



## How to make the Regulations better protect child health

IBFAN /BFLG comments on EU Commission Proposals for Working Documents on delegated Regulations pursuant to Article 11(1) of Regulation (EU) No 609/2013

1. Infant formula (IF) and Follow-on formula (FUF)
2. Food for Special Medical Purposes (FSMPS)
3. Processed cereal-based food and baby food
4. Formulas for young children

**These comments are prepared by IBFAN and the BFLG for consultations with the European Commission and Member States on the above proposals.**

The **International Baby Food Action Network** (IBFAN) is a global network of 273 groups in 168 countries. IBFAN is an independent watchdog that protects babies and their families. IBFAN monitors company practices and highlights conflict of interests in policies and programmes.

IBFAN takes no funding from the baby feeding industry.

The **Baby Feeding Law Group** (BFLG) is a coalition of 22 leading UK health professional and lay organisations. BFLG was founded in 1997 to bring UK and EU legislation into line with World Health Assembly Resolutions.

**BFLG members:** Association of Breastfeeding Mothers , Association for Improvements in the Maternity Services , Association of Radical Midwives, Baby Milk Action (secretariat), Best Beginnings, Breastfeeding Network, Community Practitioners and Health Visitors Association First Steps Nutrition Trust , Heart of Mersey, Lactation Consultants of Great Britain , La Leche League (GB), Little Angels, Midwives Information and Resource Service, NCT, Royal College of Midwives. Royal College of Nursing, Royal College of Paediatrics and Child Health, The Baby Café, UK Association for Milk Banking Unicef UK Baby Friendly Initiative, UNISON , Women's Environmental Network

## The adoption of these proposals will undermine child rights

Breastfeeding constitutes one of the single most effective interventions in order to fulfill the child's rights to life and to the enjoyment of the highest attainable standard of health.

All EU Member States (MS) have endorsed the *International Code of Marketing of Breastmilk Substitutes (IC)* and the subsequent relevant WHA Resolutions (that clarify and update the IC). These are designed to remove obstacles to breastfeeding and ensure that breastmilk substitutes are used safely if needed. They aim to protect everyone from misinformation and commercial promotion – protecting both breastfed and artificially fed babies. They are not just for developing countries: they are **minimum** requirements for **ALL countries**.

All EU MS have also ratified the *Convention on the Rights of the Child*, a Human Rights Treaty that came into force in 1990. Article 24 of CRC calls on governments to provide parents with information on nutrition and breastfeeding and the CRC General Comment No. 15 explains what this means. It stresses the obligation for States to protect, promote and support breastfeeding through the implementation of the World Health Assembly *Global Strategy for Infant and Young Child Feeding. (GSIYCF)*<sup>1</sup> It also sets a direct obligation to companies to abide by the IC universally.

Nations that ratified the Convention are bound to it by international law and thus have clear obligations. Nothing that the EU Commission says can alter this. Member states (MS) must ensure that the Commission does not undermine a human right international law and thus misinterpret duty/obligation under it.

The IC and WHA Resolutions are embedded in many global declarations, standards and strategies, including the EU Action Plan of Childhood Obesity and the INC2 Political Declaration and Framework for Action<sup>2</sup> adopted just last November. Breastfeeding is one of the EUs CORE Health Indicators for Determinants of Health. The regulations could undermine implementation and thus success of these initiatives – wasting public resources

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<sup>1</sup> **CRC General Comment No 15**, Para 44.

*Exclusive breastfeeding for infants up to 6 months of age should be protected and promoted and breastfeeding should continue alongside appropriate complementary foods preferably until two years of age, where feasible. States' obligations in this area are defined in the "protect, promote and support" framework, adopted unanimously by the World Health Assembly. States are required to introduce into domestic law, implement and enforce [...] the International Code on Marketing of Breast-milk Substitutes and the relevant subsequent World Health Assembly resolutions [...] 81. Among other responsibilities and in all contexts, private companies should [...] comply with the International Code of Marketing of Breast-milk Substitutes and the relevant subsequent World Health Assembly resolutions [...] <http://www.ohchr.org/en/HRBodies/CRC/Pages/CRCIndex.aspx>*

**CRC General Comment No 16 on State obligations regarding the impact of the business sector on children's rights** 57. *States are also required to implement and enforce internationally agreed standards concerning children's rights, health and business, including [...] the International Code of Marketing of Breast-milk Substitutes and relevant subsequent World Health Assembly resolutions.*

<sup>2</sup> Framework for Action adopted at ICN2: **Recommended actions to promote, protect and support breastfeeding** Recommendation 29: Adapt and implement the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly resolutions. <http://www.fao.org/3/a-mm215e.pdf>

## **The EU Commission's proposals fail to meet their stated objective of providing protection to vulnerable consumers.**

- Art 114 of the Treaty on the Functioning of the European Union (TFEU) requires Member States (MS) to "take as a base a high level of protection taking account in particular of any new development based on scientific facts." ie offer a high level of health, safety and consumer protection.
- Recital 20 and Art 1.2 require the rules to be in conformity with the *International Code of Marketing of Breastmilk Substitutes*. (IC)<sup>3</sup> (The Commission should encourage MSs and Commission staff to go on an ICDC training course)
- Art 5 of Regulation 609/2013 states that the precautionary approach should be applied.

