

**IBFAN comments and amendments on the revision of the Regulation on food intended for infants and young children and on food for special medical purposes**

<i>Text proposed by the Commission</i>	<i>Comment/suggested amendment</i>
<p>THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,            Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,</p> <p>Having regard to the proposal from the European Commission,            After transmission of the draft legislative act to the national Parliaments,            Having regard to the opinion of the European Economic and Social Committee,            Acting in accordance with the ordinary legislative procedure;</p> <hr/> <p><b>Recital 1 Whereas:</b>            (1) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that measures having as their object the establishment and functioning of the internal market and which concern inter alia health, safety and consumer protection must take as a base a high level of protection taking account in particular of any new development based on scientific facts.</p>	<p><b>Add</b>  <i>Having regard to the principles and the aims of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly Resolutions</i></p> <p>Having regard for the COUNCIL RESOLUTION of 18 June 1992 on the marketing of breast-milk substitutes in third countries by Community-based manufacturers (92/C 172/01) which encourages: <i>"compliance with the International Code of Marketing of Breast-milk Substitutes when these products are placed on sale in export markets, in so far as this does not conflict with the provisions in force in the countries concerned" and offers EU "effective support to competent authorities to apply the International Code in their territory."</i></p> <p><i>Having regard for the horizontal duty set out in the Lisbon Treaty that: "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities."</i></p> <p><b>Justification:</b> <i>All EU Member States endorse the International Code and Resolutions at the World Health Assembly.</i></p> <hr/> <p><b>Whereas:</b>            (1) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that measures having as their object the establishment and functioning of the internal market and which concern inter alia health, safety and consumer protection must take as a base a high level of protection. <b><i>In order to reduce existing risks associated with artificial feeding no ingredient or process must be</i></b></p>

	<p><i>used unless it has been demonstrated as safe and beneficial through an independent systematic review of all available scientific data, which must include a substantial proportion of independently funded research.</i></p> <p><b>Justification:</b>  <i>The potential for bias is present in all research, and while '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 where academic rigour can be demonstrated in the research process. Problems are compounded by publication bias where trials with negative outcomes are less likely to be published. \ Public health policy, especially in the area of infant and young child feeding, should be predominantly informed by independent, publicly financed studies that are in the public domain and subjected to a rigorous peer review process. Research carried out on babies - and babies under 12 weeks in particular - is fraught with ethical problems. Infants are an especially vulnerable group that do not consent on their own behalf so need special protection. Commercial involvement in such research also opens the door for coercion and inappropriate presentation of the risks involved.</i></p>
<p>Recital 9,10 , 11,12</p>	<p><b>The Regulation should ensure that the concept of foodstuffs for particular nutritional uses is abolished.</b></p>
<p><b>Recital 14</b>  (14) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety establishes common principles and definitions for Union food law in order to ensure a high level of health</p>	<p><b>Comment on Recital 14</b>  This recital should call for the Precautionary Principle as a provisional risk management measure.  The rules relating to EFSA’s scientific evaluation of claims and ingredients relating to foods for infants and young children should be strengthened to ensure that:</p>

protection and the effective functioning of the internal market. It establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (hereinafter referred to as 'the Authority'). Therefore, certain definitions laid down in that Regulation must also apply in the context of the present Regulation. Moreover, for the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public....

- Decisions are taken on the basis of the totality of research in the public domain.
- Health, nutrition or promotional claims should not be permitted for foods for infants and young children.
- No claim should ever be approved on the basis of cherry-picked, industry-funded, and 'proprietary' dossiers.

**Justification: It is impossible to carry out adequate risk assessments for the importing countries – especially for those countries that have not yet taken legal action to ban claims.**

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Recital 20

(20) It is appropriate to establish and update a Union list of vitamins, minerals, amino acids and other substances that may be added to infant formula, follow-on formula, processed cereal-based food and baby food, and food for special medical purposes, subject to certain criteria laid down in this Regulation. Given the fact that the adoption of the list implies the application of criteria set out in this Regulation, implementing powers should be conferred on the Commission in that respect. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>17</sup>. The Commission should adopt immediately applicable implementing acts updating the Union list, where, in duly justified cases relating to public health, imperative grounds of urgency so require

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Recital 20

See also recital 1

Add:

***In addition to the Union list all ingredients for foods for infants and young children and especially pre-term formulas, formulas for special purposes and normal formulas should undergo rigorous evaluation for safety and efficacy, using independent systematic reviews of the totality of research. Once an ingredient is established to be unequivocally safe and beneficial it should be made listed as a required ingredient.***

***Declarations of interests must be made for all research and the dossier must include a substantial proportion of independently-funded studies***

Commission Proposal	Suggested changes
<p>Recital 21 Nano Materials</p> <hr/>	<p>21 Nanomaterials should not be included. The precautionary principle should be used.</p> <hr/>
<p><b>Recital 22</b> In the interests of efficiency and legislative simplification, there should be a medium-term examination of the question whether to extend the scope of the Union list to other categories of food governed by other specific Union legislation.</p> <hr/>	<p><b>Recital 22</b> In the interests of legislative simplification there should be a medium-term examination of the question whether to extend the scope of the Union list to other categories of food governed by other specific Union legislation. <b><i>This extension may not take place without an evaluation by the Authority and the intervention of the European Parliament and the Council as co-legislator.</i></b></p> <p><b>Justification</b> <b>Any such decision should be taken subject to the expert assessment of the EFSA and under appropriate democratic scrutiny</b></p> <hr/>
<p>Recital 24 Council Directive 92/52/EEC states that infant formulae and follow-on formulae exported or re-exported from the European Union have to comply with Union law unless otherwise required by the importing country. This principle has already been established for food in Regulation (EC) No 178/2002. For the sake of simplification and legal certainty, Directive 92/52/EEC should therefore be repealed.</p>	<p>Recital 24 Since the EU is a major exporting region and it is impossible to carry out adequate risk assessments in importing countries, it is important to retain certain elements of the Export Directive (92/52/EEC) until such time as all EU legislation fully complies with the <i>International Code of Marketing of Breastmilk Substitutes</i> and subsequent relevant WHA resolutions. In particular:</p> <ul style="list-style-type: none"> <li>• All products should be labelled and presented in such a way as to avoid any risk of confusion between infant formulae, pre-term, specialised formulas and formulas for older babies.</li> <li>• Foods for infants and young children must not share the same brand names as formula milks.</li> <li>• the age of introduction of complementary foods stated on the label must be 6 months.</li> <li>• The provisions of COUNCIL</li> </ul>

	<p>RESOLUTION of 18 June 1992 on the marketing of breast-milk substitutes in third countries by Community-based manufacturers (92/C 172/01) should be incorporated, requiring: <i>"compliance with the International Code of Marketing of Breast-milk Substitutes when these products are placed on sale in export markets, in so far as this does not conflict with the provisions in force in the countries concerned"</i> and offering <i>"effective support to competent authorities to apply the International Code in their territory."</i></p>
<p><b>Chapter 1</b>  <b>Subject Matter and Definitions</b>  <b>Article 2 Definitions</b>  2 The following definitions shall also apply:  (a) 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002;  (b) 'infants' means children under the age of 12 months;  (c) 'young children' means children between one and three years;  (d) 'infant formula' means food used by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding;  (e) 'follow-on formula' means food used by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;  (f) 'processed cereal-based food' means food  (i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to</p>	<p><b>Chapter 1</b>  <b>Subject Matter and Definitions</b>  <b>Article 2 Definitions</b>  2 The following definitions shall also apply:  (a) 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002;  (b) 'infants' means children under the age of 12 months;  (c) 'young children' means children between one and three years;  (d) 'infant formula' means food <del>used by infants during the first months of life</del> <b>and</b> satisfying by itself the nutritional requirements of <del>such</del> <b>FOR THE FIRST 6 MONTHS OF LIFE</b> infants <b>FOR THE FIRST 6 MONTHS OF LIFE</b> until the introduction of appropriate complementary feeding;  (e) 'follow-on formula' means food used by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;  (f) 'processed cereal-based food' means food  (i) intended to fulfil the particular requirements of infants <del>DELETE: in good health</del>-while they are being weaned, and of young children in good health as a</p>

