</sup> Res WHA 49.15 1996: "Concerned that health institutions and ministries may be subject to subtle pressure to accept, inappropriately, financial or other support for professional training in infant and child health" urged Member States to ensure that: "financial support for professionals working in infant and young child health does not create conflicts of interest."

Res WHA58.32 2005 Urges Member States: "to ensure that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest".

Marking) Regulations 1996	
<p><b>Monitoring</b> Each food authority is responsible for enforcement and execution of these Regulations within its area.</p>	<p>There is no clarification of who is responsible for monitoring the working of law, collating breaches and co-ordinating between food authorities. This is necessary to ensure the legislation is effective.</p> <p><b>The regulation could usefully quote Article 11.3 of the Code</b> “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” and Res WHA 49.15 (1996) which urged Member States to ensure that: "monitoring ...is carried out in a transparent and independent manner, free from commercial influence.”</p>
<p><b>Regulation 30</b> <b>Amendment to Foods for Special Medical Purposes Act</b></p>	<p>Merge the regulations BFLG has always maintained that specialised formula should be covered by the same piece of legislation as regular formulas and that the definition of ‘healthy’ is not at all clear. The Codex standards include all infant formulae under the same standard.</p>
<p><b>NEW SECTION</b> <b>Sales incentives, bonuses</b></p>	<p><b>INSERT a new provision covering employees of manufacturers and distributors</b> <i>In systems of sales incentives for marketing personnel, the volume of sales of designated products should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.</i> <i>Personnel employed in marketing designated products should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children.</i></p> <p>Article 8 of the International Code is quite clear that there should be no sales incentives or bonuses for marketing personnel related to the volume of sales of breastmilk substitutes and that employees should not perform educational functions in health care systems, schools or elsewhere.</p>

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## ***i*Country warnings issued regarding the use of soy-based infant formulas**

A number of countries have reviewed and issued statements of concern about the routine use of soy formulas.

### **UK, January 2004**

Earlier this year the UK Medical Officer of Health<sup>1</sup> reiterated that soy formulas should not be used as the first choice for the management of infants with proven cow's milk sensitivity, lactose intolerance, galactokinase deficiency and galactosemia. The warning, based on a report by the Committee on Toxicity, notes the long-term risk posed for reproductive health linked to the high levels of phytoestrogens found in these products. The MOH also advises there are "no health benefits associated with the consumption of soy-based infant formulas".

### **British Dietetic Association, 2003**

In an announcement published in the Journal of Family Health Care<sup>2</sup>, the Association notes that "*Dietitians should discourage the use of soy protein in children with atopy or cow's milk allergy in the first six months of life to avoid sensitization to soya protein and exposure to phytoestrogens while organ systems remain at their most vulnerable. This would include the use of soy infant formula...When a soy based infant formula is used parents should be informed of current findings relating to phytoestrogens and health and on the clinical need for soy formula.*"

This notification follows a category of others.

### **Australia, March 1999**

The Australian and New Zealand Food Authority<sup>3</sup> warn that infants fed soy formulas are exposed to 47mg of isoflavone per day and that this level is at least 240 times greater than consumed by breastfed infants. The report notes concerns about the potential to adversely affect subsequent sexual development and fertility.

### **New Zealand, December 1998**

New Zealand's Ministry of Health recommends<sup>4</sup> that soy-based infant formulas should only be used under the direction of health professionals for specific medical indications. Other options should be considered first. As well clinicians are urged to be aware of the use of soy formulas and thyroid function and to consider assessment of thyroid function when satisfactory growth and development is not achieved.

### **Switzerland, 1997**

The Swiss Commission on Food, also issues an information sheet to all paediatricians based on a review report<sup>5</sup>. This report too warns that very restrictive use should be made of soy formulas because of the potential harm from isoflavones.

### **References:**

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3. ANZFA **Phytoestrogens: An assessment of the potential risks to infants associated with exposure to soy-based infant formula**. March 1999
4. Tuohy, P. **Soy-based infant formula**. Ministry of Health, Wellington, New Zealand, December 1998
5. Zimmerli B. et al. **Existence and development of isoflavones daidzein and genistien in baby food**. Communication regarding food stuffs in Hyg. 88:19-232, 1997