## **There are some welcome improvements in the new proposals related to composition and claims. However, if the proposals are to be considered a step forward the following MINIMUM changes must be made:**

- The Regulation must meet the minimum requirement of the International Code and subsequent relevant WHA Resolution.
- MS must have Legal surety to regulate labelling, marketing and advertising according to national health priorities and policies
- Baby food: labelling and sugar levels in line with WHO recommendations.
- Prior authorization by an independent expert body such as EFSA. - of the safety and beneficial effect of ALL ingredients – including those voluntarily added – and of foods claiming to be FSMP
- No FSMP FUF.
- Full consideration of the global impact – policy coherence with the EU's International obligations – failing that - product specific safeguards on exports.
- Revision of provisions to stop cross-promotion of IF with FUF and other baby foods
- Marketing of formulas for older babies and young children strictly controlled.
- Requirement that the process for transposition into national law and subsequent enforcement is free from commercial conflicts of interest.
- Requirement that MSs "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" as required by WHA
- Requirement that MSs publicise the authority responsible for the enforcement of the regulations and how members of the public can report violations and make criminal charges.

Despite some welcome improvements in certain areas, the proposals are out of date and contradictory to the EU's Internationally agreed commitments and current health policies. They will have an overall damaging impact.

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<sup>3</sup> The reference to the *International Code of Marketing of Breastmilk Substitutes* fails to refer to the subsequent, relevant WHA Resolutions that should be read together with the IC.

## KEY WEAKNESSES IN THE PROPOSALS

1. **They falsely imply that they are in conformity with the IC.** This is highly misleading when they claim to implement the IC but fall so far short of its key provisions in relation to scope (products covered) and commercial promotion, so clearly forbidden by the I. The IC does not specify products by age of use but focuses on the function of the products in question - whether they are marketed to partially or totally replace the breastmilk part of an infant or young child's diet. It aims to ensure complete and truthful labelling and scientific and factual information for health workers.
2. **They give no public health rationale for the stark difference in marketing rules.** Following EFSA's recommendations<sup>4</sup> the only difference between IF and FUF will be overlapping max and min levels of iron. EFSA states that IF with the minimum FUF iron requirement can continue to be used throughout the first year. Most Infant formula already meet such requirements and many IF are on sale 0-12months. Furthermore the proposals imply that FUF is a BMS over 6 months – as the *principal liquid element* (Recital 15) that should not be *used* as a breastmilk substitute during the first six months of life (Art 9.2.b). The suggestion that FUF advertising should not '*discourage breastfeeding*' (Art 9.3) is superficially appealing, but illogical. Advertising will inevitably undermine breastfeeding and manufacturers regularly refer to breastmilk as the 'gold standard' as a deliberate marketing strategy.
3. **They provide MS with no legal surety that they can regulate marketing according to national health priorities and policies.** The proposals need to be rewritten to emphasise that FUF is not necessary and that its promotion undermines breastfeeding (both above and below 6 months) and misleads mothers who use formula.<sup>5</sup> Permission for MSs to allow FUF advertising should be the exception rather the rule.

*"As reported in a number of studies, while follow-up formula may not be explicitly promoted as a breast-milk substitute, documented marketing strategies, such as packaging, branding and labelling may induce mothers to use follow-up formula in the first six months of life and/or to stop breastfeeding after this period. **If follow-up formula is marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement for breast milk, it is covered by the Code. In addition, where follow-up formula is otherwise represented in a manner which results in such product being perceived or used as a partial or total replacement for breast milk, such product also falls within the scope of the Code.**"* (Information concerning the use and marketing of follow-up formula WHO July 2013<sup>6</sup>)

4. **They are weak on cross promotion:** They repeat provisions intended to stop cross promotion that have proven ineffective in the current Directive : The regulations must address the problem of IF being cross promoted by FUF and other products to protect the public in any MS that do choose to permit advertising of FUF. Cross-promotion with infant formula that is the now the global norm. The UK Department of Health introduced Guidance Notes on interpreting the current regulations to

<sup>4</sup> Scientific Opinion on the essential composition of infant and follow-on formulae  
[www.efsa.europa.eu/en/efsajournal/pub/3760.htm](http://www.efsa.europa.eu/en/efsajournal/pub/3760.htm)

<sup>6</sup> Information concerning the use and marketing of follow-up formula WHO 17<sup>th</sup> July 2013  
[http://www.who.int/nutrition/topics/WHO\\_brief\\_fufandcode\\_post\\_17July.pdf?ua=1](http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf?ua=1)

tackle this but are not recognised as having legal weight by companies or enforceable by Trading Standards. The primary regulations must either provide the required clarity to stop cross promotion or explicitly delegate MS to introduce national requirements with equal weight to the regulations

5. **They permit labelling of processed baby foods from 4 months.** This contravenes the IC and *Global Strategy* and is out of step with current scientific evidence and health policies – policies that have proven effective. As a public health recommendation, complementary foods should not be introduced until 6 months of age (this does not prevent earlier introduction if necessary, but the recommendation should not be undermined by contrary labeling).
6. **They permit processed baby foods to have up to 30% of their energy from added sugar.** This is way higher than most recommendations, including the soon to be released WHO Guidelines. The introduction of such foods – especially so early - contributes to the rising levels of childhood obesity and affects the developing taste palates of children.<sup>7</sup>
7. **They ignore the global impact** at a critical time when law-making processes are subject to intense lobbying, legal challenges from industry interests and diplomatic interventions from trading partners. In this context the decisions of international and regional bodies, such as the Codex Alimentarius Commission, WHO and the EU can play an important role in establishing a health protective framework. The adoption of such a deficient and flawed EU Regulation, focusing only on products for the first 6 months of life, will be a retrograde step in terms of global health, sustainability, food security, childrens' fulfilment of their right to health, adequate food and nutrition.
8. **They permit badly labelled exports.** The Export Directive (92/52/EEC) requiring products to be labelled in the appropriate language will be repealed. The common rules for exports outlined in EU Directive (1061/2009), cited as the justification for repealing 92/52/EEC,<sup>8</sup> have no such requirement. Unless addressed elsewhere, the requirement that products comply with the legislation of the importing country will not be sufficient. Countries that have not yet adopted the IC into legislation and banned promotional claims (such as the discredited DHA visual acuity claim) will be forced to accept all EU imports - however risky they might be. **(Question:** what will happen to the 1992 Council Resolution that aimed to "*encourage compliance with the International Code of Marketing of Breast-milk Substitutes*" in third countries by Community-based manufacturers?<sup>9</sup>
9. **They do not take full account of the concerns expressed by MEPs** who, in any case, voted on regulation 609/2013 BEFORE the publication of the 2014 EFSA report on essential ingredients. MEPs would have been unaware of EFSA's clear opinion that IF and FUF should be virtually the same. Or that many of the ingredients in IF and FUF are not necessary and that their addition can be a burden to a young child's metabolism. Indeed for some of the maximum levels of nutrients the scientific evidence for adverse effects is missing. While Article 5 of 609/2013 does refer to the Precautionary Principle (called for by MEPs) this it is mentioned only in relation to pesticides rather than across all relevant provisions.

