



IBFAN comment to the eWG report

Agenda item 5: REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) at step 3

General Comment:

1. The protection of “consumer” health is a key mandate for Codex that is especially relevant for any discussion about the continued need for a separate standard for an industrial milk product that will be marketed to replace breastmilk during the critical stages of health, development and growth.
2. The adoption of the Follow-on Formula standard in 1987 is universally acknowledged by health advocates to be a mistake that has been used to establish and expand a market for unnecessary, risky products to the detriment of child health. It has undermined the adoption and maintenance of strong marketing regulations based on the International Code and Resolutions. Now is the time to
3. IBFAN has noted that the lack of consensus and the lack of agreement in comments submitted to the FUF Working Group is not fully reflected in the reports submitted by the chairs.
4. The report acknowledges on Page 4 that the majority of the eWG members consider that there needs to be a discussion about the need for these products. The Chair’s decision to defer such discussion, risks compromising the safeguards necessary to protect young child health.
5. The lack of necessity for these products was noted by a number of member states and by the representative of the WHO, who highlighted the critical importance of the World Health Assembly Resolution 39:28 in order to safeguard the health, growth and development of older infants and young children. . Follow-on formulas are industrial milk products that will be marketed to replace breastmilk.
6. The age of introduction of follow-on formula is reported to be from the age of six months. The preference of a considerable number of member states and observer organizations for the 12 months introduction and for FUF to be included in a renamed infant formula standard as an Annex or footnote - has consistently been ignored. Indeed there is no need for an upper cut-off age beyond 12 months. Since the composition of Follow-on Formula differs from Infant formula in very few places – such a move would help ensure the safety and marketing of these products is in line with the recommendations of the World health Assembly.
7. The compositional requirements could be readily met by the infant formula standard. A special note could be added regarding the higher iron requirements for older infants and young children, bearing in mind that the introduction of iron rich complementary foods at the age of six months can also meet these needs. Excess iron intakes from fortified commercial baby foods and milks may increase long-term health and development risks for children.
8. The protection of “consumer” health as a key mandate for Codex should especially apply in the case older infants and young children. Optimal infant and young child feeding practices have life long implications for health and development and therefore need special consideration.
9. The failure of the separate Follow-on Formula standard to protect child health while
9. favouring the marketing and trade needs of the producing countries is illustrated by the aggressive promotion of the Auckland-based Export New Zealand Ltd, *Bibere* brand to

Cambodia. Monitoring reports point to the Bibere facebook showing multiple Code violations of parents receiving free Bibere formula products. (Phnom Phen Post, Oct 22, 2015, *Watchdog calls out firm for marketing formula.*) The Cambodian government banned all such advertisements and promotions of formula milks in 2005 with Sub-Decree 133, which prohibits promotion of products up to the age of 24 months – both directly to the public and specifically throughout the health care system.

10. Overall IBFAN is concerned that the options put forward - and those overlooked - would not ensure the safety, quality, appropriate use and marketing of this product.
11. Breastmilk is environmentally sustainable. Breastfeeding has no negative impact on the environment and the capacity of our planet to allow all people to live well and healthily, now and in the future. In contrast, formula feeding is unsustainable and leaves a large, heavy ecological footprint which includes the resources consumed during the production of the formula as well as the waste left behind. The carbon footprint of greenhouse gases left behind contributes to climate change, while waste and garbage pollute our environment. Among all the categories of formulas, the Follow-up formula which includes so called 'Growing up Milks' and 'Toddler Milks' contributes significantly to the **environmental burden**.
1. IBFAN also wishes to highlight the additional health risks when infants and young children 6 to 24 months are not breastfed. A recent systematic review to determine the impact of optimal breastfeeding practices in children 6–11 and 12–23 months of age found that those who were not breastfed had 1.8- and 2.0-fold higher risk of mortality, respectively, when compared to those who were breastfed. The authors concluded that the risk was twofold higher in nonbreastfed children when compared to breastfed children aged 6–23 months.¹

Specific Comments

Page 3 - last two lines and top of Page 4:

What evidence is there that *“globally, iron and the quality of dietary fat in the diet were consistently found to be inadequate in sub-groups of the populations. Other nutrients frequently found to be limited in the diets of infants and young children....”*

Does this mean that the FUFs are now being positioned to address nutritional inadequacies or to meet some of the nutritional requirements of young children - the lack of necessity for these products makes it impossible to define what nutrients should be added to the FUF “milk” products when it is intended to be a part of a complementary feeding diet which consists of increasing intakes of nutrient and iron rich family foods and a decreased reliance on breastmilk to two years and beyond. With such a variation in complementary feeding across the globe how can a standard address “flexibility” in nutritional needs?

Page 3 - Para 10:

Rephrase to read: Several eWG members did not seem to understand that standards are designed to be read by regulators - not consumers - and can be used in trade disputes. If a revised standard is agreed upon, adding wording that the product is not necessary might assist Member States who wish to adopt strong legislation on these products.