<p>ordinary food and.....</p> <hr/> <p>3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 to adapt the definitions of 'infant formula', 'follow-on formula', 'processed cereal-based food' and 'baby food' and 'food for special medical purposes' taking into account technical and scientific progress and relevant developments at international level, as appropriate.</p>	<p>supplement to their diet and/or for their progressive adaptation to ordinary food and</p> <hr/> <p><b>Delete</b> <b>Justification</b></p> <p>Parliament and the Council must have democratic scrutiny over all aspects of the Regulation, including the definitions laid down in Article 2, which are fundamental.</p>
<p><b>SECTION 2 GENERAL REQUIREMENTS</b> <b>Article 6</b></p>	<p><b>SECTION 2 GENERAL REQUIREMENTS Article 6</b></p> <p>New Article 6a (Proposed by ENVI) <b>Precautionary principle</b> <i>Where, following an assessment of available scientific information, there are reasonable grounds for concern for the possibility of adverse effects but scientific uncertainty persists, provisional risk management measures may be chosen, necessary to ensure the high level of protection of the vulnerable categories of population specified in this regulation.</i></p> <p><b>Justification</b> When it uses delegated acts to amend existing legislation, the Commission must respect the letter of the text in force and always seek to improve consumer protection. The precautionary principle laid down in Article 6a (new) is one of the fundamental principles which must guide food safety policy</p>
<p><b>Article 9</b> <b>General composition and information requirements</b></p> <p>1. The composition of food referred to in Article 1(1) shall be such that it is appropriate to satisfy the nutritional needs of, and it is suitable for the persons to whom it is intended, in accordance with generally accepted scientific data.</p> <p>2. Food referred to in Article 1(1) shall not</p>	<p><b>Article 9</b> <b>General composition and information requirements</b></p> <p>1. The composition of food referred to in Article 1(1) shall be such that it is appropriate to satisfy the nutritional needs of, and it is suitable for the persons to whom it is intended, in accordance with generally accepted scientific data.</p> <p>2. Food referred to in Article 1(1) shall not</p>

<p>contain any substance in such quantity as to endanger the health of the persons to whom they are intended.</p> <p>3. The labelling, presentation and advertising of food referred to in Article 1(1) shall provide adequate consumer information and must not be misleading.</p>	<p>contain any substance in such quantity as to endanger the health of the persons to whom they are intended.</p> <p>3. The labelling, presentation and <del>advertising</del> information relating to all foods referred to in Article <b>1(1) shall be in conformity with the International Code of Marketing of Breast-milk Substitutes. It shall provide full and frank consumer information that is not misleading, relating to ingredients, risks of inappropriate use and shall not mislead.</b></p> <p><b>In the case of powdered formulas, an explicit <i>warning on the front of the package that the product is not sterile and may contain harmful bacteria that can cause serious illness and that correct preparation and handling reduces the risk of illness and instructions regarding the decontamination steps that need to be taken in order to minimize the risk of harm related to the lack of sterility</i></b></p> <ul style="list-style-type: none"> <li>• <i>shall not carry any health, nutrition or disease risk reduction claim</i></li> <li>• <i>shall not suggest through claim, symbol, image or text that idealises the product, suggests its use at an inappropriate age, or that the product possesses special or unique characteristics</i></li> <li>• <i>shall not imply that the product is equivalent or superior to breastfeeding or family foods.</i></li> </ul> <p><b>Justification:</b> International Code of Marketing of Breastmilk Substitutes. WHO Risk assessment: <a href="http://www.who.int/foodsafety/publications/micro/pif2007/en/index.html">www.who.int/foodsafety/publications/micro/pif2007/en/index.html</a></p>
<p>4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively by persons having qualifications in</p>	<p>4. The dissemination <b>of scientific and factual</b> <del>any useful</del> information regarding the categories of food referred to in Article 1 (1) <del>may</del> <b>SHALL</b> be made exclusively <b>TO INDEPENDENT</b> persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care. In the case of</p>

medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

*formulas, such information should not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding.*

**Justification**

Under the International Code manufacturers have a duty to ensure that relevant scientific and factual information is provided to health professionals:

*The Code 4.1 says: Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover either the planning, provision, design and dissemination of information, or their control.*

*7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding. It should also include the information specified in Article 4.2.*

*7.3 No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or their families.*

While **WHA Resolution 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".*

**SECTION 3 SPECIFIC REQUIREMENTS**

**Article 10**

Specific composition and information requirements

1. Food referred to in Article 1(1) must comply with the requirements of Article 7 and composition and information requirements provided in Article 9.
2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC and Directive 1999/21/EC as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations, no later than [2 years after the date of the