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<sup>7</sup> EU and US block Thailand's proposal to reduce sugar in baby foods IBFAN 3 Nov 2006:

[http://info.babymilkaction.org/sites/info.babymilkaction.org/files/ibfanpressrelease031106\\_0.pdf](http://info.babymilkaction.org/sites/info.babymilkaction.org/files/ibfanpressrelease031106_0.pdf)

<sup>8</sup> State of the Code by Country, 2014. IBFAN ICDC.

<sup>9</sup> COUNCIL RESOLUTION of 18 June 1992 on the marketing of breast-milk substitutes in third countries by Community-based manufacturers (92/C 172/01)

10. **They fail to protect breastfeeding and optimal young child feeding:** In addition to the above and the specifics comments outlined later, the proposals use out dated text that fails to take into account new evidence on the health risk of not breastfeeding, the need for its protection and the impact of marketing on parents perceptions and understanding of risks. These aspects are entirely missing

**Breastfeeding is cost saving** Aside from the acknowledged risks of artificial feeding, the economic impact of low breastfeeding rates is substantial. Investing in services that support women who want to breastfeed according to WHO recommendations is potentially cost saving. For example, the number of months of exclusive breastfeeding is related to potential cost savings of at least £31m (at 2009-2010 value) in breast cancer treatment in women.<sup>10</sup>

*"Treating the four acute diseases in children costs the UK at least £89 million annually. The 2009–2010 value of lifetime costs of treating maternal Breast cancer (BC) is estimated at £959 million. Supporting mothers who are exclusively breast feeding at 1 week to continue breast feeding until 4 months can be expected to reduce the incidence of three childhood infectious diseases and save at least £11 million annually. Doubling the proportion of mothers currently breast feeding for 7–18 months in their lifetime is likely to reduce the incidence of maternal BC and save at least £31 million at 2009–2010 value."*

*Potential economic impacts from improving breastfeeding rates in the UK. Pokhrel S, et al. Arch Dis Child 2014;0:1–7.*

**They fail to control Bottles, Teats and other feeding equipment:** What plans are there to implement the provisions of the International Code relating to these products in a separate regulation? The new capsule machines for preparing bottles of formula, for example, contain formula and are not regulated. (Since 1983 the UK has been calling for controls on Bottles and Teats.)

**They fail to provide legal surety for MSs on key health concerns.** Instead of providing MSs with the legal surety they need to control regulate marketing in line with national health priorities, the proposals put obstacles in their way. Many MS have tried to take action to protect their vulnerable consumers. Some have been dissuaded (eg UK, Malta, Italy). Others succeed: Luxembourg and Norway (not in EU).

Despite claims to the contrary, 91/321/EEC and 141/2006/EC were not fully harmonised Directives by any measure and as a consequence several EU MSs have forbidden FUF marketing:

- Both expressly permitted more restrictive controls on advertising of IF as does the proposed regulation
- Both allowed extensive differences in composition, through the addition of optional ingredients.

#### **The SMA case - companies seek the lowest regulatory standards**

In 2003 baby formula manufacturer Wyeth/SMA was prosecuted by Birmingham Trading Standards over an advertisement that contravened UK Law. SMA argued that UK legislation '*fetters the free movement of goods*' and should be no stricter than the weakest of any other country. Defending the UK's right to legislate more strictly, Judge Ross used the so-called Keck Case ruling that: *as long as all companies are treated equally within a country, regulations on selling arrangements, which are extrinsic to*

<sup>10</sup> *Potential economic impacts from improving breastfeeding rates in the UK. Pokhrel S, et al. Arch Dis Child 2014;0:1–7.*

doi:10.1136/archdischild-2014-306701

<http://adc.bmj.com/content/early/2014/11/12/archdischild-2014-306701.full.pdf+html>

## SPECIFIC COMMENTS

### 1 Infant formula (IF) and follow-on formula (FUF)

#### 1 Recitals

#### 2 "Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding." [emphasis added].

The use of 'first months of life' in this text is too ambiguous, given the requirement that only infant formula is marketed 'during the period'. Complementary foods are often marketed for use during the first 6 months of life.

(4) **"good health"** There is no clarity on what this means. Elsewhere (Art 2.2) the term 'normal healthy' is used.

(5) **"sophisticated"** This is idealizing language and should be replaced by **"highly processed"**

(6) **The voluntary addition of ingredients** continues to be a **MAJOR FLAW** that opens the door to promotional claims. The text here is also weak. The suitability of any ingredient in formulas should always be thoroughly scrutinised by an independent scientific Committee – not linked to food business operators - before permission for inclusion is granted. The text in (6) and Articles 3 and 4 - should be replaced with the following text from Article 5 with an extra reference to independent research and scrutiny:

*"Appropriate studies, **independently funded and reviewed**, performed following generally accepted expert guidance on the design and conduct of such studies"*

We support the [UK Government's Scientific Advisory Committee on Nutrition](#) (SACN) that states that the notion of optional/voluntary ingredients is unethical:

*"... 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."<sup>11</sup>*

(11) We welcome the provision that the nutrition information is mandatory for all package sizes. For consistency with the last sentence add a 3<sup>rd</sup> column to all tables in Annexes based on 100 ml.