Page 4:

“The majority of eWG members suggested that reference to relevant WHA resolutions be incorporated into the Scope of the Standard, similar to the approach and wording of Section 1.4 of the Standard for Infant Formula. Many of those eWG members who suggested reference to WHA resolutions be contained within the Scope, also suggested that principles contained within the relevant resolutions will also need be considered as part of the review of the labelling provisions for follow-up formula.”

Several eWG members commented that the review of the Scope and Labelling requirements did not form part of the ToR for the 2015 eWG and therefore discussions on this issue should be deferred until

¹ <http://onlinelibrary.wiley.com/doi/10.1111/apa.13147/abstract>

such time as the group is able to simultaneously review the Scope and Labelling sections of the Standard. The Chairs agree that discussions and a decision about if, and how, applicable WHA resolutions should be incorporated into the Standard for Follow-up Formula fall outside the terms of reference for the eWG, and as such should be deferred until a time when this is specifically addressed. The Chairs would however like to acknowledge the information below provided by eWG members. It is proposed that these valuable comments are noted and considered in future discussions around WHA resolutions.”

Clearly the majority of the eWG members have stated that the WHA resolutions regarding the lack of necessity for these products should be in the Scope. Why does this discussion need to be deferred if the majority have made it clear that this is fundamentally important to how the revision evolves? Deferring such a fundamental provision during the process of the revision of the FUF standard may compromise other safeguards necessary to protect young child health from the risks of using industrial milk products and industrially based nutrients as sources of nutrition during the critical stages of health, development and growth.

Page 5 – Description:

Using the wording “from the 6th month on” is ambiguous. It is critical that the products not be used before the age of six months. The term “from the 6th month on” can imply that the product may be used after the 5th month. The wording should read: “from the age of 6 months onward” .

Product that are not necessary should not be targeted consumption by older infants and young children. Nor should they be used until after 12 months as a part of a diversified complementary family food based diet.

Page 6 - 4th - para below the box: Rephrase: *the nutritional safety and adequacy of FUF shall be established by an independent systematic review of all available evidence.*

Page 6 Last para 6.1: There was **NO** general agreement that there should be a point of differentiation at 12 months.

Para 10 - beginning: *“For some nutrients....Did the majority call for a deviation from the IF standard (other than for iron)?*

Page 9 - last Para: The chair’s conclusion that trade considerations should take precedence over health concerns regarding the maximum levels of protein is not acceptable. The protection of “consumer” health is a primary mandate for Code.²

Page 11 - Box - Footnote 6: Throughout the document all references to evaluation and scrutiny and reviews should stress that such reviews should be independent of those manufacturing and distributing the products in question.

Page 13,14:The addition of **DHA** whether as an optional additive remains controversial as there is no conclusive evidence that the addition confers added benefits. *“LCPUFA supplementation of infant formulas failed to show any significant effect on improving early infant cognition. Further research is needed to determine if LCPUFA supplementation of infant formula has benefits for later cognitive development or other measures of neurodevelopment.”³*

² *“Some eWG members noted that alignment with the Infant Formula Standard would result in a reduction in protein content in follow-up formula which does not align with the current compositional range for protein in the Standard for Follow-up Formula (current range: 3.0 -5.5 g/100 kcal). It was noted that this could cause significant issues for trade as current formulations of follow-up formula will not comply with the protein requirements. Furthermore this will have issues as national jurisdictions begin to adopt the revised Standard for Follow-up Formula. The Committee will need to consider how to accommodate an approach which would result in such a shift in composition, and if this was the preferred approach whether a transition period for implementation would be required. Due to the lack of strong scientific justification in establishing a maximum limit and potential impact on trade, it is recommended that a maximum level of 3.5 g/100 kcal is established to enable the transition to lower protein content of follow-up formula globally*

³ Pediatrics 2012;129:1141–1149

Concluding comments:

1. IBFAN does not agree with the assumption that FUF are a suitable format to provide essential nutrients required for the growth and development of young children. The context in which nutrients are provided is of critical importance during the older infant and early childhood developmental stage. It is a time of exploring the tastes, textures, colours and the aromas of foods. Prolonged feeding of FUF will have a negative effect on the development of taste preferences with life long impact on dietary preferences. Moreover, in addition to the risks of excess nutrient intakes, nutrients provided as additives to industrially produced foods frequently differ in chemical configuration and impact compared to nutrients derived from natural foods and whole milk dairy products.⁴
2. IBFAN is of the opinion that there is no necessity for a separate standard for follow on formula and that one renamed *Standard for formulas for infants and young children* that could cover Infant formula and Follow-on formula and be applicable across the whole of the first year of life and beyond ., The standard could include a preamble stating that products other than infant formula are not necessary and can be banned from import.
3. IBFAN does not believe there is any need for follow-up formula products (sometimes referred to as 'Toddler' or 'growing up' milks – (a term that is in itself an implied health claim) for children over the age of 1 year, in exceptional circumstances if health professionals believe there is a need for an artificial milk product, infant formula can remain the product of choice. After six months infants and young children need a diversified diet of energy and nutrient rich culturally appropriate, local foods along with breastmilk as the way to achieve the highest attainable level of health, growth and development. The marketing of costly commercial fortified, sweetened and/or flavoured milk products will interfere with the recommended way to feed infants and young children, confuses parents and compromises the health of children by contributing to NCDs and dental disease.
4. The revoking of the Codex standard for follow-up formula has significant potential to protect infant and young child health. Major health bodies have stated that these products are not necessary (WHO, EFSA), hence the removal of this standard will prompt national governments to take effective action to reduce the widespread misleading marketing of fuf and formulas for older babies.
5. The marketing of FUF misleads parents and encourages them to believe that these products are essential , that the nutrients they provide as 'hard to get' and that they have benefits above and beyond breastfeeding and healthy family foods. Additionally the removal of the standard would facilitate the ability of national governments to restrict these products that interfere with national policies and recommendations for optimal infant and young child feeding. Where there is a need for the use of breastmilk substitutes, infant formula can continue to be used beyond six months and for young children milk of animals (such as cow's milk) can be a part of the complementary food diet.⁵
6. In 2013 the [European Food Safety Authority](#) concluded that Growing Up Milks have no additional value to a balanced diet.⁶
7. In 2014 **EFSA updated its advice on infant and follow-on formulae:** *"The Panel did not consider it necessary to propose specific compositional criteria for formulae consumed after one year of age, as formulae consumed during the first year of life can continue to be used by young children."*⁷
8. A number of studies from Australia, USA, Canada, and the UK have shown that to circumvent restrictions on the marketing of infant formula for the first six months, the

⁴ Lawrence M (2013). Food Fortification: The evidence, ethics and politics of adding nutrients to food. Oxford: Oxford University Press.

Jacobs DR, Mursu J, Meyer KA (2012). The importance of food. Archives Pediatrics and Adolescent Medicine; 166; 187-188.

Eichler K, Rothermann I, Brugger U (2012) Effects of micronutrient fortified milk and cereal food for infants and children: A systematic review. BMC Public Health, 12, 506-519.

Sacco JE, Dodd KW, Kirkpatrick SI, Tarsuk V (2013). Voluntary food fortification in the United States: potential for excessive intakes. European Journal of Clinical Nutrition (6 March 2013) Idoi:10.1038/ejcn.2013.51.

⁵ http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf

⁶ 'Growing-up' formula: No additional value to a balanced diet, says EFSA October 2013.

<http://www.efsa.europa.eu/en/press/news/131025>

⁷ EFSA updates advice on infant and follow-on formulae 24 July 2014 <http://www.efsa.europa.eu/en/press/news/140724>

promotions of FUF, toddler “milks”, increased, using cross branding to increase the profile of all their age targeted formula products.⁸

9. At national level governments should be encouraged to ensure that any product marketed for children 0 -12 months or 12-36 months do not carry health or nutrition claims, have sugar content restricted, are not flavoured, contain only ingredients that have been pre-authorized for this age group and have specified and appropriate minimum and maximum nutrient values. Any product carrying the same branding as infant formula must be suitable for newborn babies.
10. WHO makes clear in its 2013 statement entitled, *Information concerning the use and marketing of follow-up formula*, “... *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 products being perceived or used as a partial or total replacement for breast milk, such product also falls within the scope of the Code.*”⁹
11. As mentioned above, since the current standard for IF is adequate to address the needs for older infants, the labelling can be strengthened to provide better consumer protection. Inadequacies in labelling provisions such as the use of misleading claims regarding the addition of optional ingredients persist, the lack of information for reconstitution of PIF to safeguard against *Cronobacter sakazakii* infections, the lack of information about risks are all areas where labelling can be improved to be in full compliance with both Codex standards and the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions.

⁸ Smith J, Blake M. Infant food marketing strategies undermine effective regulation of breast-milk substitutes: trends in print advertising in Australia, 1950-2010. *Aust N Z J Public Health*. 2013 Aug;37(4):337-44.

Berry NJ, Jones SC, Iverson D. Circumventing the WHO Code? An observational study. *Arch Dis Child*. 2012 Apr;97(4):320-5.

Berry NJ, Jones SC, Iverson D. Relax, you're soaking in it: sources of information about infant formula. *Breastfeed Rev*. 2011 Mar;19(1):9-18.

Berry NJ, Jones S, Iverson D. It's all formula to me: women's understandings of toddler milk ads. *Breastfeed Rev*. 2010 Mar;18(1):21-30.

⁹ http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf