

## SUBMITTERS RESPONSE FORM

### Scope and Labelling of Follow-up Formula for Older Infants

2nd Consultation Paper

Responses due: 14<sup>th</sup> July 2017

Please provide your responses to the 2<sup>nd</sup> Consultation Paper on Scope and Labelling for Follow-up Formula for Older Infants in the response form below and then post your form on the Codex eWG Follow-up Formula online-platform by the due date. Electronic working group members are reminded that responses to this consultation paper will be used to inform the Agenda Paper, and are not for wider external distribution.

**Name of Member Country/Organisation: IBFAN (International Baby Food Action Network)**

### 3. PREAMBLE

#### QUESTION: Preamble

Please select your preferred option for the Preamble.

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).

**OR**

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).~~

#### RESPONSE:

**IBFAN continues to be of the opinion that there should be ONE revised renamed standard to include all breastmilk substitutes to the age of 36 months.**

**IBFAN is of the opinion the Standard for Infant Formula and Formula for Special Medical Purposes intended for Infants Codex Stan 72-1981 can accommodate all breastmilk substitutes into four sections that differentiate as follows:**

**Section A: infant formula (birth onwards or 0-12month and beyond)**

**Section B: Formulas for Special Medical Purposes (0-6 months)**

**Section C Follow-up formula for older infants (6 months onwards)**

**Section D: [Name of the Product] for Young Children (12-36 months)**

**Therefore the preamble should be worded:**

***“this Standard is divided into four sections: Section A refers to Infant Formula; Section B Formulas for Special Medical Purposes; Section C Follow-up Formula for older infants; Section D with (Name of Product) for Young Children (12 to 36 months). Follow-up formulas and Formulas for Young Children are not necessary products.***

#### ***Rationale:***

**The regulation of the use and marketing of these products at national level is best facilitated by one standard that incorporates the recommendations of the WHO technical Guidance on**

**Ending the Inappropriate Promotion of Foods for Infants and Young Children.** This Guidance clarified that “A breast-milk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products”

Research has demonstrated that parents are confused by the product differentiation.

- The 2010 UK national survey showed 16% of mothers used follow-up formula before the age of 6 months and 26% of mothers who did not work outside of the home reported using follow-up formula before the age of 6 months. (McAndrew, F., Thompson, J., Fellows, L., Large, A., Speed, M., & Renfrew, M. J. (2012). Infant Feeding Survey 2010. Leeds: Health and Social Care Information Centre. Retrieved from <http://content.digital.nhs.uk/catalogue/PUB08694/Infant-Feeding-Survey-2010-Consolidated-Report.pdf> ).
- In a report by (Crawley and Westland, 2017, Infant Milks in the UK: A Practical Guide for Health Professionals). One-third (32%) of mothers could not differentiate between various breast-milk substitute products, and health workers also not able to differentiate between these products.

A survey of mother’s perceptions of follow-up formula advertisements concluded that follow-up formula are perceived as promoting infant formula. Additionally the authors noted that, “in the European Union, the marketing of follow-up formula, and other breastmilk substitutes, should be subjected to the same restrictions currently applied only to infant formula.” Cattaneo A., et al. Arch Dis Child (2014) 0:1 to 6. Doi:10.1136/archdischild-2014-306996.

Therefore IBFAN continues to recommend one standard with 4 sections.

If the Committee agrees that there should be separate standards with two sections each, it must be made clear that there is cross over between all these products and that infant formula can be used beyond 6 months. All sections of the standards must carry all the safeguards recommended in the WHA Resolutions and the 2016 Guidance.

#### 4. SCOPE

##### 4.2.1 Scope: Section 1.1

###### QUESTION: Scope – Section 1.1

Please select your preferred option for Section 1.1 of the Scope for follow-up formula for older infants.

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

**OR**

1.1 This section of the Standard [**Section A**] applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form. [**It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)**].

###### RESPONSE:

**This section of the Standard applies to Follow-up Formula for Older Infants as defined in Section 2.1.**

**If the Committee agrees that there should be separate standards with two sections each, it must be made clear that there is cross over between all these products and that infant formula can be used beyond 6 months. All sections of the standards must carry all the safeguards recommended in the WHA Resolutions and the 2016 Guidance.**

#### 4.2.2 Scope: Section 1.2

<b>QUESTION: Scope – Section 1.2</b>
Please consider and comment on the amendments proposed in square brackets.
1.2 This section of the Standard contains compositional, quality, [ <del>and</del> ] safety, [ <b>labelling and analytical</b> ] requirements for Follow-up Formula for Older Infants.
<b>RESPONSE:</b> <b>IBFAN proposes to word Scope Section 1.2</b> 1.2 This section of the Standard contains compositional, quality, safety, <b>labelling and analytical</b> requirements <b>and information for use and warnings</b> for Follow-up Formula for Older Infants.

#### 4.2.3 Scope: Section 1.3

<b>QUESTION: Scope – Section 1.3</b>
Please select your preferred option for Section 1.3 of the Scope 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 [ <b>should be presented as</b> ] Follow-up Formula for Older Infants. <b>OR</b>
1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [ <b>may be presented as suitable for</b> ] Follow-up Formula for Older Infants <b>OR</b>
1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [ <b>would be accepted for being presented as</b> ] Follow-up Formula for Older Infants. <b>OR</b>
1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for [ <b>being named/called</b> ] Follow-up Formula for Older Infants.
<b>RESPONSE:</b> <b>IBFAN agrees to the wording with the change from <i>would to should</i>:</b> Only products that comply with the criteria laid down in the provisions of this section of this Standard <b><u>should be accepted for being presented as</u></b> Follow-up Formula for Older Infants.  <b>Regarding scope section 1.4</b> <b>Although the chairs have referred the consideration of the inclusion of WHA resolutions, recommendations and documents to the secretariat, IBFAN considers this issue to be critical for the protection of infant and young child health and to prevent the needless use of breastmilk substitutes. Hence we wish to make the following proposal and comments regarding section 1.4</b> <b>1.4 The application of this Standard <u>requires</u> conformity with the recommendations made in the International Code of Marketing of Breast-milk Substitutes (WHA 34.22(1981), the Global Strategy for Infant and Young Child Feeding, <u>the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children</u> and <u>all relevant</u> World Health Assembly resolutions, <u>in particular</u> WHA39.28(1986); WHA 54.2(2001); WHA58.21(2005); WHA61.20(2008); WHA 69.9(2016).</b> <b>Rationale:</b> <b>The Standard should require compliance with all relevant resolutions of the WHA as these clarify the obligations needed to safeguard breastfeeding and optimal infant and young</b>

child feeding.

Since 1986 and the adoption of WHA 39.28 the World Health Assembly has stated that: *“the practice being introduced in some countries of providing infants with specially formulated milks (so-called ‘follow-up-milks’) is not necessary.”*

As WHO is the parent UN agency of Codex, and the WHA is the world’s highest policy setting body, Codex should ensure that its standards are in conformity with the decisions made by the World Health Assembly. There should be health policy coherence between WHA decisions and Codex as called for in WHA res 58.32 *“(8) to ensure policy coherence at national level by stimulating collaboration between health authorities, food regulators and food standard-setting bodies;”* and WHA res 69/9.

## 5. LABELLING

### 5.4.2 Ingredient and nutrient declarations/claims

#### QUESTION: Ingredient and nutrient declarations/claims

Do you agree with the Chairs proposal that a reference to the applicability of the recommendations in the *Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)* to follow-up formula for older infants be included within the introductory paragraph for the Labelling section (Section 9)? It would also include a statement that the requirements of the Guidelines include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in the relevant Codex Standards or national legislation.

#### RESPONSE:

**YES** with the inclusion of the Code of Hygienic Practice for PIF.  
**IBFAN** Agrees that there should be a reference to the *Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)* and that follow-up formula for older infants should be included within the introductory paragraph for the Labelling section and also the Code of Hygienic Practice for Powdered Infant Formula for Infants and Young Children (CAC/RCP 66 – 2008).

*Please present an alternative approach if you do not agree with the Chairs proposal.*

Do you agree with the Chairs proposal that nutrition claims should be revisited after the completion of NRV’s for older infants and young children?

#### RESPONSE:

**NO**

*Please present an alternative approach if you do not agree with the Chairs proposal.*

**Claims for specific nutrients, ingredients or optional nutrients, additives or ingredients should not be permitted because they mislead parents. Claims on product labels and in promotions (all in violation of the International Code and WHA resolutions) have been demonstrated to have no scientific substantiation and falsely exaggerate the properties of the products. The highlighting of one or other ingredient can lead to the idealisation of the product and a masking of its inherent risks.**

**WHA58.32(2005) specifically urges member states:**

**“To ensure that nutrition and health claims are not permitted for breastmilk substitutes, except where specifically provided for in national legislation.”**

**And WHA 63.23 (2010) urges Member States “(4) to end inappropriate promotion of foods for infants and young children, and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation.”**

#### 5.4.3 Name of food

##### QUESTION: The Name of the Product

The following text is proposed for Section 9.1 for follow-up formula for older infants. Please comment on the text in square brackets, and select your preferred option for 9.1.4 and 9.1.5.

#### 9.1 The Name of the Product

9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

9.1.2 The name of the product shall be *Follow-up Formula for Older Infants* as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.

9.1.4 If ~~ewes'~~ [name of animal/plant-based] milk is the only source of protein, the product may be labelled 'Follow-up Formula for Older Infants Based on ~~ewes'~~ [name of animal/plant based] milk [protein]'.

**OR**

[If 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content, the product may be labelled 'Follow-up Formula for Older Infants based on [name of animal] Milk].

**OR**

[Delete 9.1.4, covered by 9.1.3]

9.1.5 A product which contains neither milk nor any milk derivative [shall] [may] be labelled "contains no milk or milk products" or an equivalent phrase.

##### RESPONSE:

*Please comment on the text in square brackets and select your preferred option for 9.1.4.*

*Please write out a clean copy of your preferred wording for Section 9.1 without the use of any square brackets.*

#### 5.4.4 List of ingredients

##### QUESTION: List of Ingredients

The following text is proposed for Section 9.2 for follow-up formula for older infants. Please comment on the text in square brackets.

#### 9.2 List of Ingredients

9.2.1 A complete list of ingredients [including optional ingredients] shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

**9.2.2** The specific name shall be declared for ingredients of animal or plant origin and for food additives. **[Food additives may also optionally declare the INS number]**.

**RESPONSE:**

**9.2.1** A complete list of **all** ingredients **[including optional ingredients]** shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

**9.2.2** The specific name shall be declared for ingredients of animal or plant origin and for food additives. **[Food additives may also optionally declare the INS number]**.

**The ingredient lists should be mandatory and include all ingredients that are in the product. It is critical that parents and care givers have full objective information if they are to make informed and wise decisions about infant and young child feeding.**

**5.4.5 Declaration of Nutritive Value**

**QUESTION: Declaration of Nutritive Value**

The following text is proposed for Section 9.3 for follow-up formula for older infants. Please comment on the text in square brackets and select your preferred option from the two suggestions provided in each paragraph.

**9.3 Declaration of Nutritive Value**

The declaration of nutrition information **[for follow-up formula for older infants]** shall contain the following information which should be in the following order:

- a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold **[as well as] [or]** per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold **[as well as] [or]** per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
- c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

**RESPONSE:**

**IBFAN agrees**

**5.4.6 Date marking and storage instructions**

**QUESTION: Date Marking and Storage Instructions**

The following modified text is proposed for Section 9.4 for follow-up formula for older infants to align with the wording put forward at CCFL48. The Chairs **are not seeking comment** on the modified text, but propose that once the date marking drafting is finalised at CCFL, Section 9.4 adopts the same text in order to be consistent. Do you support this proposal? YES/NO

**9.4 Date Marking and Storage Instructions**

**9.4.1** The **“Best Before Date” or “Best Quality Before Date”** ~~date of minimum durability~~

(preceded by the words "best before") shall be declared by the day, month and year in un-coded numerical sequence except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. [The day and year shall be declared by un-coded numbers with the year to be denoted by 2 or 4 digits, and the month shall be declared by letters or characters or numbers. Where only numbers are used to declare the date or where the year is expressed as only two digits, the competent authority should determine whether to require the sequence of the day, month, year, be given by appropriate abbreviations accompanying the date mark (e.g. DD/MM/YYYY or YYYY/DD/MM).]

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

- 9.4.2** In addition to the date, any special conditions for the storage of the food shall be indicated if [where they are required to support the integrity of the food and, where] the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

**RESPONSE:**

*Do you support this proposal?* **YES**

**There should also be a statement on the requirement for Lot Numbers to facilitate recalls to safeguard from the dangers of contaminated, mislabelled or wrongful ingredients.**

**5.4.7 Information for use**

**QUESTION: Information for Use**

The following two options are being proposed for Section 9.5 for follow-up formula for older infants. Please select your preferred option and comment on the text in square brackets.

**Option 1:**

**9.5 Information for Use**

**9.5.1** Products in liquid form may be used either directly or in the case of concentrated liquid 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 **at 70 degrees centigrade and 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 - 2008.** ~~that is safe or has been rendered safe by previous boiling for preparation.~~ Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

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

**9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product.

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

**9.5.5** Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label **and in any accompanying leaflet.**

**9.5.6** The label of follow-up formula for older infants shall include a statement that the product shall not be introduced before 6 months of age, **is not to be used as a sole**



**source of nutrition and that older infants should continue to receive breastmilk and complementary foods. in addition to the formula.**

**9.5.7 This product is not necessary for the growth and development of older infants.**

**Option 2:**

**9.5 Information for Use**

[The following 'Information for use' requirements are mandatory provisions that must appear on the label of follow-up formula for older infants;

**9.5.1 a statement that powdered follow-up formula for older infants should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation, adequate directions for the appropriate preparation, handling and use of product, including its storage and disposal after preparation in accordance with Good Hygienic Practice. The label shall also carry clear graphic instructions illustrating the method of preparation of the product, a warning about the health hazards of inappropriate preparation, storage and use, and adequate directions regarding the storage of the product after the container has been opened.**

**9.5.2 a statement that the product shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition, and that older infants should receive complementary foods in addition to the formula.]**

**RESPONSE:**

*Please select your preferred option (1 or 2) and comment on the text in square brackets.*

*Please write out a clean copy of your preferred option for Section 9.5 without the use of any square brackets.*

**IBFAN Prefers Option 1 with the additions as noted above:**

**9.5.1 needs to be modified to include 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 - 2008.**

**A statement to read:**

**Powdered fortified milk products are not sterile and that reconstitution, storage and handling instructions should be followed carefully to prevent serious illness.**

**A statement that this product is not necessary for the growth and development of older infants is needed as per WHA resolution 39:28.**

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**5.4.8 Additional labelling requirements**

**QUESTION: Additional labelling requirements**

Please select your preferred option below and comment on the text in square brackets including whether it should be retained, deleted, or modified.

**Option 1:** Merges 9.6.1, 9.6.2, 9.6.3 (to become 9.6.1), deletes 9.6.4, and presents modified wording (and renumbering to become 9.6.2) for the original provision 9.6.5:

**9.6 Additional Labelling Requirements**

**[9.6.1 The label of follow-up formula for older infants shall include a statement as to the superiority of breastfeeding or breast milk. The label shall have no image, text or representation that could undermine or discourage breastfeeding or which idealises the use of follow-up formula for older infants. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.]**



**[9.6.2]** Products shall 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.

~~**[9.6.4]** Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.]~~

**Option 2:** Retains individual provisions for 9.6.1, 9.6.2, 9.6.3, deletes provision 9.6.4, and presents modified wording (and renumbering to become 9.6.4) for the original provision 9.6.5:

## **9.6 Additional Labelling Requirements**

**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) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;
- [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.]
- [d] the statement; 'The use of this product must not replace breastmilk and lead to cessation of continued breastfeeding'.]**

**OR**

**[9.6.1 The label of Follow-up Formula for Older Infants should not discourage breastfeeding. It shall include a statement that exclusive breastfeeding is recommended from birth to 6 months of age, and that breastfeeding should continue to two years of age or beyond.]**

**AND**

**9.6.2** The label shall have no pictures of infants [~~and women~~] nor any other picture or text which idealizes the use of [~~infant~~] [follow-up] formula [for older infants].

**OR**

**[9.6.2** The label shall have no pictures of infants and women nor any other picture 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** suggest use for infants under the age of 6 months (including references to milestones and stages);
- 9.6.2.2** recommend or promote bottle feeding;
- 9.6.2.3** 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;
- 9.6.2.4** 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.]

**AND**

**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].**

**AND**

**[9.6.4]** Products shall 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.

~~**[9.6.4]** Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.]~~

**RESPONSE:**

Please select your preferred option (1 or 2) and comment on the text in square brackets.  
Please write out a clean copy of your preferred option for Section 9.6 without the use of any square brackets.

**IBFAN Prefers option 2 with the inclusion of modifications as follows:**

**9.6.1 (b) to add:**

**b) Breastfeeding is the normal and healthy way to feed your baby and a warning that when your baby is not breastfed she will be sick more often.**

**9.6.4 Information shall appear on the label to the effect that older infants should receive safe and appropriate complementary foods from the age of six months with the continuation of breastfeeding to two years or beyond. The use of follow-on formula should be only on the advice of an independent health worker.**

**To prevent confusion and needless and inappropriate use of these products cross branding with infant formula must be forbidden and a clear distinction must be made between the labelling and presentation of these products. The appropriate ages must be clearly visible, the colours, type of products (powdered, concentrated or ready to serve) and logos and all other information on the labels must clearly differentiate these products.**

## 6. DEFINITIONS

**QUESTION: Definition of follow-up formula for older infants**

Please select your preferred definition from the options below and your preferred wording from the options in square brackets.

New proposals:

- *Follow-up formula for older infants means a product, specially manufactured for use [as a substitute for breast-milk / or a replacement for infant formula] as a liquid part of the diet for older infants when complementary feeding is introduced.*
- *Follow-up formula for older infants means a product, specially manufactured for use as a liquid part of [a progressively / diversified] diet for older infants when complementary feeding is introduced.*

**RESPONSE:**

Please write out a clean copy of your preferred proposal for the definition without the use of any square brackets.

- **Follow-up formula for older infants means a product, in liquid or powdered forms, intended for use as a total or partial substitute for breastmilk, breastfeeding or infant formula as the liquid part of the diet for older infants when complementary feeding is introduced after the age of six months.**