2015: IBFAN/BFLG Briefing on Commission Delegated Acts[1]

The International Code and subsequent relevant World Health Assembly Resolutions are embedded in Codex instruments. These are used as benchmarks in trade disputes.

CODEX CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD CAC/RCP 20-1979 4.4*: National authorities should be aware of their obligations under the International Health Regulations (2005) with regard to food safety events, including notification, reporting or verification of events to the World Health Organisation (WHO).* ***They should also make sure that the international code of marketing of breast milk substitutes and relevant resolutions of the World Health Assembly (WHA) setting forth principles for the protection and promotion of breast-feeding be observed.***

Since 1981 when the *International Code of Marketing of Breast-milk Substitutes* (IC) was adopted at the World Health Assembly, the European Parliament has called for its adoption as an EU Directive. All EU Member States (MS) have endorsed the *International Code of Marketing of Breastmilk Substitutes* (IC) and the 15 subsequent relevant WHA Resolutions (that clarify and update the IC). (See Chronology)

After many years of protracted struggle between Parliament, health advocates and the EU Commission, two flawed Directives that implemented parts of the IC were adopted in 1991 and 1992. They were revised in 2006. A new round of discussions began in 2013 when the EP voted to repeal the Framework Directive of Foodstuffs for Particular Nutritional Uses (PARNUTS) and adopt Regulation 609/2013.

In January 2015 the Commission issued new proposals for Delegated Acts and has since consulted with industry, NGOs, WHO, other Commission DGs and EU and WTO Member States and observers. Leading health NGOs, WHO, India, Afghanistan, several EU Members States have all called for the proposals to be brought closer to the IC and WHA Resolutions. The Commission has made some welcome changes during this process (exports will now be in understandable language, three new preambular paragraphs were added and some labelling requirements strengthened) but the key problems remain. The proposals sent to Parliament in September still fail to protect children's rights to health and will effectively prevent Member States from carrying out their obligations under the *Convention on the Rights of the Child* (CRC) and the IC and WHA Resolutions.

The Parliament now has the opportunity to oppose the proposals and suggest improvements.

Why the International Code and resolutions are important for everyone

Breastfeeding constitutes one of the single most effective ways to reduce inequalities, to fulfill the child's right to life and to the enjoyment of the highest attainable standard of health. The IC and Resolutions are designed to ensure that all parents receive objective and truly independent information, to remove obstacles to breastfeeding and ensure that breastmilk substitutes are used safely if needed. Their purpose is not to pressurise parents to breastfeed but to protect everyone from misinformation and commercial promotion. When properly implemented they protect both breastfed and artificially fed babies. They are not just for developing countries but are minimum requirements for ALL countries.

All EU MS have also ratified the *Convention on the Rights of the Child* (CRC) a Human Rights Treaty

[1] Commission Delegated Regulations of 25.9.2015 supplementing Regulation (EU) No 609/2013 of the EP and Council as regards infant formula, follow-on formula, c(2015) 6478, food for special medical purposes, c(2015) 6482, processed cereal-based food and baby food C(2015) 6507.

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 Comments Nos. 15 and 16 explain what this means. They stress 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) and set a direct obligation that companies abide by the IC and Resolution universally '*in all contexts.* [2]

Nations that ratified the CRC are bound to it by international law and have clear obligations. Nothing that the EU Commission says can alter this. The Commission should not seek to undermine a human rights international law, nor should it misinterpret Member States' duties/obligations under it.

The IC and WHA Resolutions are embedded in many global declarations, standards and strategies, including the *Codex Code of Ethics,*[3] the *EU Action Plan of Childhood Obesity* [4]and the *Political Declaration and Framework for Action* adopted in the 2nd International Conference on Nutrition in November 2014. Breastfeeding is one of the EUs *CORE Health Indicators for Determinants of Health*.