**When it uses delegated acts to amend existing legislation, the Commission must respect the letter of the text in force and always seek to improve consumer protection. The precautionary principle laid down in Article 6a (new) is one of the fundamental principles which must guide food safety policy.**

**Changes of this nature may not take place without expert assessment of the EFSA and under appropriate democratic scrutiny ie the intervention of the European**



<p>entry into force of this Regulation], in accordance with Article 15, with respect to the following:</p> <ul style="list-style-type: none"> <li>(a) the specific compositional requirements of food referred to in Article 1(1);</li> <li>(b) the specific requirements on the use of pesticides in agricultural products intended for the production of such food and on pesticides residues in such food;</li> <li>(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims thereof;</li> <li>(d) the notification procedure for the placing on the market of a food referred to in Article 1(1) in order to facilitate the efficient official monitoring of such food on the basis of which food operators shall notify the competent authority of the Member State(s) where the product is being marketed;</li> <li>(e) the requirements on promotional and commercial practices relating to infant formulae; and,</li> <li>(f) the requirements on information to be provided on infant and young child feeding in order to ensure adequate information on appropriate feeding practices.</li> </ul> <p>3. Subject to the requirements of Articles 7 and 9 and taking into account relevant technical and scientific progress, the Commission shall update the delegated Regulations mentioned in paragraph 2 in accordance with Article 15.</p>	<p><b>Parliament and the Council as co-legislator.</b></p> <p><b>The rules governing SCOFCAH meeting must be revised to ensure transparency and accountability.</b></p>
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## Note on milks for older babies

There is no proven medical or nutritional need for formulas to be marketed especially for older babies. After the age of 1 year, the milk recommended as part of a diet to ensure children grow and develop well is full fat cows milk, and there is no need for modified cows milk at this stage as the nutritional emphasis should be on food.

The Infant Formula Directive already permits a wide compositional range of nutrients that meet the requirement for formulas for older infants and young children and standard infant formulas is suitable throughout the first and second year. Heavily fortified modified milks for children over the age of 1 year are generally not required, and there is no evidence that adding additional nutrients as supplements to diets is advantageous for children, and some evidence emerging that high intakes of iron in particular are potentially harmful

The Federal Institute for Risk Assessment (BfR). 16.08.2011 formulas for babies over 1 year. *"According to the Federal Institute for Risk Assessment (BfR), toddler milk does not, however, offer any advantage compared to reduced fat cow milk, as recommended by nutritional scientists for infants. "From a nutritional and physiological point of view these special toddler milks are not necessary", says BfR President Professor Dr. Andreas Hensel. Enriched vitamins and minerals in those products rather result in an uncontrolled increase in the supply of some nutrients whereas other vitamins and minerals are included in lower amounts than in cow milk. Furthermore, it is currently not sufficiently proven in scientific terms that a reduced protein supply in early childhood reduces the risk of obesity and adiposity during the later childhood. The fat content of toddler milk is more or less comparable to the content of whole milk and hence higher than the content in reduced fat milk."* [www.bfr.bund.de/en/press\\_information/2011/29/toddler\\_milk\\_drinks\\_are\\_not\\_better\\_than\\_cow\\_milk-126749.html](http://www.bfr.bund.de/en/press_information/2011/29/toddler_milk_drinks_are_not_better_than_cow_milk-126749.html)

The **German Consumer Association** survey in 2011 found that the milks on the market (called Kindermilch) were up to four times more expensive than normal milk, costing parents up to 245 euros more each year and commonly had twice as much sugar as normal milk. <http://www.vzhh.de/ernaehrung/129727/kostenfalle-kindermilch.asp>

*Iron-Fortified vs Low-Iron Infant Formula Developmental Outcome at 10 Years* Betsy Lozoff, MD; Marcela Castillo, PhD; Katy M. Clark, MA; Julia B. Smith, EdD Arch Pediatr Adolesc Med. Published online November 7, 2011. This study from Chile indicates that infants with high iron levels at 6 months, who were fed iron-fortified formulas had IQ levels 10 points lower at the age of 10 years than infants who had low-iron levels

WHA 2010 Resolution 63.23 calls on Member States (4) *to end inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation;*

This commentary is available on the following link

<http://info.babymilkaction.org/node/514>

For more information contact

Patti Rundall : [prundall@babymilkaction.org](mailto:prundall@babymilkaction.org)

+44 7786 523493