

## SUBMITTERS RESPONSE FORM

### Scope and Labelling of Follow-up Formula for Older Infants and (Name of Product) for Young Children

1<sup>st</sup> Consultation Paper

Responses due 7<sup>th</sup> April 2017

Please provide your responses to the first consultation paper on Scope and Labelling 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 second consultation paper, and are not for wider external distribution.

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

### 3. Scope

#### 3.3 Preamble

**CODEX STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND (NAME OF PRODUCT) FOR YOUNG CHILDREN  
CODEX STAN 156-1987**

#### **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).

#### **QUESTION: Preamble**

The Chairs propose the above Preamble for the Standard for Follow-up Formula.

Do you agree with the inclusion of a preamble? YES/NO. Please justify your answer. If you support the inclusion of a preamble statement, please comment on the above wording and provide an alternative statement if necessary.

#### **RESPONSE: YES**

**IBFAN agrees with the inclusion of a preamble to the standard, however we are 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; 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.*”**

The differences in composition between Infant Formula and Follow on formulas likely to be minimal – they have not yet been finalized, and while infant formula can cover the whole of the first year of life and beyond, a high iron formula should not be fed to healthy term infants under 6 months unless clinically required. Proper regulation of the 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](https://doi.org/10.1136/archdischild-2014-306996).

### 3.5 Scope: Follow-up formula for older infants

SECTION A		
<b>Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981 Rev 2007)</b>	<b>Proposal for consideration for Section A of the revised Codex Standard for Follow-up Formula for Older Infants and (Name of Product) for Young Children</b>	<b>QUESTIONS: Scope – Follow-up formula for older infants</b>
<i>1.1 This section of the Standard [Section A] applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants.</i>	<p>1.1 This section of the Standard [<b>Section A</b>] applies to [<del>infant formula</del>] [<b>Follow-up Formula for Older Infants, as defined in Section 2.1,</b>] in liquid or powdered form. [<del>intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants.</del>]</p> <p><i>Rather than define the product and role in the diet of follow-up formula for older infants in the Scope, it is proposed that 1.1</i></p>	Do you support the proposed approach and modified wording? YES/NO. If not, please provide justification for your response and an alternative statement for 1.1.

	(Section A) refer to the definition in Section 2.1 – Product Definition, rather than repeat the definition in the Scope.	
<p><b>RESPONSE: NO</b></p> <p><b>IBFAN’s preferred recommendation is for one standard – a revised and renamed version of the Infant Formula Standard - to cover all breastmilk substitutes as explained above. Any deferentiations between the differents types of formulas must be justified by “Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification.”</b></p>		
1.2 This section of the Standard contains compositional, quality and safety requirements for Infant Formula.	1.2 This section of the Standard contains compositional, quality and safety requirements for [Infant Formula] [Follow-up Formula for Older Infants].	Do you support the proposed approach and modified wording? YES/NO. If not, please provide justification for your response and an alternative statement for 1.2.
<p><b>RESPONSE: NO</b></p> <p><b>IBFAN recommends that 1.2 be reworded to state:</b></p> <p><b>Section C of the Standard contains the compositional, quality and safety requirements for follow-up formula to meet the needs of infants to 6-12 months.</b></p>		
1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.	1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for [marketing] [being named] as [infant formula] [Follow-up Formula for Older Infants]. [No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.]	Is the statement contained within 1.3 (or a similar statement) necessary in the Scope for follow-up formula for older infants? YES/NO.  Please note that it is proposed that the Preamble include the following wording: <i>It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981) and section 1.4 below will reference ‘relevant WHA resolutions’.</i>  Please provide justification for your response.
<p><b>RESPONSE:</b></p> <p><b>IBFAN proposes the deletion of the term “marketing”. The statement in 1.3 should read:</b></p> <p><b>Reword to read: All formula products that are marketed for infants and young children to the age of 36 months must comply with the provisions of this standard.</b></p> <p>The term marketing does not define the product, especially a unique product that requires marketing restrictions.</p>		
1.4 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young	1.4 The application of this <del>section of the</del> Standard should take into account <b>require</b> the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young	Which WHO documents and WHA resolutions are appropriate to be listed or referenced as part of the Scope (or Preamble) for products covered within Section A (follow-up formula for older infants) of the

