

IBFAN Comment on the Structure and the Preamble of the proposed draft standard for Follow-Up Formula

Replies are requested to the questions below on the structure and preamble of the standard for follow-up formula.

Structure

The responses to the questions presented in this discussion paper will be analysed and presented to CCNFSDU43 for consideration.

Now that the standard has been completed please indicate your preferred structure approach and clearly state why you do, or do not, support each option: ([click here to add a comment](#))

IBFAN is of the opinion that the standard has not been completed. There remain unresolved areas of the standard, such as sodium levels for drinks for young children, methods of analysis for sweetness and the lack of consensus on the use of flavourings in drinks for young children.

IBFAN is strongly opposed to Option 1.b: This option proposes the creation of two separate standards for Follow-Up Formula and Drinks for Young Children. Both products are recognized as breastmilk substitutes by the International Code of Marketing of Breast-milk Substitutes and World Health Assembly Resolution 69.9 (2016). Separating them into two standards based on age targeting, creates regulatory and consumer confusion and risk both misuse and needless use.

IBFAN considers that Option 1.d: one standard, sub-divided into four sections covering Infant Formula, Formulas for Special Medical Purposes, Follow-up Formula and Drinks for Young Children would facilitate more efficient and simplified law-making. As New Zealand has identified in Table 1, numerous provisions are common to ALL FOUR categories. In 2006, CCNFSDU decided to bring Formula for Special Medical Purposes and Infant Formula under one standard precisely because of the similarity of product categories – despite the strong lobby of the baby food industry to have two standards.

IBFAN's second choice is **Option 1a.** one standard in two parts, covering Follow-up Formula and Part B for Drinks for Young Children. However if this is the preferred option, we advocate that each standard contain a footnote to the title referencing the paired/corresponding/associated Codex standard and recommending that governments address products in both standards in national legislation or regulations so that at national level, all four categories should be covered under one national standard.

Rationale:

1. There is no justification for separating the two categories into two separate standards and to do so risks inconsistent and weaker safeguards needed to protect maternal, infant and young child health. Keeping the products under one standard with a clear overarching preamble is essential to safeguard this vulnerable population and ensure appropriate use of all these products.
2. As a global recommendation by the World Health Organization breastfeeding for the second year of life is optimal. Hence regardless of how an infant or young child is fed, Follow-Up Formula and Drinks for Young Children, both function – inappropriately – as breastmilk substitutes during the critical time of rapid growth and development when breastfeeding is recommended.

3. IBFAN notes that the **product definitions in the draft revised standard** for both categories serve the same purpose, albeit for different age groups.
 - Follow-Up Formula is defined as a breastmilk substitute: *“Follow-up formula for older infants means a product, manufactured for use as a breastmilk substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.”*
 - Drinks for Young Children is defined as a *“product manufactured for use as a liquid part of the diversified diet of young children”* with an important footnote that acknowledges that many countries regulate these products as breastmilk substitutes. *“In some countries these products are regulated as breast-milk substitutes”,* as advised by the World Health Organization.
4. The *International Code of Marketing of Breast-milk Substitutes* (1981) and World Health Assembly Resolution 69.9 (2016) are clear that both product categories function as breastmilk substitutes and no distinction is made between them. Recommendation 2 of World Health Assembly 69.9 *Guidance on ending the inappropriate promotion of foods for infants and young children* “states *“...It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products”* [milks specifically marketed for feeding infants and young children up to the age of 3 years or older].
5. Making further distinctions between these two categories of product would confuse legislators and end users about the roles they play in infant and young child diets. One standard with four parts would better facilitate policy coherence between the International Code of Marketing of Breast-milk Substitutes and World Health Assembly Resolutions, Codex standards and national laws.
6. World Health Assembly 39.28 categorically states that these products are not necessary, therefore to give them separate standard status is redundant and gives the impression that they are needed products or that so-called “Drinks for Young Children” are not breastmilk substitutes and, for unstated reasons, exempt from restrictions applicable to breastmilk substitutes, or that they are risk-free.