The EU also claims to recognise the importance of promoting high quality public health principles, standards and legislation in its relations with non-EU countries and international organisations in the field of public health. [5,6]

The Draft Delegated Acts contradict these commitments and will undermine the implementation and success of all these initiatives – wasting public resources.[7]

1 Why the Parliament should object to the draft delegated acts.

The Commission's proposals for the new Delegated Acts make some alterations to the composition of formulas, and some changes to labelling but do not significantly change the rules adopted in 1991 and 2006 (1991/323/EEC and 2006/141/EC (IF and Follow on Formula (FOF)) and 2006/125/EC (Baby foods). However, they do include three new preambular paragraphs (22-24) that place greater emphasis the importance of the IC than previous Directives. They stress the risks of advertising, the need to protect and support breastfeeding, the *EU Action Plan on Childhood Obesity 2014-2020* and MS agreement on actions to increase breastfeeding rates in the Union.[8]

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[2] CRC General Comment No 15 "…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
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 Assemblyresolutions.

[3] Codex CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD INCLUDING CONCESSIONAL AND FOOD AID TRANSACTIONS CAC/RCP 20-1979 *4.4 National authorities should be aware of their obligations under the International Health Regulations (2005) with regard to food safety events, including notification, reporting or verification of events to the World Health Organisation (WHO). They should also make sure that the international code of marketing of breast milk substitutes and relevant resolutions of the World Health Assembly (WHA) setting forth principles for the protection and promotion of breast-feeding be observed.*

[4] http://ec.europa.eu/health/nutrition_physical_activity/docs/childhoodobesity_actionplan_2014_2020_en.pdf

[5] EU in the World http://ec.europa.eu/health/eu_world/policy/index_en.htm

[6] Public Health (17-09-2015) *Commission and WHO Europe scale up cooperation* http://ec.europa.eu/dgs/health_food-safety/dyna/enews/enews.cfm?al_id=1620

[7] 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 *"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."* http://adc.bmj.com/content/early/2014/11/12/archdischild-2014-306701.full.pdf+htm

[8] OJ C 213, 8.7.2014, p. 1.

This would be excellent if they were not contradicted by the legal provisions that follow that make it almost impossible for MS to implement these tasks.

Another serious problem is the total absence of the 15+ WHA Resolutions that have been adopted since 1981. These Resolutions strengthen and clarify the IC and provide important safeguards, including in relation to Conflicts of Interest. They have been endorsed by all EU Member States, have the same status as the IC and should be read alongside it.

Despite highlight the risk of advertising, the draft Delegated Act fails to ban the advertising of IF outright and allows it in *'publications specialising in baby care and scientific publications'* (Article 10(1)) – the very publications that target parents. However the Draft Act, like the previous Directives, specifically allows Member States to further prohibit such advertising. This was because in 1991 the Commission recognised that it had no right to stop MS from implementing the IC. The restrictions on the advertising of FOF – also a breastmilk substitute - are minimal and MS have given no legal certainty that they can go further at national level.

Unless changed the Delegated Act will undermine MS ability to respect and implement the IC, WHA Resolutions and national health priorities.

- **Recommendation 1:** *Parliament should oppose the adoption of all three Delegated Acts.*

2 New evidence why MEPs should reconsider controls on the advertising of Follow-on Formula (FOF) C(2015) 6478:

In 2013, MEPs, with a narrow majority, voted to reject an amendment of **Regulation 609/2013** which would have banned advertising on FOF. Parliament now has an opportunity to reconsider this decision – in the light of new evidence that was not available in 2013:

2.1 A few months after the Parliament voted on 609/2013 WHO issued a statement, clarifying its position on FOF.[9]

"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**

2.2 In 2013 and 2014 EFSA published opinions on the essential composition of IF and FOF and Young Child Formula (YCF).[10] [11]

These opinions changed the situation radically.