12 The **'further information'** may be an entry point for promotional claims or statements that could mislead and confuse parents. This needs careful attention. *"Given the different role of infant formula and follow-on formula in the diet of infants, it is appropriate to lay down provisions requiring that a clear distinction can be made between different formula products so as to avoid any risk of confusion."* [Also see Art9 (4)].

On the issue of making a 'clear distinction', the existing Commission Directive uses similar language, which has proved to be ineffective in practice; Across Europe products are labelled to be cross promotional and it is a challenge to distinguish what is infant formula, follow-on formula and growing-up milk. Evidently, more robust wording is needed in the Directive, perhaps stating that the brand name and logo used for infant formula must be unique (note, clearer provisions are also required on logos as the above are idealising, encompassing shields, hearts and breastfeeding mothers).

(13) The Nutrition information should include a clear statement that

<sup>11</sup> [http://www.sacn.gov.uk/pdfs/position\\_statement\\_2007\\_09\\_24.pdf](http://www.sacn.gov.uk/pdfs/position_statement_2007_09_24.pdf)

**IF can continue to be fed to babies over 6 months** alongside family foods  
**FUFs are NOT Necessary.**

*EFSA sees no problem with using IF throughout the first year of life provided its iron content is appropriate.*<sup>12</sup> *Many infant formulas are marketed for the first 12 months of life.*

- (15) **DHA:** We welcome the Commission's acknowledgement that in principle the use of claims for ingredients that are mandatory is inappropriate for infant formula. However unless such thinking is extended to FUFs and unless the voluntary addition of ingredients is stopped, the safeguard is meaningless. Despite the legal requirement that FUFs are packaged differently to IF (and now to FSMP also) a huge range of formulas for older babies and young children are aggressively marketed. These products are hardly distinguishable from each other and invariably shelved right alongside IF. FUF and formulas for babies over 12 month were invented by industry to get round marketing restrictions. Unless these proposals are tightened up, they will all be allowed to carry any claim approved by EFSA – including the visual acuity claim so hotly challenged by MSs, MEPs, Health professionals and others.<sup>13</sup> This issue has to be addressed.

We understand that the Commission believes that the modest wording on the IF claim/statement and the restriction to 5 years is a good compromise however it makes no sense in terms of health.

Given the lack of post-market surveillance and the weakness and inconsistency of the available evidence - especially in relation products for older babies - the DHA health claim must be reconsidered. only following a Freedom of Information Request. If DHA is to be mandatory for all formulas, a warning rather than a claim may be needed.<sup>14</sup>

The Precautionary Principle should be employed and EFSA asked to re-examine their opinion. The evidence that a subset of babies could not tolerate synthesized DHA came to light in the USA

*"... in order to ensure comparisons with other foods that can be included in the diet of infants and young children together with complementary feeding, expression of nutrition information for follow-on formula as percentage of daily reference intake values. (Article 10 (7))."*

Follow-on formulas are unnecessary products and this labelling will be used for promotional purpose. Follow-on milks and so-called growing-up milks are already promoted with the suggestion that children may not receive adequate nutrients unless fed with the products. The Advertising Standards Authority (ASA) in the UK has upheld complaints against Nestlé and a supermarket for an email campaign promoting SMA toddler milk, stating it, 'told them not to state or imply that health could be affected by not consuming a product, or to give rise to doubt the nutritional adequacy of a reference product.

- (16) **HA/Allergy claim** We believe that HA claims are misleading, highlight promotional and should not be permitted. The claim Recital 25 of Regulation 609/2013 also states: *The labelling, presentation or advertising of food covered by this Regulation should not attribute to such food the property of preventing, treating or curing a human disease nor should they imply such properties.*

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<sup>12</sup> Para 6.7.6: *If the same formula is to be used from the first months of infancy and be suitable for the whole first year of life, the minimum iron content should be 0.6 mg/100 kcal (0.14 mg/100 kJ) for milk-based formulae and formulae containing protein hydrolysates and 0.9 mg/100 kcal (0.22 mg/100 kJ) for formulae containing ISP". EFSA Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760*

<sup>13</sup> <http://www.babymilkaction.org/wp-content/uploads/2015/01/DHA-V13.pdf>

<sup>14</sup> 98 reports obtained after a Freedom of Information request US FDA. *Replacing mother - Imitating Breast Milk in the Laboratory.* [www.cornucopia.org](http://www.cornucopia.org) FDA Q&A: [www.fda.gov/Food/FoodSafety/Product](http://www.fda.gov/Food/FoodSafety/Product): FDA letter regarding the lack of post-market surveillance: [http://info.babymilkaction.org/sites/info.babymilkaction.org/files/FDA Post market.pdf](http://info.babymilkaction.org/sites/info.babymilkaction.org/files/FDA%20Post%20market.pdf)



[First Steps Nutrition Trust Statement](#) on Partially hydrolysed whey based infant formula.<sup>15</sup>

(17) **Subsequent relevant resolutions** are missing. They clarify and update the IC and should be always read together with it. A reference or footnote to this effect should be included. We are not aware of any particular legal and factual situations in the EU that would constrain full implementation of the IC and Resolutions, all of which are consistently endorsed by all EU MSs. (see above).

