



IBFAN comment on the Review of the Standard for Follow-up Formula (Codex Stan 158-1987) at Step 3 ¹ 7th November 2017

GENERAL COMMENTS

1. To simplify the implementation of regulations at national level and avoid confusion, **IBFAN is proposing that products targeting babies 6-36 months be included in the standard for Infant Formula and Formula for Special Medical Purposes intended for Infants Codex Stan 72-1981**. This one standard can easily accommodate all breastmilk substitutes. The could be four sections to differentiate products as follows:
 - Section A: Infant formula (birth onwards or 0-12month and beyond)
 - Section B: Formulas for Special Medical Purposes
 - Section C: Follow-up formula for older infants (6 months onwards)
 - Section D: [Name of the Product] for Young Children (12-36 months)
2. IBFAN agrees to an over-arching preamble that specifically references all the relevant WHO documents, the *Global Strategy on Infant and Young Child Feeding*, the *International Code of Marketing of Breastmilk Substitutes* and relevant WHA resolutions, including the WHA resolution 69.9 (2016) and its accompanying *WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children*. It is important that these documents and Resolutions are also embedded in each section of the Standard. This is necessary to ensure that Member States apply these safeguards into national regulations that will protect older infants and young children from needless and inappropriate use of these products, consistent with national nutrition and health policies.
3. IBFAN does not agree with the deletion of provision 1.4 in the Scope. The scope must remind Regulatory Authorities of the safeguards contained in the over-arching Preamble WHO recommendations must underpin the marketing and labelling of each product category. The safeguarding of the health of older infants and young children through the protection of breastfeeding and optimal complementary feeding as recommended to two years or beyond must be prioritized.
4. The preamble should clearly state that these products are not necessary as endorsed by Member States in WHA Resolution 39.28 and that Member States are free to refuse their entry.
5. Appropriate nutrient levels for these products are difficult to determine because they are dependent on the amount of breastmilk consumed, the availability, quality and quantity of complementary foods consumed and cultural food practices. Infant formula that is appropriate for the first 6 months of life can continue to be consumed by older infants and young children. IBFAN is of the opinion that it is not possible to match the nutrients supplied by follow-up formula for older infants and for young children to their nutrient and energy needs.
6. Added sugars should be in accordance with the WHO recommendation of 5% of total energy. We agree that the percentage limit of sugars contributing to a sweet taste be converted to an absolute amount based on the energy density (g/100kcal and g/100kj) of the product for older infants and young children.

¹ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-39%252Fnf39_04e.pdf

7. IBFAN agrees that the requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX Stan1-1985), the Guidelines on Nutrition Labelling (CAC/GL2-1985) and the Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to the labelling of follow-up formula for older infants and to follow-up formula for young children.
8. In addition, the labelling Section 9 must clearly specify that prohibit cross branding with infant formula and the use of nutrition, health and convenience claims is clearly prohibited.
9. It is critical that the Standard states clearly that all products in powdered form are reconstituted with water not less than 70 degrees centigrade in accordance with the WHO/FAO *Guidelines on the Preparation, Storage and Handling of Powdered Infant Formulas* and the *Code of Hygienic Practice for Powdered Infant Formula for Infants and Young Children* (CAC/RCP 66-2009).
10. IBFAN does not agree with the inclusion of optional ingredients, especially ingredient such as DHA that are not supported by relevant convincing scientific evidence. If an ingredient is proven by such evidence to be safe and beneficial it should be included in the list of essential ingredients.

As mentioned above IBFAN proposes ONE standard and agrees with an overarching Preamble.

If this is not agreed then we suggest the following changes for the PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)

[PREAMBLE]

*The Codex Alimentarius Commission acknowledges the need to [protect and support / recognize] breastfeeding as an unequalled way of providing **normal** food for the healthy growth and development of infants **and young children**. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, **DELETE: where [necessary / appropriate]**, as a substitute for human milk in meeting the **normal** nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods.*

Since infant formula can continue to be used beyond 6 months, these products are not necessary.** The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children **should only be permitted if it is** consistent with national health and nutrition policies and relevant national/regional legislation. **The marketing of these products** and these products should not discourage breastfeeding **and must be in accordance with take into account, [as appropriate]**, the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), **and** the Global Strategy for Infant and Young Child Feeding, relevant WHO guidelines and policies, as well as relevant World Health Assembly (WHA) resolutions, **including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children. DELETE: that have been [endorsed / supported] by member states. [may also] provide guidance to countries in this context.

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

The following comments apply to Follow-up Formula for Older Infants (Section A) and [Name of product] for Young children (Section B)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

SCOPE:

This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

1.2 This section of the Standard contains compositional, quality, safety, ***information for use, warnings against needless and inappropriate use***, labelling and analytical requirements for Follow-up Formula for Older Infants.

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / ~~shall~~] be presented as] Follow-up Formula for Older Infants

Add: 1.4 ***IBFAN does not agree with the deletion of provision 1.4 in the Scope. The scope must remind Regulatory Authorities of the safeguards contained in the over-arching Preamble if they are to ensure that the WHO recommendations underpin the marketing and labelling of each product category.***

3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 Follow-up formula [for older infants] is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants

3.1.2 The nutritional safety and adequacy of follow-up formula for older infants ***must*** be ~~scientifically~~ demonstrated, ***through relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification***, to support growth and development of older infants.

3.1.4 c) Carbohydrates

IBFAN agrees that preferred carbohydrate should be lactose, and questions the addition of glucose polymers. We agree that Sucrose and Fructose should not be added, and question when they would be needed as a carbohydrate source. IBFAN supports the WHO recommendation for added sugars for older infants and young children, that is based on their negative effect on body weight, dental caries as well as their impact on taste development.