After an extensive literature review EFSA recommended minimal compositional difference between IF and FOF (apart from a slight difference in target iron levels). EFSA also found no scientific evidence, or insufficient evidence, to support the inclusion of many of the ingredients commonly used in formulas and promoted as having a health benefit. EFSA went further to warn that the

[9] World Health Assembly Resolution (WHA 39.28) adopted in 1986 stated: (b) *the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary.*

[10] *Scientific Opinion on the essential composition of infant and follow-on formulae* 2014 www.efsa.europa.eu/en/efsajournal/pub/3760.htm

[11] *'Growing-up' formula: No additional value to a balanced diet, says EFSA*, 25th October 2013 http://www.efsa.europa.eu/en/press/news/131025

unnecessary addition of nutrients can be a burden to a young child's metabolism: (our emphasis)

"*From a nutritional point of view, the minimum contents of nutrients in infant and follow-on formula proposed by the Panel cover the nutritional needs of virtually all healthy infants born at term and there is no need to exceed these amounts in formulae, as nutrients which are not used or stored have to be excreted and this may put a burden on the infant's metabolism.* ***Therefore, the Panel emphasises that maximum amounts should be interpreted not as target values but rather as upper limits of a range which should not be exceeded.***"[12]

2.3 New research in Italy reaffirmed previous findings that mothers perceive advertisements for FOF as promoting IF: *"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."*[13]

2.4 EFSA saw no problem with using IF throughout the first year of life provided its iron content is appropriate. Many IF are marketed for the first 12 months of life and there is no harm continuing IF use thereafter.[14]

The above facts undermine any rationale for having totally different advertising rules for almost identical products.

NB: The promotion of formulas and processed baby foods often focuses on the nutritional advantages of supposedly 'hard to get' nutrients – undermining national health messages about breastfeeding and family foods.

- **Recommendation 2:** MS must have the legal certainty that they can implement the IC and subsequent relevant WHA Resolutions and ban promotion of FOF

3 **Young Child Formula (YCF)** - Growing-Up,Toddler milks

The Commission has failed to present to the Parliament and Council the required report on YCF [15] This is a significant and serious failing. Parliament is being asked to make a decision on FOF marketing with no information on the impact this will have on the marketing of YCF. If advertising of FOF is permitted (albeit with the few minimal constraints specified in Article 6.6) MS efforts to control YCF marketing will be sabotaged along with their efforts to protect optimal young child feeding and reduce childhood obesity.

The draft Delegated Acts fail to take account of changes in the world market and the global increase

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[12] *Scientific Opinion on the essential composition of infant and follow-on formulae, EFSA, EFSA Journal 2014;12(7):3760*

[13] *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

[14] EFSA Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760 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*".

[15] Regulation 609 2013 *Article 12 Milk-based drinks and similar products intended for young children By 20 July 2015, the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children regarding compositional and labelling requirements and, if appropriate, other types of requirements. The Commission shall consider in the report, inter alia, the nutritional requirements of young children, the role of those products in the diet of young children and whether those products have any nutritional benefits when compared to a normal diet for a child who is being weaned.* Such a report may, if necessary, be accompanied by an appropriate legislative proposal.

in promotion of formulas for children over 6 months. IBFAN's monitoring reports [16] show how unrestricted promotion is resulting sales gains of 17% in 2012 for YCF and 12% for FOF. YCF now account for one-third of the global formula market by value. Market analyses show that these products occupy expanding retail shelf space in supermarkets.[17]

This demonstrates the power of marketing over health advice and that promotion is not distributing revenue between brands. Parents are unaware of the global consensus that fortified milks for young children are not only *not* necessary [18] [19] but can also pose a risk to health. These products:

- Have higher sugar content: *"Fortified milks are frequently high in sugar and are likely to contribute to higher energy intakes, which may contribute to chronic disease, and the voluntary fortification of foods and drinks needs to be questioned as there is increasing evidence that giving additional nutrients to those who do not need them may have adverse consequences."* [20]

- They are expensive.[21.22]

- They are often cross-branded with IF so risk undermining of breastfeeding. [23]

Recommendation 3: The draft delegated act should be changed to extend the restrictions on advertising of IF to FOF, providing Member States' with legal certainty that they can adopt stricter rules in line with the *International Code* and WHA Resolutions and national priorities. A decision to allow FOF advertising should not be taken before Parliament has had time to consider the Commission proposals for YCF.

4 Pre-authorisation of optional ingredients – the Precautionary Principle

Article 5 of Regulation 609/2013 clearly calls for the Precautionary Principle (PP). However in the draft Delegated Acts the PP is referred to only in relation to pesticides - not across all relevant provisions. This is especially important in relation to the addition of *'other ingredients, as the case may be'* to IF and FOF.