(18) This paragraph should make it clear that the **Regulation is a minimum and that countries can regulate marketing according to the national health priorities and policies.**

Change the word “**choosing**” to “**deciding**”

After “**products in question**” ADD “**for infants who need them**”

**REMOVE: ~~the promotion of~~ breastfeeding** (note: breastfeeding should be ONE WORD)

(19) See comments under article 12.1

(20) Does this refer to monitoring of composition or also labelling and marketing?

## B Articles

**Art1.1** see comment on **Recital 4)**

**Art 1.2** see **Recital 17**

**Arts 3,4:** see recital **(6)**

**Article 5.** Box linking to para 3. Should the evaluation of ingredients and products be left to national authorities alone? Are all Member States ready and able to carry out thorough independent reviews of all evidence?

## ARTICLE 9. (see comment on page 1)

**Title: Remove all references to ADVERTISING from the title and the Article unless it refers to the regulation /prohibition of advertising.**

This article is the most problematic. Considering the strong health concerns expressed by MS, health and development NGOs and parliamentarians about follow on milk marketing the Commission must change this section giving MSs the legal surety that they can regulate promotion according to their national priorities and policies. ADVERTISING of these products will inevitably discourage and undermine breastfeeding and is specifically forbidden by [Article 5 of the International Code](#).<sup>16</sup> ..

### Art 9. 2.

A Add that the product can continue to be used AFTER 6 months.

B ADD to the Statement this NEW TEXT:

***FOLLOW ON FORMULAS are NOT NECESSARY (with a reference to WHO Statement [http://www.who.int/nutrition/topics/WHO\\_brief\\_fufandcode\\_post\\_17July.pdf](http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf) and continued breastfeeding /use of infant formula, alongside appropriate complementary food is the preferred recommendation for optimal infant and young child feeding.***

<sup>15</sup> <http://www.firststepsnutrition.org/pdfs/Statement%20on%20partially%20hydrolysed%20whey%20based%20formula.pdf>

<sup>16</sup> <http://www.who.int/nutrition/publications/infantfeeding/9241541601/en/>

- c) The appropriate preparation instructions must follow [WHO Recommendations](#), including on reducing the risk from intrinsic pathogens using boiled water that is cooled to no less than 70 degrees.<sup>17</sup>

**NEW: ADD requirement for a prominent warnings about the health risks associated with the products, including a warning that a subset of babies may not tolerate the mandatory artificial DHA.**

**Art.9.3** This is a particularly misleading article that appears superficially to be health protective. However all advertising of these products will inevitably promote alternatives and discourage and undermine breastfeeding. It is common for manufacturers to refer to breastfeeding as the gold standard as a way to promote their products. See comment above on the title.

**Art 10 2** This is not clear. See comments on Recital 12.

**Art 11: ADD Follow-on Formula and change to read:** *Nutrition and health claims for infant formula and follow-on formula should be forbidden.*

**Art 12 This should include follow-on formula in the title and all sub paras.**

**Art 12.1** Advertising should not be permitted in any parents magazines. Some MS consider that baby care publications are parents' magazines. The IC permits scientific and factual information for health workers not advertising.

**Art 13.1 Change to read:** *Member States shall ensure that objective and consistent information, **free from commercial influence**, is provided on ...*

**Art 13.2 (c)** replace 'bottle feeding' with '**formula feeding**' *When such materials contain information about the use of infant formula **ADD: OR FOLLOW-ON FORMULA** they shall.... Such materials shall not use any pictures or text which may idealise the use of infant formula **ADD: OR FOLLOW ON FORMULA***

**13.3** This para is now totally out of date and all such donations should be forbidden. Several WHA Resolutions (WHA 49.15 (1996) and WHA58.32 (2005) have called on Member States not to permit inappropriate funding of programme :**"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"** [Subsequent relevant resolutions](#)<sup>18</sup>

**13.4 This paragraph is also out of date. Since 1992 and 1994 the WHA has been clear that donations of breastmilk substitutes should not be made.**  
*2 (2) to ensure that there are no donations of free or subsidized supplies of breast-milk substitutes and other products covered by the International Code of Marketing of Breast-milk Substitutes in any part of the health care system; (WHA 47.5 (1994)*

**Art 14.** We have many concerns about the notification system proposed. See comments on Recital 6. All ingredients should be pre-authorized and thoroughly scrutinized.

**Art 15** The 5 Year permission allowed for Art 5.3 is far too long. Why is it needed at all when it's a mandatory ingredient?

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<sup>17</sup> [http://www.who.int/foodsafety/fs\\_management/No\\_01\\_Esakazakii\\_Jan05\\_en.pdf?ua=1](http://www.who.int/foodsafety/fs_management/No_01_Esakazakii_Jan05_en.pdf?ua=1)

<sup>18</sup> [http://www.who.int/nutrition/topics/wha\\_nutrition\\_itycn/en/](http://www.who.int/nutrition/topics/wha_nutrition_itycn/en/)

## Annexes:

See previous comment: Following EFSA 's recommendations <sup>19</sup> the only difference between IF and FUF will be overlapping max and min levels of iron. EFSA identifies risks of unnecessary overload on infant metabolism but no explanation is given for the permitted maximum levels.

The EFSA values '*should be understood as target values which cover the nutritional needs of virtually all infants born at term*' EFSA also say that '*maximum values were mostly calculated as 3-5x these amounts and were not based on scientific evidence for adverse effects as there was no evidence*'.

The Regulations should clearly state that no 'HA' claim should be permitted.