IBFAN strongly supports the inclusion of a Preamble.

The preamble is essential to assist Member States in understanding where these older infant and young child products ‘fit’ in the national regulatory context. In order to make certain the Codex mandate of protecting consumer health is realized, the preamble can inform the Member States to the need to include international instruments, primarily the International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly Resolutions, into their national laws.

The preamble can play an important role in helping ensure policy coherence between Codex and the World Health Organization recommendations and World Health Assembly outcomes. This can provide the essential safeguards to protect maternal and child health. It can inform governments about the unique infant and young child nutritional and immunological contributions provided by breastfeeding and the serious long-term risks of these sweetened, highly processed products. Follow-up Formulas and Drinks for Young Children are not like other food products. These follow-up

formula products are marketed for use by older infants and young children at their critical stage of their growth and development. A considerable body of scientific peer-reviewed literature documents the health and nutrition risks. This evidence has informed the global consensus that the marketing and promotion of these products must be in full compliance with the International Code of Marketing Breast-milk Substitutes and World Health Assembly Resolutions in order to safeguard the health of children at these vulnerable stages of life.

Follow-up Formula and Drinks for Young Children are not necessary as confirmed by the World Health Assembly in WHA 39.28, *“The practice being introduced in some countries of providing infants with specially formulated milks (so-called follow-up milks) is not necessary.”* Energy and nutrient dense family foods and cow’s milk can provide the essential complementary foods to meet energy and nutrient requirements for older infants and young children.

Proposed Preamble

The Codex Alimentarius Commission acknowledges the need to protect breastfeeding as a vastly safer and nutritionally superior way of providing optimal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [necessary / appropriate], as a substitute for breastfeeding in meeting the nutritional requirements of infants, provided, they are prepared under hygienic conditions; given in adequate amounts; refraining from advertising and claims; and ensuring labels contain prominent, recommended warnings of health risks and hazards of replacing breastfeeding and improper use of substitutes. Preparation instructions must be in applicable local languages. In addition, various products have also been produced intended specifically for older infants and young children as they progress to a more diversified diet of nutrient and energy-dense family foods. These products are not necessary as determined by Member States (World Health Assembly 39.28) and should not undermine breastfeeding. The production, distribution, marketing, sale and use of follow-up formula for older infants and drinks for young children should be consistent with national health and nutrition policies. and be in conformity with the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding as well as Relevant WHO guidelines, policies, World Health Assembly Resolutions that have been endorsed and supported by Member States which provide guidance to countries in this context, including urging Member States to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children, including the misleading practice of cross-promotion.

This Standard is divided into four (or two as our less preferred option) sections. Section A refers to Infant Formula, Section B to Formula for Special Medical Purposes, Section C to Follow-up Formula for Older Infants (6 to 12 months of age), and Section D deals with Drinks for Young Children (12 to 36 months of age).

Notes:

Milk-related FAQs - **What are the benefits of giving human milk to children over 1 year of age?**
<https://www.firststepsnutrition.org/milks-marketed-for-children> <https://www.firststepsnutrition.org/faq-page>

Global recommendations support continued breastfeeding into the second year of life and WHO guidance recommends all infants are breastfed for up to 2 years and beyond (WHO, 2003). The rationale for encouraging continued consumption of a milk in young children beyond 1 year of age is based on a combination of meeting energy needs (proportionally driven by the fat content), calcium requirements for bone deposition and the other nutrients that mammalian milk provides. However, in contrast to animal milks, breastmilk can offer not only nutritional benefits but significant health benefits to both mother and child. That said, whilst there is no shortage of evidence for the benefits of breastfeeding during the first year of life, there are relatively few studies that attempt to quantify the benefits of breastfeeding children over 1 year of age. Nevertheless, those that do support the idea that breastfeeding continues to provide nutrition and immunological protection, is beneficial for IQ and subsequent achievement, provides some protection against overweight and obesity later in life, and offers emotional benefits for as long as it continues. Some benefits continue to be felt beyond the period of breastfeeding (Lopez et al, 2021; NHS, 2020, Grummer-Strawn et al, 2004).