Regulation 609/2013 Article 11 2 d gives the Commission power to set (d) *the notification requirements for the placing on the market of food referred to in Article 1(1), in order to facilitate the efficient official monitoring of such food, and on the basis of which food business operators shall notify the competent authorities of Member States where that food is being marketed;*

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[16] Breaking the Rules, Stretching the Rules 2014 http://www.babymilkaction.org/archives/358
http://www.babyfeedinglawgroup.org.uk/reports/bflgreports
[17] *Safety First: Global Baby Food Opportunities and Challenges to 2015* February 2011, Euromonitor International.
[18] WHA Resolution (WHA 39.28) adopted in 1986 3. REQUESTS the Director-General 3(2) to specifically direct the attention of Member States and other interested parties to the following:...(b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary.
[19] *'Growing-up' formula: No additional value to a balanced diet, says EFSA*, 25th October 2013
http://www.efsa.europa.eu/en/press/news/131025
[20] First Steps Nutrition Trust: http://www.firststepsnutrition.org/pdfs/Statement%20on%20Growing-up%20milks_July_2014.pdf
[21]"…. *recommended daily serving of powdered toddler milk can cost up to £235 per year, using ready-to-feed toddler milk increases this cost to up to £593, the annual cost of 300ml of cow's milk is £62….. Cow's milk contains 4.7g sugar per 100ml, compar A ed to 7.9g of sugar per 100ml of Hipp Organic Combiotic Growing up milk. And some daily servings contain twice as much sugar - three teaspoons a day for cow's milk compared to seven teaspoons a day for SMA Toddler milk.*
SMA Toddler milk also contains vanilla flavouring, which encourages children to prefer sweetened products.
http://www.which.co.uk/news/2013/08/should-parents-buy-toddler-milks-330947/
[22] A survey by the German consumer centres on the products being sold as "Kindermilch" ("milk for children") targeting the age from 12 months found that Kindermilch was up to four times more expensive than normal milk, costing parents up to 245 euros more each year.
http://www.vzhh.de/ernaehrung/129727/kostenfalle-kindermilch.aspx
[23] *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

Article 3(3) of the Delegated Act (C (2015) 6478 leaves the task of checking that companies use suitable ingredients to MS: [24] Suitability must be *'demonstrated by the food business operator through a systematic review of the available data related 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'*.

This is risky. It may be that not all MS will have the capacity to do this. Once an ingredient appears on sale in one country it can then be marketed throughout the EU. If the PP were to be taken into account the wording in Article 3(3) would be more specific and stringent. The Draft Delegated Act (C (2015) 6478 should specify that:

a) all ingredients are pre-authorised following rigorous independent scrutiny, (with particular care over new technologies, such as nanotechnologies;
b) systematic reviews of all available evidence is carried out *independently* of the manufacturers and distributers of the products in question;
c) evidence is reviewed on a regular basis to ensure infants are not exposed to levels of nutrients that might put a burden on their metabolism, (a concern already raised by EFSA);[25]
d) there is regular post market surveillance indicating the frequency of such reviews;
e) food ingredients not listed as essential are kept to the bare minimum;

Recommendation 4: Requirements a-e above should incorporated into the delegated act.

5 Mandatory addition of DHA

DHA, Docosahexaenoic acid, an omega-3 fatty acid, is currently an optional ingredient in FOF and IF but will become a mandatory ingredient if this delegated act is adopted. This is despite EFSA's opinion that *'there is currently no conclusive evidence for any effects beyond infancy of addition of DHA to IF or FOF on any of the health outcomes studied.'*

In the USA, the evidence that 98 babies could not tolerate synthesized DHA came to light only after a Freedom of Information request to the Food and Drink Administration. (FDA). FDA called for post market surveillance of formulas containing DHA. [26]

In 2011 a majority of MEPs voted against the approval of the DHA visual acuity health claim (328+, 323 -) [27]Because the necessary qualified majority was not reached FOF on sale in Europe and exported from it to Third countries can continue to carry the misleading health claim that DHA *"contributes to the normal visual development of infants up to 12 months of age*" alongside any other claims that are approved in future.

In addition, even though DHA will be mandatory, for 9 years after the entry of force of the delegated act IF can carry the following statement: *'contains Docosahexaenoic acid/DHA (as required by the legislation for all infant formula)'* (Article 9 (3)). Unless prevented by national governments, IF will

[24] Comments submitted by the EU to the Codex eWG on the revision oft he Follow-up Formulas Standard: „A similar approach has been applied under existing EU legislation which allows for the voluntary addition of optional ingredients to infant formulae and follow-on formulae under the condition that these ingredients have to be safe and suitable for particular nutritional use by infants (from birth in the case of infant formula; over six months in the case of follow-on formula), as established by generally accepted scientific data. *National authorities of Member States are responsible for checking compliance with this requirement. Control is performed according to Member States' systems for food control."*

[25] *ibid*

[26] *10 reasons to stop this DHA'claim* IBFAN Baby Feeding law Group Briefing http://archive.babymilkaction.org/pdfs/DHA_V13.pdf

[27] European Parliament votes to block DHA health claim – but not by a large enough majority to guarantee action by the Commission http://www.babymilkaction.org/archives/757

appear on shelves alongside FOF so will be linked to any number of misleading DHA claims that will undermine breastfeeding

Recommendation 5: Given the lack of post-market surveillance and the weakness and inconsistency of the available evidence - especially in relation to its efficacy for older babies - the mandatory addition of DHA must be reconsidered. The statement on IF should not be permitted. Clear nutrition labelling and warnings that some babies may not tolerate synthetic DHA may be more appropriate.

6 No limit on promotional claims for FOF and baby foods

The Basic Act 609/2013 allow the Commission to set: (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 in relation thereto;*

Allowing any claims on IF or FOF is inappropriate, as such formula will always "compete against" breast milk, which is the healthiest option for the child. There can be no health advantage over breastfeeding for IF or FOF.

The UK's Government's Scientific Advisory Committee on Nutrition (SACN) agrees: *'We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupportable. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods."* [28]

Article 8 the Draft Delegated Act (C2015) 6478 explicitly bans claims on IF. However it is immediately contradicted by Article 9 that allows a DHA 'statement' for IF for 9 years.

There are no restrictions on the number of health and nutrition on FOF (and other products targeting infants and young children) provided they are authorised by the Commission under the *'Regulation on nutrition and health claims made on foods'* (EC No 1924/2006).

Following the approval of the unfounded DHA claim, the Commission is currently considering the approval of 17 new highly promotional claims relating to *'children's development and health'* many of which relate to mandatory ingredients that EFSA has stated *"can be easily consumed as part of a balanced diet."*[29]

The following claims (to be followed by many more) are being considered: *'All (categories of food this food) contain DHA. DHA contributes to normal brain development'…Thiamin contributes to the maintenance of normal neurological development and function… .. Alpha-linolenic acid contributes to brain and nerve tissue development…. Magnesium contributes to normal development of bone… Vitamin A contributes to the normal function of the immune system… Iron contributes to normal cognitive development.. Riboflavin contributes to normal energy-yielding metabolism…. Iron contributes to normal formation of haemoglobin and red blood cells.. Iodine contributes to normal cognitive development… Vitamin D contributes to normal development of bones and teeth… Zinc contributes to normal function of the immune system… Selenium contributes to the protection of*

[28] http://www.sacn.gov.uk/pdfs/position_statement_2007_09_24.pdf
[29] 10891/2015 Annex to the COMMISSION REGULATION (EU) …/..authorising certain health claims made on foods and referring to children's development and health
BFLG comments: http://www.babymilkaction.org/wp-content/uploads/2014/10/BFLG-IBFAN-Health-Claim-Comments.23.7.15.pdf

DNA, proteins and lipids from oxidative damage… Zinc contributes to normal growth [in infants and young children].

These claims are of course all true – but when they appear of formulas they will be misleading. They will compete with breastfeeding and family foods that are universally acknowledged to be nutritionally superior but are not 'on sale'. Formulas can have no health *advantage* over breastfeeding – so there is no basis for a health or nutrition claim. Claims on FOF undermine the intent of the Health Claims Regulations:

Para 18: *"A nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or if it encourages or condones excessive consumption of any food or disparages good dietary practice."*

Para 16*: "Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case."*

Claims are fully harmonized across the EU. MS will have no right to ban them.

Recommendation 6: The Draft Delegated Act must remove the reference to the DHA statement on IF and ban all health and nutrition claims on FOF and baby foods.

7 Why the Parliament should object to the draft delegated act C(2015)6482 on Food for special Medical Purposes (FSMP)

Foods for Special Medical Purposes (FSMPs) are necessary products for infants who have metabolic disorders where breastfeeding is contraindicated or where full or partial feeding with specialised formulas is needed.[30] The marketing of FSMPS has been a major concern and attention to the aggressive promotion of these products is long overdue. The majority of sick babies need breastfeeding or donor human milk. However they are fed, all babies and especially sick babies, need the protection of the *IC.*

FSMPs are often the sole food for children at a vulnerable stage of growth and development when the energy and nutrient intake per kilo bodyweight is greater. Their manufacturing and marketing requires more - not less - care. The EU Commission now acknowledges that the exploitation of its lax rules has led to a growth in the market for products claiming to be FSMPs. Many of these products are simply avoiding composition and other safeguards, such as the legal requirement for a *'breastfeeding is best'* statement. Many contain thickeners and other ingredients that would not otherwise be permitted.

The proposed Delegated Act:

Many of the proposals for controls on the marketing of FSMP are welcome, (Article 8) including the labelling requirements, the ban on promotional claims and the provisions that bring the advertising controls into line with those for standard infant formula.

[30] . The number of babies needing such feeding is extremely small [globally possibly less than 25,000 babies]. Maple Syrup Disease (0.0005% of 129 million) and babies with PKU are often cited. However, even though PKU babies need a formula without phenylalanine, they benefit from the addition of partial, carefully managed breastfeeding as do babies with other inborn errors of metabolism.

However questions remain about whether the new rules outlined in 8.2 will be adequate, for example will they ban the use of misleading brand names such as *Staydown*, *Anti-Reflux, Comfort, Easy Digest* - terms that medicalise common feeding occurrences. The EU Health Claims Regulations. [31] are not clear about Brandnames, so names such as Staydown, and Anti-reflux may still be permitted.

FSMP labelling and information should be at least if as strong, ideally stronger, than Art 6.2c of the Infant formula Delegated Act that calls for a *".. a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care*." Ideally the last part of the sentence "*or other professionals responsible for maternal and child care* " should be deleted.

The requirement in Article 5.2 needs to be strengthened to ensure that FSMPs carry all the warnings and notices required by the IC. The argument that including the breastfeeding statement poses risks to health is not valid in the majority of cases. The need for FSMPs is often exaggerated and it is very rare for breastfeeding to be contra-indicated. Babies suffering from *Phenylketonuria* (PKU) still need managed breastfeeding.

Article 8.4 allows advertising in baby care publications and specialist publications. Any information should list under the IMPORTANT NOTICE all the points in Article 5.1 a-i.

Recommendation 7: Information about FSMPs should only be permissible in specialist health publications. This information should include all points listed in Article 5.2 and all the warnings and notices required by the IC.

8 Why the Parliament should object to the draft delegated act on Processed cereal-based food and baby food (C(2015) 6507)

The draft Delegated Acts allow baby foods to provide 30% of their energy from sugar (7.5g sugar/100kcal means 30kcal from sugar in 100kcal energy). The Commission has failed to ask EFSA to look into the sugar issue, despite being asked to do so since 2006.[32]

As a consequence the current proposal contradicts the advice from the WHO and scientific committees in MS who recommend significant reductions in total sugar intake especially for young children.[33] The proposals will undermine MS efforts to tackle rising levels of childhood obesity. They may also affect the developing taste palates of children.