## 2 Food for special medical purposes (FSMPS)

*"...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.'*

*Summary Record of the Standing Committee on the Food Chain and Animal Health, 22 June 2012*

The marketing of FSMPS has been a major concern and attention to the aggressive promotion of these products is well overdue. We welcome the Commission's explicit proposal they should not carry promotional claims and that the marketing of FSMP infant formula is controlled in the same way as standard infant formula. For examples [CLICK HERE](#)

However the regulation contains several loopholes. For example it refers to the advertising of FUF. At the recent Code Nutrition Meeting in Bali in November 2014, the European Commission supported a comment made by IACFO that there could be no medical need for an FSMP follow-on formula. The reference to FUF advertising in this regulation should be deleted.

The definition of FSMPS should stress the need for continuing medical supervision: (eg. extreme prematurity, high dependency care, congenital metabolic syndromes, organ failure and severe malnutrition.)

FSMPS for infants and young children that are fed orally must carry all the warnings and notices required by the *International Code* regarding the superiority of breastfeeding and risks of artificial feeding, alongside the necessary precautions, known side-effects, contraindications, product-drug interactions, and alongside appropriate information about the correct use of the product. The argument that including the breastfeeding statement poses risks to health is not valid in the majority of cases.

**Art 3.2: ADD:** Any products claiming to be an FSMP should first get prior approval that they are safe and beneficial for the specific disease or condition from an independent body such as EFSA.

**Art 9, 3, 4 5:** There should be no commercial promotion, including samples to Health Workers.  
Replace the reference to **Advertising in 9.3** to **Information**

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<sup>19</sup> Scientific Opinion on the essential composition of infant and follow-on formulae  
[www.efsa.europa.eu/en/efsajournal/pub/3760.htm](http://www.efsa.europa.eu/en/efsajournal/pub/3760.htm)

### 3 Processed cereal-based food and baby food

The Regulation covering processed baby foods is out of step with current scientific thinking and apart from the welcome provisions on pesticides, is very weak in terms of labelling, marketing and advertising. Labelling from 4 months is outdated and will undermine government's efforts to protect and support optimum infant and young child feeding practices. It contravenes WHA recommendations which were established after a systematic review of over 3000 studies and is now policy in over 70 countries, including the UK.<sup>20</sup>

Labelling of baby foods as suitable from 4-months encourages the introduction of solid foods before the vast majority of babies are developmentally ready to eat family foods. Too early introduction of solids along with the high levels of sugar permitted in EU legislation contributes to the rising levels of childhood obesity.<sup>21</sup> The current regulation permits processed cereal foods to have up to 30% of their energy from added sugar.

The **2009 EFSA Opinion** that underpins the Regulation is in many ways illogical and contradictory. It acknowledges that *"full breast feeding for up to 6 months provides greater protection than partial breast feeding or shorter breast feeding against the risk of infectious morbidity."* But in its conclusion states that *"the introduction of complementary food....between the age of 4 and 6 months is safe and does not pose a risk for adverse health effects...."* If foods are started 4-6 months, breastfeeding cannot be full or exclusive for 6 months so babies are put at unnecessary risk of increased morbidity.<sup>22</sup>

**Impact on public health recommendations:** EFSA has failed to consider the issue of developmental readiness, or the wider issue of how public health recommendations are interpreted. Before the UK adopted the WHO 6 month recommendation, the 5-yearly UK Infant Feeding Surveys shows that most babies were given solids far too early, before 4 months.<sup>23</sup> The message to start solids from 6 months led to a postponement until the 4-5 months, an important behavioural shift in public health terms. The proportion of mothers introducing solid foods by 4 months fell from 85% in 2000 to 51% in 2005. The proportion introducing by 3 months halved in that five years, from about 23% to 10%. (6) If the EFSA opinion is used to inform policy one can expect a reversal of this positive trend.

**Over-emphasis on Coeliac Disease.** The studies used by EFSA regarding the age of introduction of gluten use at risk populations, but give no convincing argument for introducing solids to breastfed babies between 4-6 months rather than after six months. A much more important factor in reducing the incidence of Coeliac Disease seems to be the continuation of breastfeeding alongside the introduction of gluten. This EFSA opinion seems to indicate that there has been commercial influence. One member of the EFSA Working Group tasked with examining this issue, Carlo Agostini, declares funding from 9 baby food companies<sup>24</sup> and was also a co-author of a paper on *Complementary Feeding by the European Society for Pediatric Gastroenterology,*

<sup>20</sup> Resolution (WHA 54.2) 2001 URGES Member States: 2.6: to improve complementary foods and feeding practices by ensuring sound and culture-specific nutrition counselling to mothers of young children, recommending the widest possible use of indigenous nutrient-rich foodstuffs; 3 REQUESTS the Director-General: 3.3) to provide support to Member States in the identification, implementation and evaluation of innovative approaches to improving infant and young child feeding, emphasizing exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding (note 1), the provision of safe and appropriate complementary foods, with continued breastfeeding up to two years of age or beyond, and community-based and cross-sector activities; [www.who.int/nutrition/publications/infantfeeding/en/index.html](http://www.who.int/nutrition/publications/infantfeeding/en/index.html)

<sup>21</sup> EU and US block Thailand's proposal to reduce sugar in baby foods 3 Nov 2006:

[http://info.babymilkaction.org/sites/info.babymilkaction.org/files/ibfanpressrelease031106\\_0.pdf](http://info.babymilkaction.org/sites/info.babymilkaction.org/files/ibfanpressrelease031106_0.pdf)

<sup>22</sup> *Breastfeeding Duration and Associated Decrease in Respiratory Tract Infection in US Children* PEDIATRICS Vol. 117 No. 2 February 2006, pp. 425-432 (doi:10.1542/peds.2004-2283)

<sup>23</sup> Infant Feeding Survey 2005, Keith Bolling, Catherine Grant, Becky Hamlyn, Alex Thornton, ONS [www.ic.nhs.uk](http://www.ic.nhs.uk) Infant Feeding Survey 2005: A commentary on infant feeding practices in the UK Position statement by the Scientific Advisory Committee on Nutrition 2008 paras 40 and 90-100

<sup>24</sup> Carlo Agostini Annual Declaration of Interest (06/07/2009) lists fees for Scientific publications, speaker's fees and conference expenses from Danone, Heinz, Hipp, Humana, Martek, Mead Johnson, Mellin, Milupa and Nestlé.

*Hepatology, and Nutrition* (ESPGHAN). This paper reintroduces the concept of complementary feeding from 4-6 months.<sup>25</sup> At the time of this paper ESPGHAN was sponsored by the Nestlé Nutrition Institute and Dr Schar, the leading European manufacturer of gluten free foods for sufferers of Coeliac Disease - a condition that is emphasised in the opinion.

### **WHO Guidance on Inappropriate Promotion of baby foods**

In order to provide clarification and guidance on the inappropriate promotion of foods for infants and young children WHO convened a *Scientific and Technical Advisory Group (STAG) on Inappropriate Promotion of Foods for Infants and Young Children Technical Paper on Definition of Inappropriate Promotion of foods for infants and young children*.<sup>26</sup> It has arrived at the following clarifications:

#### **What do we mean by “inappropriate promotion”:**

##### **1. Promotion is inappropriate if it undermines recommended breastfeeding practices<sup>3</sup>**

- a. Products should not be promoted as suitable before 6 months.
- b. Products should not be promoted to be given by bottles or using teats.
- c. Products should not be portrayed as equivalent or superior to breast milk.
- d. Products should not be promoted as a replacement for breast milk.
- e. Products should not be promoted using brands/labels/logos that are the same/similar to those used for breast-milk substitutes.
- f. Daily ration size should not exceed the amount of energy needed from complementary foods by breastfed children.

##### **2. Promotion is inappropriate if it contributes to childhood obesity and non-communicable diseases**

- a. Products should be limited in saturated fat, trans-fatty acids, free sugars, and salt.
- b. The portion size shown or recommended should provide an appropriate energy amount for the meal or part of a meal that it is designed to provide.

##### **3. Promotion is inappropriate if the product does not make an appropriate contribution to infant and young child nutrition in the country**

- a. Products should adhere to all applicable standards for safety and nutrient composition.
- b. Products should provide essential nutrients other than calories. minimally processed fruits, vegetables, and
- c. Promotion should encourage a diet based on a wide variety of foods, including animal-source foods.

##### **4. Promotion is inappropriate if it undermines the use of suitable home-prepared and/or local foods**

- a. Products should not be marketed as a complete substitute for home-prepared and/or local foods.
- b. Promotion should not suggest that commercial products are inherently superior to home prepared foods.
- c. Promotion should not imply that home-prepared or local foods should be delayed until after commercial products are fed.

##### **5. Promotion is inappropriate if it is misleading, confusing, or could lead to inappropriate use**

- a. Health claims should not be allowed unless specifically approved by national or international authorities.
- b. Information and instructions should be clear and correct and appropriate for the language and literacy of the target population.
- c. Promotion should not imply that products contain more of an ingredient than they in fact do.

<sup>25</sup> Complementary Feeding: A Commentary by the ESPGHAN Committee on Nutrition. *Journal of Pediatric Gastroenterology and Nutrition* 46:99–110 # 2008 by European Society for Pediatric Gastroenterology, Hepatology, and Nutrition and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition [http://espghan.med.up.pt/joomla/position\\_papers/con\\_28.pdf](http://espghan.med.up.pt/joomla/position_papers/con_28.pdf)

<sup>26</sup> [http://www.who.int/nutrition/events/2013\\_STAG\\_meeting\\_24to25June\\_recommendations.pdf](http://www.who.int/nutrition/events/2013_STAG_meeting_24to25June_recommendations.pdf)

## 4 Formulas for young children

The Commission has asked for opinions on various options for the marketing of these products. BFLG and IBFAN consider these products to be unnecessary and that a clear statement to this effect must appear in all public health guidance. These formulas are a risk nutritionally, both in terms of their higher sugar and iron content and that they extend the problems of cross branding identified already with FUF. See statement First Steps Nutrition Trust.<sup>27</sup>

If these products are to be allowed on the market, it is essential that they are covered by the IF FUF regulations and their marketing strictly regulated in line with MSs health priorities and policies. They must not in any case share branding with IF.

The Commission's new proposal to address marketing of these products through voluntary agreements is simply not credible or workable. It would simply compound the problem and feed into the CSR notion that manufacturers can be trusted to self-regulate.

The EU must take a position at Codex that supports the position of WHO and IBFAN. There should be no separate standard for these products, they should be brought into an overarching renamed standard for formulas for infants and young children where safety, composition and marketing can be addressed. Any reference to these products should be as a footnote to the that Standard.

Any Codex Standard or EU Regulation should state prominently that these products are not necessary and EU MSs and Third countries can refuse their import.

*"Our study confirms the results of previous studies legal advertisements of follow-on, or toddler, formula are perceived by pregnant women and mothers as promoting infant formula, which is forbidden by law."<sup>28</sup>*  
*Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy, Cattaneo A, et al. Arch Dis Child 2014;0:1–6*

<sup>27</sup> [http://www.firststepsnutrition.org/pdfs/Statement%20on%20Growing-up%20milks\\_July\\_2014.pdf](http://www.firststepsnutrition.org/pdfs/Statement%20on%20Growing-up%20milks_July_2014.pdf)

<sup>28</sup> *Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy, Cattaneo A, et al. Arch Dis Child 2014;0:1–6. doi:10.1136/archdischild-2014-306996*

NOP World for Department of Health. Attitudes to feeding: report of survey findings. London: Crown, 2005.