Nutrition Breastmilk composition changes over time to meet the needs of the growing child so that whilst the volume consumed may decrease, an appropriate level of nutrients remains present and immunological protection is not compromised (LLL, 2010). Studies looking at the composition of breastmilk into the second year of lactation have reported a large degree of stability in the macronutrient content with only a small reduction in protein. Mineral elements stay largely stable, although after two years, some studies report a reduction in calcium and zinc content. Four hundred millilitres of mature breastmilk can meet the following percentage of daily nutrient requirements for a 1-2 year old child: 32% energy. 36% protein 58% vitamins 53% vitamin C

Immunological protection. Studies in breastmilk composition in the second year of lactation have reported inconsistent results. Some studies report increasing concentrations of the antimicrobial protein lysozyme (Perrin et al, 2017; Hennart et al, 1991; Prentice et al, 1984). Perrin et al also reported increasing concentrations of immunoglobulin A (IgA) and lactoferrin (Perrin et al, 2017). These breastmilk proteins provide responsive and protective immunity (Breakey et al, 2015) and support the development of a beneficial gut microflora (Mastromarino et al, 2014). The secretion of antimicrobial proteins differs between mothers and this may mask changes over time and may help to explain differences between studies (Perrin et al, 2017; Lewis-Jones et al, 1985). More consistently, results of a systematic review and meta-analysis indicate that breastfeeding protects against acute otitis media until 2 years of age, and protection is greater for breastfeeding of longer duration (Bowatte et al, 2015).

IQ and general ability Research on the relationship between cognitive achievement (i.e. IQ scores and school grades) and breastfeeding has shown the greatest gains for those children breastfed the longest. Some studies show that participants who were breastfed for 12 months or more score higher on IQ and general ability tests than those with shorter durations of breastfeeding (Victora et al, 2015; Lopez et al, 2021). The positive influence on IQ as a result of breastfeeding may also impact upon long-term earnings and productivity. One large retrospective cohort study reported that participants who were breastfed for 12 months or more had higher IQ scores, more years of education, and higher monthly incomes than did those who were breastfed for less than 1 month (Victora et al, 2015).

Overweight and obesity It is becoming widely accepted that breastfeeding protects against overweight (Victora et al, 2016). Analysis of 2015-2017 surveillance data collected in 22 European countries reported that, compared to children who were breastfed for at least 6 months, the odds of living with obesity were significantly higher among children never breastfed or breastfed for less than 6 months. Several studies have reported that longer durations of breastfeeding are associated with a lower risk of obesity in later life (Qiao et al, 2020; Zheng et al, 2020; Rito et al, 2019; Horta et al, 2015). A dose response relationship between breastfeeding and protection against overweight and obesity has been reported by several studies (Qiao et al, 2020; Grummer-Strawn and Mei, 2004) and those that have included a breastfeeding duration category of 12 months + have reported significant reductions in risk for overweight and obesity in later childhood. When comparing those who were breastfed for at least 12 months with those who were never breastfed, Von Kreis et al reported a 57% reduction in the odds of being overweight in a subset of over 9,300 Bavarian 5- and 6-year-olds (Von Kries et al, 1999). When comparing those who were breastfed for more than 12 months to those breastfed for less than 6 months, Liese et al reported a 20% reduction in odds of being overweight among children between 9 and 10 years of age (Liese et al, 2001). A much larger national analysis of longitudinal data drawn from the US Centers for Disease Control and Prevention Pediatric Surveillance System reported a 51% reduced risk of obesity for white non-Hispanic children who were breastfed for more than 12 months compared to those never breastfed (Grummer-Strawn and Mei, 2004).

References

Abul-Fadl AAM, Fahmy EM, Kolkaliah N and Narouz N (2005). The Psychological Benefits of Continued Breastfeeding into The Second Year for Mother and Child. *The International Journal of Child Neuropsychiatry*, 2, (2), 143-153

Bowatte G, Tham R, Allen KJ, et al. (2015). Breastfeeding and childhood acute otitis media: a systematic review and meta-analysis. *Acta Paediatrica* 104 (467), 85-95. DOI: 10.1111/apa.13151.

Breakey AA, Hinde K, Vallengia CR, et al. (2015). Illness in breastfeeding infants relates to concentration of lactoferrin and secretory Immunoglobulin A in mother's milk. *Evolution, Medicine, and Public Health* 1, 21–31.

Grummer-Strawn LM and Mei Z (2004). Does breastfeeding protect against pediatric overweight? Analysis of longitudinal data from the Centers for Disease Control and Prevention Pediatric Nutrition Surveillance System. *Pediatrics*, 113 (2).

Hennart P, Brousseau D, Delogne-Desnoeck J, et al. (1991). Lysozyme, lactoferrin, and secretory immunoglobulin A content in breast milk: influence of duration of lactation, nutrition status, prolactin status, and parity of mother. *American Journal of Clinical Nutrition* 53, 32–39

Horta BL et al. (2015). Long-term consequences of breastfeeding on cholesterol, obesity, systolic blood pressure and Type 2 diabetes mellitus: a systematic review and meta-analysis, *Acta Paediatrica*, 104 pp. 30-37.

La Leche League. Breastfeeding beyond a year. <https://www.laleche.org.uk/breastfeeding-beyond-a-year/> Accessed 15/06/2021

La Leche League International. (2010). *The Womanly Art of Breastfeeding*, 8th Edition, 191.

Liese AD, Hirsch T, von Mutius E, et al. (2001). Inverse association of overweight and breast

Lopez DA, et al. (2021). Breastfeeding Duration Is Associated With Domain-Specific Improvements in Cognitive Performance in 9–10-Year-Old Children. *Frontiers in Public Health*. doi.org/10.3389/fpubh.2021.657422

Mastromarino P, Capobianco D, Campagna G, et al. (2014). Correlation between lactoferrin and beneficial microbiota in breast milk and infant's feces. *BioMetals* 27, 1077–1086

NHS (2020). *What To Feed Young Children*. Available at: <https://www.nhs.uk/conditions/baby/weaning-and-feeding/what-to-feed-young-children/> (Accessed 25 May 2021).

Perrin MT, Fogleman AS, Newburg DS and Allen JC (2017). A longitudinal study of human milk composition in the second year postpartum: implications for human milk banking. *Maternal & Child Nutrition* 13 (1).

Prentice A, Prentice AM, Cole TJ, et al. (1984). Breast-milk antimicrobial factors of rural Gambian mothers. I. Influence of stage of lactation and maternal plane of nutrition. *Acta Paediatrica Scandinavica* 73, 796.

Qiao J, Dai L, Zhang Q and Ouyang Y-Q (2020). A Meta-Analysis of the Association Between Breastfeeding and Early Childhood Obesity, *Journal of Pediatric Nursing*, 53, 57-66

Rito AI, Buoncristiano M, Spinelli A, et al. (2019). Association between characteristics at birth, breastfeeding and obesity in 22 countries: The WHO European Childhood Obesity Surveillance Initiative – COSI 2015/2017. *Obesity Facts*, 12, 226-243.

Victora CG, Bahl R, Barros AJD, et al. (2016). Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *The Lancet*, 387, 475-490

Victora CG, et al. (2015). 'Association between breastfeeding and intelligence, educational attainment and income at 30 years of age: a prospective birth cohort study from Brazil', *Lancet Global Health*, 3 e199-e205.

Von Kries R, Koletzko B, Sauerwald T, et al. (1999). Breast feeding and obesity: cross sectional study. *BMJ*. 319:147–150

WHO (2003). *Global Strategy for Infant and Young Child Feeding*. Geneva, WHO.

Zheng M, Cameron AJ, Birken CS et al. (2020). Early infant feeding and BMI trajectories in the first 5 years of life. *Obesity*, 28 (2), 339-417.