<p><i>Child Feeding and World Health Assembly resolution WHA54.2 (2001).</i></p>	<p>Child Feeding, [<b>the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children</b>] and [<b>relevant</b>] World Health Assembly resolution[s] [<b>including WHA .....</b>] [<del>WHA54.2 (2001).</del>]</p> <p>NOTE: the WHO Guidance could also be referenced by the relevant resolution – WHA69.9.</p>	<p>Standard (see 2.1)?</p> <p>Please provide justification for your response?</p>
<p><b>RESPONSE:</b></p> <p><b>IBFAN proposes that 1.4 be reworded as:</b></p> <p><b>1.4</b> The application of this Standard <b>requires</b> 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, <b>the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children</b> and <b>all relevant</b> World Health Assembly resolutions, <b>in particular</b> WHA39.28(1986); WHA 54.2(2001); WHA58.21(2005); WHA61.20(2008); WHA 69.9(2016).</p> <p><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 child feeding.</b></p> <p><b>Since 1986 and the adoption of WHA 39.28 the World Health Assembly has stated that: “the practice being introduced in some counties of providing infants with specially formulated milks (so-called “follow-up-milks”) is not necessary.”</b></p> <p><b>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.</b></p>		

### 3.6 Scope: (Name of product) for young children

SECTION B		
<p><b>Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981 Rev 2007)</b></p>	<p><b>Proposal for consideration for Section B of the revised Codex Standard for Follow-up Formula for Older Infants and (Name of Product) for Young Children</b></p>	<p><b>QUESTIONS: Scope – (Name of Product) for young children</b></p>
<p><i>1.1 This section of the Standard [Section A] applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants.</i></p>	<p>1.1 This section of the Standard [<b>Section D</b>] applies to <del>infant formula</del> <b>for young children, as defined in Section 2.1,</b> in liquid or powdered form <b>intended for use for young children from the age of 12 months.</b> the use[<del>intended for use,</del> where necessary, as a substitute for human milk in meeting the normal nutritional requirements</p>	<p>Do you support the proposed approach and modified wording? <del>YES</del>/NO. If not, please provide justification for your response and an alternative statement for 1.1.</p>

	<p>of infants.]</p> <p><i>Rather than define the product and role in the diet of (name of product) for young children in the Scope, it is proposed that 1.1 (Section B) refer to the definition in Section 2.1 – Product Definition, rather than repeat the definition in the Scope.</i></p>	
<p><b>RESPONSE:</b></p> <p><b>IBFAN Proposes the following wording:</b>  <b>This section of the Standard [Section D] applies to [name of the products] for young children, as defined in Section 2.1,] in liquid or powdered form intended for use for young children from the age of 12 months.</b></p> <p><b>IBFAN’s preferred recommendation is for one standard for all breastmilk substitutes as explained above. Product differentiations in formulas targeting infants 0 to 6 months and 6 to 12 months and 12 to 36 months must be justified by and “Relevant convincing / generally accepted scientific evidence or the comparable level of evidence under the GRADE classification.”</b></p>		
<p><b>1.2</b> This section of the Standard contains compositional, quality and safety requirements for Infant Formula.</p>	<p><b>1.2</b> This section of the Standard contains compositional, quality and safety requirements for [Infant Formula] [(name of product) for young children].</p>	<p>Do you support the proposed approach and modified wording? YES/NO. If not, please provide justification for your response and an alternative statement for 1.2.</p>
<p><b>RESPONSE: NO</b></p> <p><b>IBFAN recommends that 1.2 be reworded to state:</b></p> <p><b>Section D of the standard contains compositional, quality and safety requirements for [name of the product] for young children to meet the needs of young children 12 to 36 months.</b></p>		
<p><b>1.3</b> Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.</p>	<p><b>1.3</b> Only products that comply with the criteria laid down in the provisions of this section of this Standard would be for <del>accepted for [marketing] [being named] as [infant formula]</del> [Name of Product for young children]. <del>[No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.]</del></p>	<p>Is the statement contained within 1.3 (or a similar statement) necessary in the Scope for (name of product) for young children? YES/NO.</p> <p>Please note that it is proposed that the Preamble include the following wording: <i>It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981) and section 1.4 below will reference ‘relevant WHA resolutions’.</i></p> <p>Please provide justification for your response.</p>
<p><b>RESPONSE: NO</b></p> <p><b>IBFAN proposes the deletion of the term “marketing”. The statement in 1.3 should read:</b></p>		