Maltodextrose: IBFAN opposes the addition of industrially produced carbohydrates (many of which are made from genetically modified corn). Maltodextrin (MDX), has been implicated in an increased growth of E. coli and the altering of the microbiome. It has also been linked to Crohn's Disease and diabetes related to its high glycemic index (Nickerson KP, McDonald C (2012) Crohn's Disease-Associated Adherent-Invasive *Escherichia coli* Adhesion Is Enhanced by Exposure to the Ubiquitous Dietary Polysaccharide Maltodextrin. PLoS ONE 7(12): e52132. ²

Fructose: The consumption of fructose has been linked to negative metabolic and clinical outcomes, including obesity, glucose intolerance and hepatic steatosis. Since older infants and young children may be consuming FUF products on a daily basis, these added carbohydrates with known negative effects should not be the carbohydrate sources for these products.

Footnote 4 to read:

Mono and di-saccharides, other than lactose should not exceed 5% of available carbohydrate. Sucrose, maltodextrose or fructose should not be added.

²<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0052132><https://doi.org/10.1371/journal.pone.0052132>

3.2 **Optional** Ingredients

IBFAN is opposed to the addition of optional ingredients and suggest that 3.2 is replaced with the following text:

The addition of optional ingredients may have adverse effects on child health and should not be permitted. The addition of ingredients and/or nutrients that have not been proven to be essential to the growth and development of an older infant and a young child may be an added chemical burden. Competent national and/or regional authorities wishing to alter the list of essential ingredients listed under 3.2.4 to 3.2.6, must ensure that the ingredients are evaluated and demonstrated as safe and nutritional useful by relevant convincing scientific evidence or the comparable level of evidence under the GRADE classification.

After an extensive literature review The European Food Safety Authority (EFSA) 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 unnecessary addition of nutrients can be a burden to a young child's metabolism.³

*"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".
UK Scientific Advisory Committee on Nutrition SACN 2007*

IBFAN has concerns about the lack of evidence supporting the addition of DHA:

- A meta-analysis on the use of LCPUFA concluded, "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." (Qawasmi A, Landeros-Weisenberger A, LeckmanJF, Bloch MH. *Meta-analysis of long-chain polyunsaturated fatty acid supplementation of formula and infant cognition. Pediatrics.* 2012 June;129(6):1141-9).
- A Cochrane review on supplementation of the LCPUFA in infant formula concluded, "The majority of the RCTS have not shown beneficial effects of LCPUFA supplementation on the neuro developmental outcomes of term infants. The beneficial effects on visual acuity have not been consistently demonstrated. Routine supplementation of term infant milk formula with LCPUFA cannot be recommended." (Simmer K, Patole SK, Rao SC. *Long-chain polyunsaturated fatty acid supplementation in infants born at term. Cochrane Database Syst Rev.* 2011 Dec 7;(12): CD000376).
- The European Food Safety Authority (EFSA), in their report published in the *EFSA Journal* 2014;12(7):3760, has explicitly stated that "There is no necessity to add arachidonic acid, eicosapentaenoic acid, non--digestible oligosaccharides, "probiotics" or "synbiotics", chromium, fluoride, taurine and nucleotides to infant and follow-on formulae".

Section 9 Labelling IBFAN agrees with the intent of this section.

9.5 Information for Use

9.5.1 *[Ready to use] products in liquid form may be used [either] directly or in the case of concentrated liquid products [and powdered products], must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. [Products in powder form should be reconstituted with water that is safe or has been*

³ Scientific Opinion on the essential composition of infant and follow-on formulae, EFSA, *EFSA Journal* 2014;12(7):3760

rendered safe by previous boiling for **preparation and no less than 70 degrees before being reconstituted with the powder**. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice **and the WHO/FAO Guidelines on the Preparation, Storage and Handling of Powdered Infant Formulas and the Code of Hygienic Practice for Powdered Infant Formula**.

9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that [product] remaining after feeding should be discarded, shall appear on the label.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. **There should be no preparation instructions showing bottles and teats for follow-up formula or for (name of the product) for young children, Graphics should only illustrate cup feeding.**

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use etc etc .

9.6 Additional Labelling Requirements REMOVE BRACKETS FROM THE FOLLOWING SAFEGUARDS. THEY ARE ALL ESSENTIAL

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

[a] the words "important notice" or their equivalent;]

(b) **Breastfeeding is the normal and healthy way to feed your baby. When your baby is not breastfed she is likely to be sick more often. Exclusive breastfeeding is recommended from 0- 6 months of age, with continued breastfeeding along with appropriate complementary foods to two years of age or beyond.**

[c] a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.]

9.6.2 The label shall have no pictures of infants ~~and~~ or women nor any other pictures, ~~or~~ text, which idealizes the use of follow-up formula. The label shall have no pictures, images, text or other representation that might:

9.6.2.1 idealize the **use of the product** ~~follow-up formula for older infants~~; .

9.6.2.2 suggest **its** use for infants under the age of 6 months (including references to milestones and stages);

9.6.2.3 recommend or promote bottle feeding or its **use with a bottle feeding**; **(Preparation instructions should illustrate cups, not bottles and teats.)**

9.6.2.4 undermine or discourage breastfeeding, ~~that makes a comparison to breast-milk, or suggests that the product is nearly equivalent to or superior to breast-milk;~~

9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.]

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used. **[In addition, the product should not be compared to breast-milk].**

9.6.4 Products targeting babies 6 to 36 months shall not be cross branded with other infant formula or infant food products.

9.6.5 Products targeting babies 6 to 36 months must be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes **REMOVE BRACKETS** **and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.**

9.6.6 The use of nutrition, health and convenience claims are prohibited.

All the above comments and safeguards must apply Section B – [Name of product] for Young children