25 National Childbirth Trust. *Follow-on milk advertising survey: topline results*. London: UNICEF UK, 2005.

26 Berry NJ, Jones S, Iverson D. *It's all formula to me: women's understandings of toddler milk ads*. *BF Rev* 2010;18:21–30.

27 Berry NJ, Jones SC, Iverson D. *Toddler milk advertising in Australia: Infant formula advertising in disguise?* *Australasian Marketing Journal* 2012;20:24–7.

### Chronology of the International Code in the EU

- **May '81** The *International Code (IC)* is adopted at the World Health Assembly (WHA) with endorsement from **ALL EU countries**
- **Oct '81** EU Parliament (EP) votes to implement it
- **'82** EU Commission, under Commissioner Narjes, proposes that a weak code drawn up by the Association of Dietetic Foods industries (IDACE) should be used as a basis. During consultations with Member States (MS) the Commission claims that there is no proof that advertising undermines Breastfeeding. (BF)
- **'83** EU Parliament calls for the IC again rejecting the IDACE Code.
- **'84** Wyeth (SMA) launches FUF in UK with a £1/2 m campaign. Health Visitors mount a campaign against them, highlighting their risks.
- **'85** 3 EP Committees (ACP Lome, Economic and Social and Development) call for the IC.
- **'86** EP votes in 33 strengthening amendments to IDACE Code, and new Commissioner Lord Cockfield accepts them.
- **'86-89** Bureaucratic limbo. The Council adopts the Framework Directive for Foodstuffs for Particular Nutritional Uses (PARNUTS), granting power to the Commission to finalise legislation in this area with no second reading from the EP. The Commission is challenged for failing to include all the amendments proposed by the EP.
- **'89** UK Health Minister Edwina Curry bans free and low-cost supplies.
- **'91** 1,500 letters to the Commission. Several meetings with Commission. WHO highlights 20 weaknesses. Commission accepts that aim of Directive is to protect health.
- **May '91** Directive 91/321/EEC adopted with new clause permitting prohibition of IF advertising and strengthened supplies section. NL votes against because of the Code. The Danes against because of sugar. UK regrets lack of B&T and exports and weak FUF section.
- **'92** Export Directive (92/52/EEC) calls for appropriate language (s) Council Resolution calls for Code compliance in 'third countries'.
- **'94** Global consensus is achieved on the IC under the Clinton administration.
- **'96, '99** New Regulations are passed that strengthen controls on Pesticides but allow an disease risk reduction allergy claim. UK argues against this claim and requires formulas to carry a warning.
- **'99** 900 health and development NGOs petition against the Medical Food Directive. The EU Commission resigns over corruption charges and the Directive is slipped through unnoticed
- **2000** Glenys Kinnock MEP and Baby Milk Action succeed in getting members of the Scientific Committee for Food (SCF) to publicly declare interests. Prof Jean Rey resigns. SCF is closed down, the EU Scientific advisory system is reformed with the intention of being at arms length from the political process. EFSA is created.
- **2003** SMA Case – the European point – SMA loses its case that UK legislation '*fetters the free movement of goods*' and should be no stricter than the weakest of any other country.
- **2005** Lisbon Strategy aims to make the EU the world's most competitive trading block by 2010
- **2006** Directive (2006/141/EC) adopted with many weaknesses.
- **2011** A majority of MEPs vote against the DHA visual acuity claim. But this was not an *absolute* majority (59 MEPs were not present) so the claim is legal.
- **2013** EP vote to repeal PARNUTs, ushering in Regulation No 609/2013. The Commission retains its power to finalise legislation - for 5 years.

## Key WHA resolutions:

### Scope of the International Code of Marketing of Breastmilk Substitutes,

Article 2 sets out the scope of the Code in terms of which products it applies to

*'The Code applies to the marketing, and practices related thereto, of the following products: breast-milk 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 breastmilk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.'*

Article 3 provides important definitions:

*,'Breast-milk substitute' means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.*

#### WHA Resolution 39.28 1986

*'Any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period*

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

#### WHA Resolution 49.15 1996

Member States are urged to *'ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding.'*

(2) *to ensure that the financial support for professionals working in infant and young child health does not create conflicts of interest, especially with regard to the [WHO/UNICEF Baby Friendly Hospital Initiative](#);*

#### 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".*

#### WHA Resolution 55.25 2002 endorses the Global Strategy for infant and young child feeding.

*Recognizing that infant and young-child mortality can be reduced through improved nutritional status of women of reproductive age, especially during pregnancy, and by exclusive breastfeeding for the first six months of life, and with nutritionally adequate and safe complementary feeding through introduction of safe and adequate amounts of indigenous foodstuffs and local foods while breastfeeding continues up to the age of two years or beyond;*

Member states are urged *'to ensure that the introduction of micronutrient interventions and marketing of nutrient supplements do not replace or undermine support for sustainable practice of exclusive breastfeeding and complementary feeding.'*

#### WHA Resolution 63.23 2010

Recognised *'that the promotion of breast-milk substitutes and some commercial foods for infants and young children undermines progress in optimal infant and young child feeding' and 'expressed deep concern over persistent reports of violations of the Code by some infant food manufacturers and distributors.'* It called on Member States to *'end inappropriate promotion of foods 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*

#### WHA Resolution 65.6 2012

Requested the Director-General *'to provide clarification and guidance on the inappropriate promotion of food for infants and young children cited in resolution 63.23, taking into consideration the ongoing work of the Codex Alimentarius Commission.'*

(2) *developing or, where necessary, strengthening legislative, regulatory and/or other effective measures to control the marketing of breast-milk substitutes;*

(3) *establishing a dialogue with relevant national and international parties and forming alliances and partnerships to expand nutrition actions with the establishment of adequate mechanisms to safeguard against potential conflicts of interest;*