**Reword to read: All formula products that are marketed for infants and young children to the age of 36 months must comply with the provisions of this standard.**

The term marketing does not define the product, especially a unique product that requires marketing restrictions.

<p><i>1.4 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).</i></p>	<p>1.4 The application of this section of the Standard should <del>take into account</del> <b>require</b> the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, <b>[the WHA69.9 and WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children]</b> and <b>[relevant]</b> World Health Assembly resolution[s] <b>[including WHA .....]</b> <b>[WHA54.2 (2001).]</b></p>	<p>Which WHO documents and WHA resolutions are appropriate to be listed or referenced as part of the Scope (or Preamble) for products covered within Section B ((name of product) for young children) of the Standard (see 2.1)?</p> <p>Please provide justification for your response.</p>
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**RESPONSE:**  
**To avoid inappropriate marketing, misleading labelling and inappropriate use of these products, all the provisions of the International Code and WHA resolutions must apply. The stated position of the WHO and WHA regarding use of follow-up formula is unambiguous that follow-up formula and [name of the product] for young children function as breastmilk substitutes**

**The International Code and WHA resolutions aim to protect the health of infants and young children and prevent the global rise in child obesity and other non communicable diseases. The extended use of bottle-feeding for young children undermines sustained breastfeeding to the age of 24 months or beyond and the use of nutrient rich, culturally appropriate and locally available family foods. The marketing restrictions recommended by the WHA apply to all products marketed for young children to the age of 36 months.**

**The following WHO documents and WHA resolutions must be listed and referenced as part of the Scope of a single revised Infant formula standard in 4 sections (or any standards the Committee decides):**

**International Code of Marketing of Breast-milk Substitutes (1981) and all subsequent relevant WHA Resolutions and the Global Strategy for Infant and Young Child Feeding (2002), specifically WHA Resolution 39.28 (1986), WHA 69.9 and the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children**

### 3.7 Reference to WHO documents and WHA resolutions

<p><b>QUESTION: Reference to WHO documents and WHA resolutions</b></p>
<p>Please comment on whether any reference to relevant WHO documents and WHA resolutions within the Standard should sit in the Preamble to the Standard or within the individual Scope sections for the respective products.</p>
<p><b>RESPONSE: YES</b></p>
<p><b>The International Code of Marketing of Breast-milk Substitutes (1981) and all subsequent relevant WHA Resolutions and the Global Strategy for Infant and Young Child Feeding (2002), specifically WHA resolution 39.28 (1986), WHA 69.9 and the WHO Guidance on</b></p>

**Ending the Inappropriate Promotion of Foods for Infants and Young Children should all be referenced in both the Preamble and the Scope of all the relevant standards to emphasize the critical importance of avoiding needless use of these products.**

Should the Standard;

- a) refer to 'all relevant WHA resolutions' without providing a definitive list of what these are;
- b) refer to 'relevant WHA resolutions' followed by a list of these in the Scope (or Preamble); or
- c) have relevant WHA resolutions referenced as a footnote to the Scope (or Preamble)?