Growth retardation in young children is exacerbated by dental caries and sugar induced caries is a

[31] Nutrition and Health Claims regulations (REGULATION (EC) No 1924/2006):4. *"This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities…**This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.***
(5) Generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, such as 'digestive' or 'cough drops', should be exempted from the application of this Regulation.
3. A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.
2. Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.
[32] *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
[33] WHO Healthy Diet Fact sheet N°394 Updated September 2015 http://www.who.int/mediacentre/factsheets/fs394/en/

contributor to the prevalence of malnutrition. [34] Nearly 500 children a week are admitted to UK hospitals for tooth extractions under general anaesthetic. This is a major drain on hospital services in the UK.

The draft Delegated Act is weak in terms of labelling, marketing and advertising. Labelling from 4 months will confuse parents and contravene WHA Resolution 54.2 that recommends Exclusive Breastfeeding for 6 months. This Resolution was adopted after a systematic review of over 3000 studies and is now policy in over 70 countries.[35]

EFSA has not *recommended* 4 months labelling. It just found no evidence of harm for the introduction of solids at this age. A change to six months in the draft would be in line with public health recommendations and Codex standards and still allow flexibility based on individual needs.

The draft Delegated Act also allows idealising promotional claims, marketing strategies that hide the risks of the product as a whole. More sustainable, bio-diverse, nutritious family foods are not on sale so cannot compete. Nestlé (Gerber) is facing legal action in California US over its marketing of Graduates Puffs.[36] *The lawsuit claims the company labels the product as though it contains a significant amount of fruits and vegetables because they are "vibrantly" depicted on the packaging. "In fact, Gerber Graduates Puffs do not contain any, or significant amounts of, the fruits or vegetables shown on the label." the lawsuit said. "The closest ingredient to fruits or vegetables in the Puffs is little more than a powder."*

Recommendation 8: This Draft Delegates Act must be opposed and delayed until EFSA has reviewed the evidence on sugar and introduction of complementary foods. in relation to the undermining of breastfeeding and exacerbation of childhood obesity.
Change the text of article 4.2 (a) to read: *"The stated age shall not be less than **six** months for any product. Products recommended for use from the age of six months may indicate that they are suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy advise otherwise"*

Other issues relevant to all three draft delegated acts

Global impact

The proposals 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. The EU should support – not sabotage - the establishment of a health protective framework in international and regional bodies, such as the Codex Alimentarius Commission and WHO. The adoption of such a deficient and flawed EU Regulation will be a retrograde step in terms of global health, sustainability, food security, children's fulfillment of their right to health, adequate food and

[34] Acs G, Lodolini G, Kaminsky S, Cisneros GJ. Effect of nursing caries on body weight in a pediatric population. Pediatr Dent. 1992 Sep-Oct;14(5):302-5.

[35] 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

[36] *Nestle sued over claims of false advertisement of the ingredients in its Gerber baby food, http://www.babymilkaction.org/archives/6246*

nutrition.

The Draft Delegated Act ignores the clear recommendation of the *Codex Code Of Ethics for International Trade In Food Including Concessional And Food Aid Transactions* (CAC/RCP 20-1979) that calls on National Authorities to *"make sure that the international code of marketing of breast milk substitutes and relevant resolutions of the World Health Assembly (WHA) setting forth principles for the protection and promotion of breast-feeding be observed*."

The EU cannot adopt these proposals while claiming *"to recognise the importance of promoting high quality public health principles, standards and legislation in its relations with non EU countries and international organisations in the field of public health."*[37,38]

Inequalities 120 million Europeans at risk of poverty or social exclusion. 100 million Europeans lack access to piped water in their homes and 66 million lack access to adequate sanitation. This issue is an important health and food safety issue.

Environmental impact Artificial feeding adds to environmental burden: 800 litres of water are needed to make a 1 litre of milk and 4700 litres for 1 kilo of milk powder.

- **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

[37] *EU in the World* http://ec.europa.eu/health/eu_world/policy/index_en.htm
[38] Public Health (17-09-2015) *Commission and WHO Europe scale up cooperation* http://ec.europa.eu/dgs/health_food-safety/dyna/enews/enews.cfm?al_id=1620

- **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 ye