**RESPONSE: b)**

**All the WHA resolutions together with specific references to the most pertinent resolutions should be cited in both the Preamble and the Scope. Since the use of promotional claims and the definition of the products covered are likely to be the most confusing issues for policy makers, it would make sense to include the following excerpts from the texts as footnotes:**

- Footnote to WHA resolution 39.28 (1986): "the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary".
- Footnote to Resolution 63.23: **member states are urged to:** (3) to develop and/or strengthen legislative, regulatory and/or other effective measures to control the marketing of breastmilk substitutes in order to give effect to the International Code of Marketing of Breastmilk Substitutes and relevant resolutions adopted by the World Health Assembly;
- (4) to end inappropriate promotion of food 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;
- Footnote to the Guidance A69/7 Add 1: ***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"***

## 4. LABELLING

### 4.4.1 Introductory paragraph

#### QUESTION: Introductory paragraph

Do you agree that following Codex Standards and Guidelines are applicable to ***follow-up formula for older infants*** and for ***(name of product) for young children*** and should be referenced in an introductory paragraph to the Labelling section as per the Infant Formula Standard? Please provide justification for your response.

	Follow-up formula for older infants	(Name of Product) for young children
<i>General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)</i>	YES/ <del>NO</del>	YES/ <del>NO</del>
<b>RESPONSE:</b>		
<i>Guidelines on Nutrition Labelling (CAC/GL 2-1985)</i>	YES/ <del>NO</del>	YES/ <del>NO</del>
<b>RESPONSE:</b> <b>Code of Hygienic Practice for Powdered Infant Formula for Infants and Young Children CAC/RCP 66 –</b>		

2008 should also be referenced in the Labelling sections of the Standard.

**QUESTIONS: Ingredient and nutrient declarations/claims**

The intent of this question is to explore the appropriate way(s) to communicate to consumers the composition of follow-up formula for older infants and of (name of product) for young children.

Should voluntary declarations about nutrients and ingredients be permitted on *follow-up formula for older infants*? If no, why not? **YES/NO**. If yes, what type(s) of declaration/claim should be permitted and how should they be regulated? Consider both the declaration of mandatory compositional parameters and of optional nutrient and ingredient provisions.

**RESPONSE: NO**

**The nutrient content and ingredient lists should be mandatory. It is critical that consumers have full objective information if they are to make informed and wise decisions regarding infant and young child feeding.**

**Claims for specific nutrients 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.”**

Should voluntary declarations about nutrients and ingredients be permitted on (name of product) for young children? **YES/NO**. If no, why not? If yes, what type(s) of declaration/claim should be permitted and how should they be regulated? Consider both the declaration of mandatory compositional parameters and of optional nutrient and ingredient provisions.

**RESPONSE:**

**The nutrient content and ingredient lists should be mandatory. It is critical that consumers have full objective information if they are to make informed and wise decisions about infant and young child feeding.**

**Claims for specific nutrients 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 nutrient content and ingredient lists should be mandatory. It is critical that consumers have full objective information if they are to make wise decisions regarding infant and young child feeding.. Promotional Claims for specific nutrients 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. 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.”**

**4.4.2 Name of Food**

**QUESTION: Name of food**



Based on comments received from the 2016 eWG, the Chairs propose the following drafting text for Section 9.1 (using the Infant Formula Standard as the starting point for a review of this section). Please comment on whether you support the deletions and text proposed in the square brackets, or provide an alternative approach/wording.

#### 9.1 The Name of the ~~[Food]~~ [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 either ~~["Infant Formula"]~~ ["**Follow-up Formula for Older Infants**" or "**(Name of Product) for Young Children**" as defined in Section 2.1] or any appropriate designation indicating the true nature of the product, in accordance with national usage.

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

9.1.4 If cows' milk is the only source of protein, the product may be labelled ~~["Infant Formula Based on Cows' Milk"]~~ ["**Follow-up Formula for Older Infants Based on Cows' Milk**" or "**(Name of Product) for Young Children Based on Cows' Milk**"]

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

Do you agree with the proposed drafting text? YES/NO. If you do not agree, please provide an alternative approach and/or wording, as well as justification for your response.

#### RESPONSE:

**IBFAN is of the opinion that the IF standard should be revised to include all breastmilk substitutes - formula products targeting children 0-36 months. The name of products for young children over 12 months needs further discussion.**

**IBFAN agrees with the statements for 9.1.1; 9.1.2; 9.1.3; 9.1.4 and 9.1.5**

#### 4.4.3 List of Ingredients

##### QUESTION: List of ingredients

It is proposed that provisions 9.2.1 and 9.2.2 of the Infant Formula Standard (as written above) are adopted for both follow-up formula for older infants and (name of product) for young children.

Do you agree with this approach? YES/NO. If you do not agree, please provide an alternative approach and/or wording, as well as justification for your response.

**RESPONSE: IBFAN agrees**

#### 4.4.4 Declaration of Nutritive Value

##### QUESTION: Declaration of Nutritive Value: follow-up formula for older infants

It is proposed that the following modified drafting text for section 9.3 for follow-up formula for older infants is adopted.

##### 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]** ~~[grammes]~~ of protein, carbohydrate and fat per 100 **[grams]** ~~[grammes]~~ or per 100 millilitres of the food as sold as well as 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 ~~[, choline]~~ as listed in paragraph 3.1.3 **[of Section A]** and any other ingredient as listed in paragraph 3.2 of **[Section A]** ~~[this Standard]~~ per 100 **[grams]** ~~[grammes]~~ or per 100 millilitres of the food as sold as well as

<p>per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</p> <p>c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.</p>
<p>Do you agree with the proposed modified drafting text for follow-up formula for older infants? YES/NO. If you do not agree, please provide an alternative approach and/or wording, as well as justification for your response.</p>
<p><b>RESPONSE: IBFAN agrees for this text to be used for products for young children.</b></p>
<p><b>QUESTION: Declaration of Nutritive Value: (name of product) for young children</b></p>
<p>It is proposed that the following modified drafting text for section 9.3 for (name of product) for young children is adopted.</p> <p><b>9.3 Declaration of Nutritive Value</b> The declaration of nutrition information [for (name of product) for young children] shall contain the following information which should be in the following order:</p> <p>a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of <b>[grams]</b> <del>[grammes]</del> of protein, carbohydrate and fat per 100 <b>[grams]</b> <del>[grammes]</del> or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</p> <p>b) the total quantity of each vitamin, <b>[and]</b> mineral <del>[-choline]</del> as listed in paragraph 3.1.3 <b>[of Section B or added under paragraph 3.1.4]</b> and any other ingredient as listed in paragraph 3.2 of <b>[Section B]</b> <del>[this Standard]</del> per 100 <b>[grams]</b> <del>[grammes]</del> or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</p> <p>c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.</p>
<p>Do you agree with the proposed modified drafting text for (name of product) for young children? YES/NO. If you do not agree, please provide an alternative approach and/or wording, as well as justification for your response.</p>
<p><b>RESPONSE: IBFAN agrees to the modifications for 9.3 for the products for young children.</b></p>

#### 4.4.5 Date Marking and Storage Instructions

<p><b>QUESTION: Date marking and storage instructions</b></p>
<p>It is proposed that provisions 9.4.1 and 9.4.2 of the Infant Formula Standard (as written below) are adopted for both follow-up formula for older infants and (name of product) for young children:</p> <p><b>9.4 Date Marking and Storage Instructions</b></p> <p><b>9.4.1</b> The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. 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.</p> <p><b>9.4.2</b> In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking.</p>
<p>Do you agree with this approach? YES/NO. If you do not agree, please provide an alternative approach and/or wording, as well as justification for your response.</p>
<p><b>RESPONSE: YES</b> <b>IBFAN agrees</b></p>

#### 4.4.6 Information for Use

<b>QUESTION: Information for Use</b>
Please indicate your support for the following proposals, or provide an alternative approach and wording, with justification for your answer.
It is proposed that the title of section 9.5 be re-worded to; Information for [Use] Utilization, to align with the Infant Formula Standard. Do you agree? YES/ <del>NO</del>
<b>RESPONSE: YES</b>
It is proposed that a requirement for the labelling of follow-up formula for older infants include a statement that follow-up formula for older infants shall not be introduced before the 6th month of life be retained. Do you agree? <b>YES/NO</b> . Please provide justification for your response.
<b>RESPONSE: Infant Formula can be used for infants and young children to the age of 36 months. However follow-up formulas with high levels of iron should not be fed to babies under 6 months.</b>
It is proposed that a similar amended provision for (name of product) for young children is included which requires that the product should not be introduced before 12 months of age. Do you agree? YES/ <del>NO</del> . Please provide justification for your response.
<b>RESPONSE: IBFAN agrees</b>
It is proposed that a requirement for the labelling of follow-up formula for older infants include information that older infants shall receive other foods in addition to the formula be retained. Do you agree? YES/ <del>NO</del> . Please provide justification for your response.
<b>RESPONSE: IBFAN agrees that the statement 9.6.4 of the IF standard is suitable.</b>
Should a similar provision be required for (name of product) for young children? YES/NO Please provide justification for your response.
<b>RESPONSE:</b> <b>The following statements should be on the label that:</b> <ul style="list-style-type: none"> <li>• <b>WHO recommends exclusive breastfeeding for the first 6 months of life and sustained breastfeeding to two years or beyond with the introduction of safe and appropriate complementary foods commencing at 6 months of age.</b></li> <li>• <b>“name of the product” is not necessary and should not be used for infants under the age of 12 months.</b></li> </ul> <b>These statements are in conformity with the WHA resolutions WHA 54.2 and WHA39.28</b>
Please comment on whether any of the provisions contained within section 9.5 of the Infant Formula Standard should be adopted for follow-up formula for older infants, and for (name of product) for young children. Please provide justification for your response.
<b>RESPONSE:</b> <b>Follow-up formula for older infants:</b>
<b>(Name of Product) for young children:</b> <b>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.</b> <b>A statement to read:</b> <b>Powdered fortified milk products are not sterile and that reconstitution, storage and handling instructions should be followed carefully to prevent serious illness.</b> <b>9.5.2 Directions for preparation of powdered [name of the product] for older infants must be in accordance with the WHO/FAO Guidelines: Safe preparation, storage and handling of powdered infant formula.</b>
Please comment on whether there are any additional ‘information for use’ provisions that should be considered by the eWG for inclusion in the Standard for follow-up formula for older infants, and for (name of product) for young children. Please provide justification for your response.
<b>RESPONSE:</b> <b>Additional provisions for follow-up formula for older infants:</b>

**Additional provisions for (name of product) for young children:**  
**A statement that this product is not necessary for the growth and development of young children.**

#### 4.4.7 Additional Labelling Requirements

##### QUESTIONS: Additional Labelling Requirements

Please indicate your support for the following proposals, or provide an alternative approach and wording, with justification for your answer.

It is proposed that the title of section 9.6 be re-worded to Additional [Labelling] Requirements to align with the Infant Formula Standard. Do you agree? YES/NO.

##### RESPONSE:

**IBFAN agrees that the wording should align with the Infant Formula Standard. As mentioned before, IBFAN believes that bringing all products targeting babies 0-36 months under one revised standard in product/age differentiated sections would be the safest course for child health and the easiest for policy makers to translate into national regulations.**

Should the following statement in the current Follow-up Formula Standard be retained for follow-up formula for older infants and for (name of product) for young children; *‘products covered by this standard are not breast-milk substitutes and shall not be represented as such’*? YES/NO. Please provide justification for your answer.

##### RESPONSE:

**Follow-up for older infants:**

**No. This statement is incorrect and should be deleted. Follow-up formula for older infants are not necessary but function as breastmilk substitutes.**

**WHA69.9 and the WHO Guidance clarifies that milk products to the age of 36 months are breastmilk substitutes and come under the scope of the International Code and WHA resolutions.**

***“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”.***

**(Name of Product) for young children:**

**No.**

**This statement is incorrect and should be deleted. (Name of Product) for young children function are not necessary but function as breastmilk substitutes.**

**WHA69.9 and the WHO Guidance clarifies that milk products to the age of 36 months are breastmilk substitutes and come under the scope of the International Code and WHA resolutions.**

**WHA69.9 notes that the milk products to the age of 36 months are breastmilk substitutes and come under the scope of the International Code and WHA resolutions.**

***“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”.***

Should provision **9.6.1** within the Infant Formula Standard be adopted for follow-up formula for older infants, and for (name of product) for young children)? YES/NO. Please provide justification for your response and include any modified text if considered necessary.

**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 a independent health worker as to the need for its use and the proper method of use.

**RESPONSE:**

**Follow-up formula for older infants:**

**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:

**IBFAN recommends the rewording as follows:**

- a) WHO recommends exclusive breastfeeding for the first 6 months of life and sustained breastfeeding to two years or beyond with the introduction of safe and appropriate complementary foods commencing at 6 months of age.
- b) Breastfeeding is the normal and healthy way to feed your baby.
- c) A warning that when your baby is not breastfed she will be sick more often.
- d) 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.

**(Name of Product) for young children:**

**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:

**IBFAN recommends the rewording as follows:**

- a) WHO recommends exclusive breastfeeding for the first 6 months of life and sustained breastfeeding to two years or beyond with the introduction of safe and appropriate complementary foods commencing at 6 months of age.
- b) Breastfeeding is the normal and healthy way to feed your baby.
- c) A warning that when your baby is not breastfed she will be sick more often.
- d) 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.

Should provision **9.6.2** within the Infant Formula Standard be adopted for follow-up formula for older infants, and for (name of product) for young children)? YES/~~NO~~. Please provide justification for your response and include any modified text if considered necessary.

**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 formula.

**RESPONSE: YES**

**Follow-up formula for older infants:**

**IBFAN agrees with this important inclusion.**

**This statement is in conformity with Article 9 of the International Code of Marketing of Breastmilk Substitutes.**

**(Name of Product) for young children:**

**IBFAN agrees with this important inclusion.**

**This statement is in conformity with Article 9 of the International Code of Marketing of Breastmilk Substitutes.**

Should provision **9.6.3** within the Infant Formula Standard be adopted for follow-up formula for older infants, and for (name of product) for young children)? YES/NO. Please provide justification for your response and include any modified text if considered necessary.

**9.6.3** The terms "humanized", "maternalized" or other similar terms shall not be used.

**RESPONSE:**

**Follow-up formula for older infants:**

**IBFAN agrees that these terms should not be used as this would imply that the product is similar to human milk. The use of these terms would be false and misleading.**

**The prohibitions of these terms is in conformity with Article 9 of the International Code of Marketing of Breastmilk Substitutes.**

**(Name of Product) for young children:**

**IBFAN agrees that these terms should not be used as this would imply that the product is similar to human milk. The use of these terms would be false and misleading.**

**The prohibitions of these terms is in conformity with Article 9 of the International Code of Marketing of Breastmilk Substitutes.**

Whilst provision **9.6.4** within the Infant Formula Standard is relevant, particularly for follow-up formula for older infants, it is proposed that this be covered under section 9.5. It is therefore proposed that this requirement be removed from section 9.6. Do you agree? YES/NO.

*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:**

*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.*

**Since the above statement is ambiguous IBFAN recommends the addition of the following to this statement:**

**WHO recommends exclusive breastfeeding for the first 6 months of life and sustained breastfeeding to two years or beyond with the introduction of safe and appropriate locally available complementary foods prepared and fed safely commencing at 6 months of age.**

It is proposed that a provision similar to that contained within section **9.6.5** of the Infant Formula Standard be adopted for both follow-up formula for older infants and (name of product) for young children to assist in meeting Recommendation 5 of the WHO Technical Guidance on ending the inappropriate promotion of foods for infants and young children relating to cross promotion. It is proposed that the following wording be adopted;

*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.*

Do you agree with this approach and the proposed wording? YES/NO. If not, please provide an alternative approach and wording.

**RESPONSE:**

**IBFAN proposes that the following be added to the above statement:**

**To prevent confusion and needless and inappropriate use of these products cross branding 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.**

## 5. DEFINITIONS

### 5.1.1 Definition 2.1.1

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

Please select a preferred definition for follow-up formula for older infants from those provided below, or provide a modified definition for consideration by the eWG.

Original proposal:

- **Follow-up formula for older infants** means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced.

Proposals from Committee Members:

- **Follow-up formula for older infants** means a product, [in liquid or powdered forms], intended for use [as a total or partial substitute for breast-milk given] as the liquid part of the diet for older infants when complementary feeding is introduced.
- **Follow-up formula for older infants** means a product intended for use as ~~the liquid part of the diet for older infants when complementary feeding is introduced~~ [a substitute for human milk in helping to meet the normal nutritional requirements of older infants]
- **Follow-up formula for older infants** means a product intended for use as the liquid part of the diet for older infants [as either a breast milk substitute or a replacement for infant formula] when complementary feeding is introduced.
- **Follow-up formula for older infants** means a product [specially manufactured] ~~intended~~ for use as the liquid part of the diet for older infants when [appropriate] complementary feeding is [progressively] introduced
- **Follow-up formula for older infants** means a product intended for use as the liquid part of ~~the~~ [a diversified] diet for older infants when complementary feeding is introduced

#### RESPONSE:

**IBFAN proposes the following definition:**

- **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.

#### QUESTION: Definition of (Name of Product) for young children

Please select a preferred definition for (name of product) for young children from those provided below, or provide a modified definition for consideration by the eWG.

Original proposal (note the options for the product name have been removed):

- **(Name of Product) for young children** means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.

Proposals from Committee Members:

- **(Name of Product) for young children** means a product [specifically manufactured] ~~intended~~ for use as a liquid part of the progressively diversified diet [in order to contribute to the nutritional needs of young children] when nutrient intakes may not be adequate to meet ~~the~~ nutritional requirements. ~~of young children.~~
- **(Name of Product) for young children** means a product intended for use as a [substitute for breast-milk in helping to meet the normal nutritional requirements of young children as a] liquid part of the progressively diversified diet. ~~when nutrient intakes may not be adequate to meet the nutritional requirements of young children.~~
- **(Name of Product) for young children** means a product ~~intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to~~

~~meet the nutritional requirements of young children~~ [that is not necessary but may be used as part of a child’s progressively diversified diet. It should not share branding with infant formula, nor be promoted, since this would undermine breastfeeding and the consumption of culturally appropriate and more nutritious bio-diverse family foods.]

**RESPONSE:**

**IBFAN supports the following definition:**

- **IBFAN supports the following definition: (Name of Product) for young children means a product, [in liquid or powdered forms], that while not necessary may be used as part of a child’s progressively diversified diet [as a total or partial substitute for breastmilk, breastfeeding or infant formula]**
- **While these products function as breastmilk substitutes they should not share branding with infant formula and follow-up formula, nor be promoted, since this would undermine breastfeeding and the consumption of culturally appropriate and more nutritious bio-diverse family foods.**

## 6. NAME OF PRODUCT

**QUESTION: Name of product for older infants**

It is proposed that *Follow-up Formula for Older Infants* be adopted as the name of product for older infants. Do you support adoption of this name? YES/NO. If no, please provide justification for your response as well as an alternative name for consideration by the eWG.

**RESPONSE: YES**

**QUESTION: Name of product for young children**

In considering the name of product for young children, the following parameters/issues have been identified either by the Committee at CCNFSDU38, or within the 2016 eWG:

- product for young children should not be considered a ‘formula’
- product for young children must have a distinctly different name to follow-up formula for older infants
- the name of the product for young children needs to include plant-based products, noting that these products cannot use the denomination of ‘milk’ since these are not based on milk from cows or other animals.

Please identify if there are further issues or parameters that the eWG should consider when deciding on the name of product for young children.

**RESPONSE:**

Please comment on the suggestions to date, for the name of product for young children, being mindful of the issues identified above. Please indicate a preferred name or provide an alternative for consideration by the eWG

- Fortified milk product for young children
- Processed milk product for young children
- Drink for young children
- Fortified milk for young children
- Formulated milk powder for young children
- Young child milk-based (or plant based) beverage.

**RESPONSE:**

**IBFAN prefers the term: “Processed milk product for young children” as a parameter that the eWG should consider.**