

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4c

NFSDU/41 CRD 10

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-first Session

Dusseldorf, Germany
24 – 29 November 2019

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987): PROPOSED DRAFT PRODUCT DEFINITION AND LABELLING FOR [PRODUCT] FOR YOUNG CHILDREN

Comments by Indonesia, Mali, Philippines, Senegal, HKI, ISDI, WPHNA

INDONESIA

Indonesia would like to provide the following comment:

- Indonesia proposes to open the square bracket in section 2.1.1, section 9.3 c), and section 9.6.2.
- Indonesia supports the proposed sentence in section 9.5.1.

MALI

La présentation de ce document de travail a suscité des questions, commentaires, observations et contributions ci-après :

A la section B [**NOM DU PRODUIT**] le Mali « **Boisson à base de lait pour les enfants de 12-36 mois** » pour être cohérent avec la définition proposé ;

Au paragraphe 9 le Mali soutient le texte proposé et la suppression des textes barrés ;

Au paragraphe **Liste des ingrédients** le Mali soutient le texte tel que proposé et la suppression du texte barré ;

Au paragraphe **Déclaration de la valeur nutritive** le Mali soutient le texte tel que proposé et la suppression du texte barré.

Au paragraphe **Datage et instructions d'entreposage** le Mali soutient le texte tel que proposé ;

Au paragraphe **Mode d'emploi**, le Mali soutient le texte tel que proposé et la suppression du texte barré.

Au paragraphe **Spécifications d'étiquetage supplémentaires**, le Mali soutient le texte tel que proposé et la suppression du texte barré et les crochets.

PHILIPPINES

The Philippines supports the proposed Draft Revised Standard Standards for [Product] for Young Children. This has been consistent with the outcome of the electronic working group and consensus of the previous Committee Session as justified by generally accepted scientific evidence. These are also in line with the previous Philippine Positions.

	Type of Change	Proposed Changes
Preamble The Codex Alimentarius Commission acknowledges the need to protect and support breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use , where appropriate as a substitute for human	Editorial	We support retention of the Preamble and the first two statements with modification" The Codex Alimentarius Commission acknowledges the need to protect and support breastfeeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use

<p>milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts.</p>		<p>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.</p> <p>We are of the opinion that the “protect and support” are the most appropriate terms to refer to breast feeding as the gold standard in food for growth and development of infants. We also agree that the intended use for follow up formula, where appropriate as a substitute for human milk in meeting the nutritional needs of infants meeting the hygienic and adequacy requirements</p>
<p><i>The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, [as appropriate,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (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 that have been [endorsed / supported] by member states [may also] provide guidance to countries in this context.</i></p>	<p>Substantive</p>	<p>The Philippines supports deletion of “as appropriate” in this statement “The production, distribution, sale and use of follow up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account, the recommendations made in the International Code of Marketing Breast-milk Substitute (1981) and the Global Strategy of Infant and Young Child feeding”. Relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions that have been supported by member states provide guidance to countries in this context. We support deletion of “may also” since it should be definite that the International Code of Marketing Breastmilk Substitute and relevant WHA resolutions provide firm guidance to countries in policies on infant and young child feeding.</p> <p>The Philippines reiterates the existing agreement of the CCNFSDU that reference to WHA resolutions will appear either in the Preamble or in the individual Scope text of the follow up formula and [product] for young children. Such referencing is consistent with the report of the 75th Session of the Executive Committee of the Codex Alimentarius Committee (REP18/Exec2-Rev.1). We remind the Committee that the positioning of the references to WHA resolutions is still under discussion. However, in the event that there will be two stand alone Codex Standards for follow up formula and [product] for young children, we intend to recommend placement of such references, including reference to WHA Resolution 69.9 as we deemed appropriate.</p>

<p>SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN</p>		
<p>1. SCOPE</p> <p>1.1 <i>This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.</i></p> <p>1.2 <i>This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for [name of product] for young children.</i></p> <p>1.3 <i>Only products that comply with the criteria laid down in the provisions of this section of this Standard [should / shall] be presented as [name of product] for young children.}]</i></p>	<p>Editorial</p>	<p>1 SCOPE</p> <p>We support statements 1.1.-1.3 under Scope and prefer to use the word “shall” in 1.3</p> <p>1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.</p> <p>1.2 This section of the Standard contains compositional, quality, safety, labelling and analytical requirements for [name of product] for young children.</p> <p>1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as [name of product] for young children.}]</p>
<p>2. DESCRIPTION</p> <p>2.1 Product Definition</p> <p>2.1.1 <i>[Name of product] for young children means a product specially [formulated and] manufactured for use [as a breast-milk substitute], as a liquid part of the [progressively] [diversified] diet of young children [in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements].-</i></p> <p>2.1.2 [Name of product] for young children [Follow-up formula] is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.</p> <p>2.2 Other Definitions</p> <p>2.2.1 The term young child means a person from the age of more than 12 months up to the age of three years (36 months).</p>	<p>Substantive</p>	<p>DESCRIPTION</p> <p>The Philippines is of the opinion that the [name of product] for young children is considered as a breastmilk substitute and is promoted and marketed as such around the world and should therefore conform with the International Code of Marketing Breast milk Substitute.</p> <p>In the 40th Session of CCNFSDU, there was no consensus if the [product] for young children could be considered as as breastmilk substitute or not as indicated in Paragraph #55 of REP 19/NFSDU since there are polarizing views among delegates. Hence, the phrase [as a breastmilk substitute] should remain in square brackets pending consensus.</p> <p>2.1 Product Definition</p> <p>2.1.1 [Name of product] for young children means a product manufactured for use as a breast-milk substitute as a liquid part of the [diversified] diet of young children in order to contribute to the nutritional needs of young children.</p> <p>2.1.2. [Name of product] for young children is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.</p>

		<p style="text-align: center;">2.2 Other Definitions</p> <p>2.2.1 The term young child means a person from the age of more than 12 months up to the age of three years (36 months).</p>
<p>LABELLING</p> <p><i>The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.</i></p>		<p>LABELLING</p> <p>We propose to retain the statement “These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provide for in relevant Codex Standards or national legislation”.</p> <p>The Philippines supports this statement to reiterate the prohibition of health and nutrition claims for foods for infants and young children as provided and in compliance with the Codex Guidelines on Health and Nutrition Claims for Food Use. While this is already covered by the Nutrition and Health Guidelines, it is still necessary to emphasize that all types of health and nutrition claims should not be allowed on labels of [Product] for young children. We believe that the proposed statements are sufficient to prevent any claims on this product. To date, no health and nutrition claims are allowed on any Codex Standards for foods for infants and young children.</p> <p>The requirements of the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to [Name of Product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.</p>
<p>The Name of the Product</p> <p>9.1.1 <i>The text of the label and all other information accompanying the product shall be written in the appropriate language(s).</i></p> <p>9.1.2 <i>The name of the product shall be [Name of Product] for Young Children as defined in Section 2.1, or any appropriate designation indicating the true</i></p>	<p>Editorial</p>	<p>The Philippines is supportive of the Statements 9.1.1-9.1.4. The use of “shall” is preferred in Statement 9.1.4 since it is more reinforcing than “may”.</p>

<p>nature of the product, in accordance with national {or regional} usage.</p> <p>9.1.3 The sources of protein in the product shall be clearly shown on the label.</p> <p>a) If [name of animal] milk is the only source of protein{*}, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk {protein}'].</p> <p>b) If [name of plant] is the only source of protein{*}, the product may be labelled '[Name of Product] for Young Children Based on [name of plant] {protein}'].</p> <p>c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled '[Name of Product] for Young Children Based on [name of animal] milk protein and [name of plant] protein' or '[Name of Product] for Young Children Based on [name of plant] protein and [name of animal] milk protein'.</p> <p>{* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.}</p> <p>9.1.4 A product which contains neither milk nor any milk derivative {shall} {may} be labelled "contains no milk or milk products" or an equivalent phrase.</p>		
<p>List of Ingredients</p> <p>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</p>	<p>Editorial</p>	<p>List of Ingredients</p> <p>We support deletion of the bracketed phrase "including optional ingredients" in Statement 9.2.1 and 'the INS number in Statement 9.2.2.</p> <p>9.2.1 A complete list of 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</p>

<p>descending order of proportion.</p> <p>9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes names for these ingredients and additives may be included on the label. {The food additives INS number may also be optionally declared the INS number.</p> <p>Date Marking and Storage Instructions</p> <p>9.4.1 (i) The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf-life of more than three months, at least the month and year shall be declared. {The day and year shall be declared by uncoded 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).}</p> <p>(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words “Best before end <insert date>; or “Best Quality Before end <insert date>”.</p> <p>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.</p> <p>Where practicable, storage instructions shall be in close proximity to the date marking</p>	<p>Editorial</p>	<p>and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.</p> <p>9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes names for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared.</p> <p>Date Marking and Storage Instructions</p> <p>We support deletion of the brackets in Statement 9.4.1.</p> <p>9.4.1 (i) The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf-life of more than three months, at least the month and year shall be declared. The day and year shall be declared by uncoded 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).}</p> <p>(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words “Best before end <insert date>; or “Best Quality Before end <insert date>”.</p> <p>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.</p> <p>Where practicable, storage instructions shall be in close</p>
---	------------------	---

<p>Information for use</p> <p>9.5.1 {Ready to use} products in liquid form should may be used {either} directly. or in the case of eConcentrated liquid products {and powdered products}, must be prepared with potable 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 rendered safe by previous boiling for preparation.} Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.</p> <p>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.</p> <p>9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. {Pictures of feeding bottles are not permitted on labels of (name of product) for young children.}</p> <p>9.5.4 {The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use}.</p> <p>9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.</p> <p>9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should</p>	<p>Editorial</p>	<p>proximity to the date marking</p> <p>Information for use</p> <p>We are in agreement to delete the brackets in the following statements:</p> <p>9.5.1 {Ready to use} products in liquid form should be used directly. Concentrated liquid products {and powdered products, must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.</p> <p>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.</p> <p>9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.</p> <p>9.5.4 The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use}.</p> <p>9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label.</p> <p>9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a progressively diversified diet and <u>is not suitable as sole source of nutrition.</u></p>
<p>Additional Labelling Requirements</p> <p>9.6.1 The label of [name of product] for young children shall have no image, text or representation {,including pictures of feeding bottles,}</p>	<p>Editorial</p>	<p>Additional Labelling Requirements</p> <p>We support deleting the brackets in the following statements:</p> <p>9.6.1 The label of [name of product] for young children shall have no</p>

<p><i>that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.}]</i></p> <p>{9.6.2} <i>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[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used].}</i></p>		<p>image, text or representation ,including pictures of feeding bottles,]—that could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.</p> <p>{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 purpose, and to enable consumers to make a clear distinction between them.</p> <p>We also recommend to delete the phrase “as to the text, images and colours used” in Statement 9.6.2 since these could be considered as trade barriers.</p>
	<p>Substantive</p>	<p>While we support the above proposed statement; the Philippines reiterates its strong support for addition of the following additional labelling requirements:</p> <p>9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following:</p> <ul style="list-style-type: none"> a) the words ‘important notice” or their equivalent b) the statement “Breast milk is the best for baby up to two years old or beyond.” c) a statement that the product should only be used upon the advice of an independent health worker as to the need for its use and the proper method of use. <p>The label shall have no pictures of infants and women nor any other picture, text, representation that might:</p> <ul style="list-style-type: none"> 9.6.2.1 idealize the use of [name of product] for young children; 9.6.2.2 suggest use for infants under the age of 12 months (including references to milestones and stages); 9.6.2.3 recommend or promote

		<p>bottle feeding;</p> <p>9.6.2.4 undermine or discourage breastfeeding, or suggest that the product is equivalent to or superior to breast-milk;</p> <p><u>9.6.2.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body.</u></p>
--	--	---

SENEGAL

Les produits destinés aux enfants en bas âge (12-36 mois), doivent être définis comme des substituts du lait maternel et respecter les mêmes exigences d'étiquetage que celles de la section A pour les préparations de suite de 6 -12 mois.

Commentaire: Ces produits sont considérés comme des substituts de lait maternel et ne doivent pas remplacer le lait maternel mais le compléter.

HKI – HELEN KELLER INTERNATIONAL

[NAME OF PRODUCT] FOR YOUNG CHILDREN

[**Note:** We recognise that this might not be discussed here but our comments are included here]

The suggestion for the name is: [**Formulated**] drink for young children.

Helen Keller International strongly opposes the use of the word formulated in the name of this product and does not believe there has been sufficient discussion or consensus to include the word in the Standard and that other options must be open for discussion at the 2019 CCNFSDU meeting.

Justification: Recognising that the new standard will have new compositional requirements, Helen Keller International draws the Committee's attention to a recent (2019) assessment, using Innova Market Insights data, that considered the composition of growing-up milks available on the Indonesian market. Almost all the growing-up milks (97%) contained one or more added sugars. Three quarters (76%) contained sucrose and many contained a variety of added sugars, the average being 5 different added sugars. Of the growing-up milks which provided enough information for analysis, 86% were found to have high sugar levels according to calculations based on the UK Front of Pack algorithm. As it has globally been agreed that these products are not necessary and cow's milk is recommended for young children who for whatever reason are not breastfed, the research also compared the Indonesian growing-up milks to full fat (whole) cow's milk. Replacing full fat (whole) cow's milk with growing-up milk has a substantial impact on daily sugar intake and adds an additional 10 – 16g of sugar/day to the young child's diet. This goes against global recommendations to reduce and limit sugar in young children's diets to reduce the future risk of overweight and non-communicable diseases. Growing-up milks are not recommended in the diets of young children and the name given to them should not imply that they give any benefit. The name 'formulated drink for young children' cannot be considered as appropriate for these products.

1. 2019 saw the release of a technical scientific report on Healthy Beverage Consumption in Early Childhood that provides recommendations from key US national health and nutrition organisations [Academy of Nutrition and Dietetics (AND), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Pediatrics (AAP), and the American Heart Association (AHA)] on optimal beverage consumption during early childhood and supports a life course approach to the development of healthy dietary patterns and prevention of chronic disease. The experts give a clear recommendation: *“For infants 0-12 months, avoid supplementation with “transition” or “weaning” formulas; nutrient needs should be met primarily through human milk and/or infant formula.”* The expert panel concluded that *“although there is no evidence to indicate that toddler milk is harmful, these products offer no unique nutritional value beyond what could be achieved through a nutritionally adequate diet; furthermore, they may contribute added sugars to the diet. Toddler milk is also more expensive than an equivalent volume of cow’s milk... Infants and young children should first aim to meet nutrient needs primarily through human milk and/or infant formula, and then increasingly through healthy foods and beverages as they transition to solid foods. If nutrient-rich food intake appears to be inadequate, other strategies to increase food acceptance should be tried first, before resorting to toddler milks, such as repeated exposures to healthy foods.”* As these products are not recommended, their name should not be allowed to imply that they offer any benefits.
2. WHA 69.9 was adopted by consensus and specifically urged Member States to *“take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children, including in particular implementation of the guidance recommendations...”*. Further WHA 69.9 *“calls upon manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion as set forth in the guidance”*.

Recommendation 2 in the Guidance states that these products are breast-milk substitutes and fall under the International Code of Marketing of Breast-milk Substitutes, which prohibits any promotion and idealisation of these products. Governments and companies are obliged to implement the Guidance and thus the word formulated must be removed from the name of the product as it makes the product sound ‘special’, implies a claim, and is contrary to recommendation 2 of the global guidance.

3. Helen Keller International is of the opinion that adding the word ‘formulated’ to the name of the product contradicts the decision by the Committee not to refer to the products as ‘specially’ manufactured. It is our understanding that this deletion was due to the fact that the Committee agreed that the word added no value and all commercially produced foods were specially manufactured. The same applies to the word formulated. An extensive review of the definitions of the word formulate (the verb for which formulated is the past participle) shows it to mean ‘create or prepare methodically’; ‘to develop a formula for the preparation of’; ‘prepare according to a formula’; ‘to develop all the details of a plan for doing something’; ‘invent it, thinking about the details carefully’. Thus, indeed all commercially produced foods are formulated, and the adjective adds no value to the name of the product unless it is being included to imply some benefit, which Helen Keller International strongly objects to and for which we believe there is no justification.
4. Helen Keller International has continually raised the concern and strongly believes that the name given to this product must be neutral and contain no implied benefit/claim. It has globally been agreed that these products are not necessary. These products should therefore in no way be idealised. There is therefore no need to include any adjective in the name of the product.

The use of the proposed adjective ‘formulated’ could be interpreted as indicating a benefit making it potentially misleading. The introductory text makes direct reference to the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) which applies to this product. This Guideline explicitly prohibits use of nutrition and health claims for foods for infants and young children, except where specifically provided for in relevant Codex Standards or national legislation. Helen Keller International accepted this introductory text on the grounds that currently none of the relevant Codex standards allow for claims on these products. Thus, only national legislation can allow for any nutrition or health claims. We support this and strongly believe that only national governments should have the authority to decide if any nutrition or health claim is relevant in their national context. Helen Keller International believes allowing for an adjective that is in fact a claim to be used in the name of a product will be setting a very dangerous precedent and must not be permitted.

5. The word ‘formulated’ is very similar to the word ‘formula’ and mothers/caregivers could misinterpret the word or link it to ‘formula’ or ‘follow up formula’. This is problematic and could result in severe negative nutritional consequences as its composition is not suitable to satisfy the nutritional requirements of a younger child. Helen Keller International is aware that in some countries, including the United Kingdom, breast-milk substitutes are referred to as ‘formula milk’. Thus, the use of the word ‘formulated’ for the name of this product could lead to consumer confusion. Research demonstrates that

mothers/caregivers misinterpret the names of these types of products and incorrectly feed them to children of an inappropriate age. Research shows that mothers have even misinterpreted the term 'Follow-up Formula' in both high-income and low-income settings. In the United Kingdom, 16% of mothers in a 2010 national infant feeding survey reported that they first used follow-up formula before 6 months of age. Among mothers who had never worked, 26% reported that they used baby follow-up formula before 6 months of age (Infant Feeding Survey 2010). One-third (32%) of mothers reported they did not know the difference between various breast-milk substitutes, and health workers were unable to differentiate them as well (Crawley and Westfield, 2016, *Infant Milks in the UK: A Practical Guide for Health Professionals* – February 2016). In Senegal, nearly 10% of mothers of infants and children under 2 years of age were unable to state what stage of formula they gave their infants (ARCH research, 2016, unpublished analyses). Other research by Cattaneo et al. has also shown that confusion exists among these different products by mothers because of how these products are labelled, clearly indicating the need for Codex to address this critical issue to protect older infant and young child health. In a study in Italy, Cattaneo et al. found that only 43% of mothers could correctly identify the age of use of the products following careful reading of a follow-up formula advertisement (Cattaneo et al. *Archives of Disease in Childhood* 0, 1–6. 2014).

As reported by Watson and Heath (2013), (*The role and use of fortified milk-based products in the diets of older infants and young children*, MPI Technical Paper No: 2013/40, New Zealand), "recommendations for the minimum age of follow-up formula introduction are not always followed. France, Ireland, Luxembourg, and the United Kingdom all reported introduction earlier than their country's recommendation, as did Ghana and the Philippines. There is a large range in the age at which follow-up formula is first introduced. The earliest follow-up formula introduction reported was at 1 month by 2% of children in a United Kingdom study of 9,416 mothers. Even within countries there is a range of ages at which follow-up formula is introduced, such as in Sweden, where 44% of children were introduced to follow-up formula at less than 4 months of age and 30.5% between 4 and 6 months of age. Rates of follow-up formula consumption at or before 6 months of age were reported by eight high-income countries and three low- and middle-income countries."

If the [Name of product] for young children is the only product fed to an infant less than 6 months of age, nutritional deficiencies would likely result as its proposed composition requires only 50% of the different nutrients required of infant formula. Helen Keller International believes this should be avoided and removing the term 'formulated' will reduce risk of confusion and misuse.

Helen Keller International feels strongly that the word formulated must be removed from the name. This, being presented as the only name for consideration does not reflect feedback from the earlier EWG consultations. Helen Keller International recommends the name 'Drink for young children'.

[PREAMBLE]

Helen Keller International notes the existing agreement of the CCFSDU that reference to WHA resolutions will appear either in the Preamble or in the individual Scope text of the 2 categories of product under consideration. Helen Keller International notes that such referencing is in line with the text recorded in the report of the 75th Session of the Executive Committee of the Codex Alimentarius Committee (REP18/Exec2-Rev.1). Helen Keller International therefore reminds the Committee that the positioning of the references to WHA resolutions is still under discussion and reserves the right to decide on where it recommends the placement of such references, including reference to WHA Resolution 69.9, once the discussion as to the structure of the Standard has been concluded.

Based on the current Preamble text:

1. Helen Keller International strongly supports that the Preamble refers to 'protect and support' of breastfeeding and not the word 'recognize', as 'protect, promote and support' are the globally recognised terminology and the wording used by the World Health Assembly, the highest global health policy making body.

Thus, the opening sentence would read:

"The Codex Alimentarius Commission acknowledges the need to protect and support breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants."

2. Helen Keller International also supports the use of the word ‘necessary’ rather than ‘appropriate’ as we believe that the use of formula should only be used where necessary on the advice of a health worker. These concepts – ‘necessity’ and ‘on advice of a health worker’ - have already been agreed in the text included under Additional Labelling Requirement (Clause 9.6.1 c) of the follow-up formula for older infant’s product category and so should both be used in the Preamble. It is also important to remember that the WHO has declared that these products are in general, not necessary and so it must be emphasised in the text that their use is only necessary on the advice of a health worker.

Thus, the second sentence would read (underlined **bold** text added):

*“At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where ~~{necessary / appropriate}~~, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions, are given in adequate amounts, **and only used on the advice of a health worker.**”*

3. With regards to the second paragraph, Helen Keller International strongly believes that the words [as appropriate] should be deleted and be replaced with the wording used in World Health Assembly (WHA) resolutions, which usually use the terminology that Codex should ‘give full consideration’ to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant WHA resolutions. At the minimum the words [as appropriate] should be deleted.
4. Further, with regards to the use of the word ‘endorsed’ or ‘supported’, Helen Keller International strongly supports the use of the term endorsed when it comes to reference the resolutions of the WHA that have been endorsed, as is the case with the relevant resolutions being considered in this matter. Helen Keller International also believes that the [may also] is not necessary and must be deleted as there is no issue of possibility that WHA resolutions provide guidance- they are the guidance of the world’s highest health policy setting body.

Thus, Helen Keller International proposes that the second paragraph should read (underlined **bold** text added):

*“The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and ~~take into account, [as appropriate,]~~ **give full consideration** to 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 that have been ~~{endorsed / supported}~~ by member states ~~[may also]~~ provide guidance to countries in this context.*

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

2. DESCRIPTION

2.1 Product definition

2.1.1

Helen Keller International does NOT support the text as proposed and believes that there is not sufficient consensus to delete the reference, in square brackets, to these products being breastmilk substitutes. In addition, Helen Keller International does not support the text in [] that reads [in order to contribute to the nutritional needs of young children].

Helen Keller International believes the definition should read:

‘[Name of product] for young children means a product manufactured for use as a breast-milk substitute, as a liquid part of the diversified diet of young children.’

The justification for including them as breast-milk substitutes is:

1. The WHO recommendation for optimal infant and young child feeding is to practice exclusive breastfeeding from birth to 6 months of age and introduce complementary foods at 6 months of age (180 days) while continuing to breastfeed until 2 years of age or beyond. WHA 54.2 also called on governments to strengthen activities to protect, promote and support these practices and lead communities to adhere to them. Thus, any product used towards the liquid part of the diversified diet will displace breastmilk, especially when the product is a milk-type product (whether from animal or plant origin) and this must be made clear in the definition.

The definition should be clear as to the function of the product and this is only partially covered if the text does not say 'as a substitute for breastmilk'. Functionally, any milk product for older infants and young children 6 to 36 months of age may be used with other foods, displacing rather than complementing the intake of breastmilk. They are thus ipso facto breast-milk substitutes, and this must be made clear in reading the Standard and the inclusion of the words 'as a breast-milk substitute' is therefore essential. There can be no lack of clarity in the definition that could cause any misinterpretation or confusion.

2. WHA 69.9 was adopted by consensus at the World Health Assembly in 2016 and specifically urged Member States to *"take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children, including in particular implementation of the guidance recommendations..."*. Further WHA 69.9 *"calls upon manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion as set forth in the guidance."*

Recommendation 2 of the Guidance clearly states that these products are breast-milk substitutes. For this reason, and to ensure the implementation of the guidance as per WHA 69.9 that both governments and companies are obliged to implement, the definition should be explicit that these are breast-milk substitutes. The guidance does not differentiate between these products and follow-up formula for older infants and neither should Codex.

3. The International Code of Marketing of Breast-milk Substitutes (1981) defines a breast-milk substitute as *"...any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose."* It does not provide an upper age limit for the definition of a breast-milk substitute and the Global Strategy for Infant and Young Child Feeding adopted by the World Health Assembly (2003) recommends breastfeeding continue for 2 years or beyond. Furthermore, the Code makes a clear distinction between foods that 'replace' breastmilk (and are thereby breast-milk substitutes) and those that 'complement' breastmilk when it no longer satisfies infant nutritional requirements. Thus, distinguishing between a breast-milk substitute and a complementary food depends on whether the food directly reduces breastmilk consumption or adds to it.

The WHO Scientific Advisory Group, which developed the recommendations that underpin the WHO Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children (2016) concluded that there was sufficient evidence that milks targeted specifically to children under 3 years of age do replace the intake of breastmilk.

The WHO (2013) note 'Information concerning the use and marketing of follow-up formula' states that *"...follow-up formula is not a suitable substitute for breast milk due to its content."* A suitable substitute for breast milk is not the same as a breast-milk substitute. In the current draft of the review of the Follow-up Formula Standard, [Name of product] for young children (12-36 months) are nutritionally suitable as a sole source of nutrition. They are, however, breast-milk substitutes.

Definitions of infant formula and complementary feeding by Codex Alimentarius, the European Food Safety Authority and the United States are consistent with this interpretation.

- The Codex Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CODEX STAN 72 – 1981) defines infant formula as *"... a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding."* This definition clarifies that a breast-milk substitute includes - but is not limited to - infant formula. Otherwise, the term "breast-milk substitute" would not have been included in the definition. [http://www.fao.org/fao-who-codexalimentarius/\[...\].pdf](http://www.fao.org/fao-who-codexalimentarius/[...].pdf)
- The European Food Safety Authority (EFSA) (2009) in its definition of complementary feeding clarifies that a breast-milk substitute includes products not designed to be a sole source of nutrition for an infant. It defines complementary feeding as *"...the period, when complementary foods are given together with either human milk or a breast milk substitute"*. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.1423>
- The United States Infant Formula Act (1980) does not limit its definition of infant formula to a formula that satisfies all the nutritional needs of an infant. It defines infant formula as *"... a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk"*. <https://www.gpo.gov/fdsys/pkg/STATUTE-94/pdf/STATUTE-94-Pg1190.pdf>

These products are breast-milk substitutes and should be labelled as such in the definitions text.

Justification for removal of text [in order to contribute to the nutritional needs of young children].

1. There has been global agreement that these products are not necessary. The text in [] implies that they have a role to play. This is not the case and so it should not be implied in the definition of these products.
2. Recent assessment using Innova Market Insights data has considered the current composition of these products in Indonesia. While recognising the revised standard will require composition changes, the findings are still important. They show that despite their fortification with a range of vitamins and minerals the composition of these products for the 12-36 month age group does not support the nutritional needs of these young children. Over a quarter of milks for this age category were not compliant with the agreed upon revised recommendation of less than 2.5g of free sugar per 100kcal and 1 in 10 (11%) did not supply sufficient information to assess their compliance. In addition, almost all the products contained one or more added sugar (the average being 5) and three quarters contained sucrose. Further, when compared with full fat (whole) cow's milk, which is what is recommended for these young children, the use of these products has substantial impacts on daily sugar intake and adds an additional 10-16g of sugar a day to the young child's diet. This goes against global recommendations to reduce and limit sugar in young children's diets and places them at risk of future overweight and non-communicable diseases. A great deal of composition changes are required before these products even meet the Codex compositional standard. In the interests of child health, and considering that they are not necessary, they cannot be defined as contributing to the nutritional needs of young children. Furthermore, 2019 saw the release of a technical support on Healthy Beverage Consumption in Early Childhood provides recommendations from key US national health and nutrition organisations [Academy of Nutrition and Dietetics (AND), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Pediatrics (AAP), and the American Heart Association (AHA)] on optimal beverage consumption during early childhood and supports a life course approach to the development of healthy dietary patterns and prevention of chronic diseases. The experts give a clear recommendation, "*0-12 months: Avoid supplementation with "transition" or "weaning" formulas; nutrient needs should be met primarily through human milk and/or infant formula. The rationale given is: The expert panel concluded that "although there is no evidence to indicate that toddler milk is harmful, these products offer no unique nutritional value beyond what could be achieved through a nutritionally adequate diet; furthermore, they may contribute added sugars to the diet. Toddler milk is also more expensive than an equivalent volume of cow's milk... Infants and young children should first aim to meet nutrient needs primarily through human milk and/or infant formula, and then increasingly through healthy foods and beverages as they transition to solid foods. If nutrient-rich food intake appears to be inadequate, other strategies to increase food acceptance should be tried first, before resorting to toddler milks, such as repeated exposures to healthy foods."* As these products are not recommended, their name should be allowed to imply that they offer any benefits.

1.3.1 Helen Keller International supports the text as proposed – deletion of the strikethrough text in square brackets.

2.2 Other definitions

2.2.1 Helen Keller International supports the text as proposed.

9. LABELLING Helen Keller International supports the text as proposed – deletion of the strikethrough text.

9.1 The name of the Product

9.1.1 Helen Keller International supports the text as proposed.

9.1.2 Helen Keller International supports the text as proposed – deletion of the square brackets.

9.1.3 a) b) c) Helen Keller International supports the text as proposed – deletion of the square brackets.

9.1.4 (previously 9.1.5) Helen Keller International supports the text as proposed – deletion of the square brackets and strikethrough text.

9.2 List of Ingredients

9.2.1 Helen Keller International supports the text as proposed – deletion of the strikethrough text.

9.2.2 Helen Keller International supports the text as proposed – additional words, deletion of strikethrough text and deletion of square brackets.

9.3 Declaration of Nutritive Value

- 9.3 a) b) c) Helen Keller International supports the text as proposed – deletion of square brackets and strikethrough text.

9.4 Date Marking and Storage Instructions

- 9.4.1 (i)(ii) Helen Keller International supports the text as proposed and believes that this text and the equivalent text relating to follow-up formula for older infants should be aligned.

- 9.4.2 Helen Keller International supports the text as proposed – deletion of square brackets and strikethrough text.

9.5 Information for use

- 9.5.1 Helen Keller International supports the text as proposed – deletion of square brackets, deletion of strikethrough text and additional words.

- 9.5.2 Helen Keller International supports the text as proposed - deletion of square brackets, deletion of strikethrough text.

Helen Keller International points out a grammatical error – there should be no ‘s’ on the end of the word preparations.

- 9.5.3 Helen Keller International understands the justification given by the Chair of the EWG that there is already a prohibition on the use of images of bottles on the labels of these products, however we believe this should be reinforced in this text. Helen Keller International proposes that the text read “The label shall carry clear graphic instructions illustrating the method of preparation of the product, but such graphics shall not include pictures of feeding bottles.”

- 9.5.4 Helen Keller International supports the text as proposed – deletion of the square brackets.

- 9.5.5 Helen Keller International supports the text as proposed.

- 9.5.6 Helen Keller International supports the text as proposed – deletion of the square brackets, deletion of the strikethrough text.

9.6 Additional Labelling Requirements

Helen Keller International strongly believes that this section of the text has not been discussed comprehensively enough to make any decision and that consensus was NOT reached in the EWG. Helen Keller International strongly believes that the additional labelling requirements for this product should be the same as those for follow-up formula for older infants and that the concept of alignment, where possible and relevant, was agreed as a general principle by the Committee. Helen Keller International therefore recommends that the text, when agreed for the additional labelling requirements for older infants, then be discussed here.

ISDI – INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES

ISDI would like to take the opportunity to submit its comments on REP19/NFSDU Appendix IV. ISDI notes that CCNFSDU40 did not have a chance to discuss the scope, definition and labelling of [name of product] for young children in detail. The Committee briefly discussed the definition but taking into account the lack of consensus and limited time at the plenary, the Chair postponed the discussion to CCNFSDU41. ISDI notes that the draft text is held at step 4 since CCNFSDU40.

PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

2 DESCRIPTION

2.1 Product Definition

- 2.1.1 **[Name of product] for young children** means a product ~~specialy~~ ~~[formulated and]~~ manufactured for use ~~[as a breast-milk substitute]~~, as a liquid part of the ~~[progressively]~~ [diversified] diet of young children **[in order to contribute to the nutritional needs of young children]** ~~[when nutrient intakes may not be adequate to meet nutritional requirements].~~

ISDI Comment

ISDI supports the following definition (clean copy): *[Name of product] for young children means a product manufactured for use as a liquid part of the diversified diet of young children in order to contribute to the nutritional needs of young children.*

ISDI proposal (clean copy)

2 DESCRIPTION

2.1 Product Definition

2.1.1 [Name of product] for young children means a product manufactured for use as a liquid part of the diversified diet of young children in order to contribute to the nutritional needs of young children.

ISDI welcomes the deletion of “as a breast milk substitute” in the sentence and finds it appropriate the product in the Standard is not defined as a ‘breast milk substitute’.

ISDI reiterates that the revised Standard for Follow-up formula prescribes compositional requirements for [Name of product] for young children. Its composition is not the same as Infant formula or follow-up formula for older infants and it does not constitute the sole source of nutrition. The composition of [name of product] for young children means that they cannot be considered as Breast Milk Substitutes as they do not provide the full suite of nutrients provided by breast milk.

The revised Standard for [name of product] for young children lays down mandatory requirements for only 8 micronutrients (Vitamin C, A, D, B2, B12, Iron, Calcium, Zinc). In comparison, the current Infant Formula Standard lays down mandatory requirements for 22 micronutrients. There are also differences between both products in terms of the mandatory requirements for macronutrients.

[Name of product] for young children are formulated to be consumed as a complement (supplementary) to the daily diet, not to replace breast milk nor to discourage consumption of family foods. They are often used in conjunction with continued breastfeeding similarly to other complementary foods. They are also used as a partial or complete replacement for cow’s milk or in place of other beverages that are often inappropriate like sugar sweetened beverages (sodas, sweetened tea etc.) or micronutrient fortified beverages intended for adults.

Due to the diet pattern of young children the electronic working group in charge of the revised criteria for [name of product] for young children at Codex level concluded these products could not be classified as Breast milk Substitutes (eWG on FUF 2018).

Therefore, it would be factually incorrect to define [name of product] for young children as a ‘breast milk substitute’.

In fact, such terminology:

- would introduce risk as it could lead parents/caregivers to believe that these products are a suitable replacement for breast-milk. This could result in serious adverse health consequences if these products were mistakenly used as a sole source of nutrition (e.g. 0-6 months).
- would contravene the general principles of labelling ‘Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect’ (Ref: Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods).

9.5 Information for use

9.5.1 [Ready to use] products in liquid form ~~should~~ **may** be used ~~[either]~~ directly. ~~or in the case of~~ concentrated liquid products ~~{and powdered products}~~, must be prepared with **potable** 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 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.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. ~~{Pictures of feeding bottles are not permitted on labels of (name of product) for young children.}~~

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.

{9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and should be used as part of a {diversified} ~~{balanced}~~ diet.}

ISDI Comment

ISDI generally supports the content of paragraph 9.5. However, ISDI suggests to slightly modify 9.5.3, to read (clean copy): *The label shall carry clear instructions illustrating the method of preparation. Use of graphics is permitted and encouraged for multi-step instructions.*

ISDI recommends that the section 9.5.6. is re-worded to capture text in section 9.6. (*Additional Labelling Requirements*) of the current Standard to read as follows (clean copy): *9.5.6 The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and is not a breast milk substitute. It should be used as part of a diversified diet and not suitable as a sole source of nutrition.*

ISDI highlights that section 9.6 (*Additional Labelling Requirements*) of the current Codex Standard for Follow-up Formula states *“The products covered by this Standard are not breast-milk substitutes and shall not be presented as such”*. This wording is not captured under revised section 9.6 and ISDI proposes that its intent is now captured under 9.5.6 to ensure appropriate use.

There was a strong support within the eWG that [name of product] for young children are not breast milk substitutes. [Name of product] for young children contains a limited number of essential nutrients. It can only be used as part of a diversified diet of a young child.

This additional wording is proposed to clarify the role of [name of product] for young children in the diet.

The revised Standard for Follow-up formula lays down compositional requirements for [Name of product] for young children. It is critical to point out that its composition is not the same as Infant formula (sole source of nutrition) OR breast milk. For example, the revised Standard for [Name of product] for young children lays down mandatory requirements for only 8 micronutrients (Vitamin C, A, D, B2, B12, Iron, Calcium, Zinc). In comparison, the current Infant formula Standard lays down mandatory requirements for 22 micronutrients. There are also differences between products in terms of the mandatory requirements for macronutrients.

This additional wording: *“and is not a breast milk substitute. It should be used as part of a diversified diet and not suitable as a sole source of nutrition”* also ensures that:

- Parents/caregivers are provided with clear and accurate information on feeding.
- There is no contravention to the general principles of labelling ‘*Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect*’ (Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods).

ISDI proposal (clean copy)**9.5 Information for use**

- 9.5.1** Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. 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 product remaining after feeding should be discarded, shall appear on the label.
- 9.5.3** The label shall carry clear instructions illustrating the method of preparation. Use of graphics is permitted and encouraged for multi-step instructions.
- 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.
- 9.5.6** The label of [name of product] for young children shall include a statement that the product shall not be introduced before 12 months of age and is not a breast milk substitute. It should be used as part of a diversified diet and not suitable as a sole source of nutrition.

WPHNA - WORLD PUBLIC HEALTH NUTRITION ASSOCIATION

WPHNA thanks the chair and the co-chairs for their work on the revision of the proposed draft revised Standard for Follow-up Formula (CXS 156-187) at Step 6. We are pleased to provide the following submission. Our specific **comments are in red**.

SECTION B: FOLLOW-UP FORMULA FOR YOUNG CHILDREN**1. SCOPE**

- 1.1.** This section of the Standard applies to [name of the product], for young children as defined in Section 2.1, in liquid or powdered form.
- 1.2.** This section of the Standard contains compositional, quality, safety, **use**, labelling and analytical and sampling requirements for [name of the product] for young children.
- 1.3.** Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as [name of the product] for young children.

ADD:

- 1.4.** The application of this section of the Standard **shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), 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 the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).**

2. DESCRIPTION**2.1. Product Definition**

- 2.1.1.** [Name of the product] for young children means a product, manufactured for use **as a breast-milk, substitute** as a liquid part of the diet of young children [in order to contribute to the nutritional **intake** of young children].
- 2.1.2.** [Name of the product] for young children is so processed by physical means only and so packaged as to prevent spoilage and contamination under all **normal recommended** conditions of handling, **use**, storage and distribution in the country where the product is sold.

2.2. Other Definitions

- 2.2.1.** The term **young child** means a person from the age of 12 months up to the age of three years (36 months).

9. LABELLING

The requirements of the General Standard for the Labelling of Pre-packaged Foods (**CXS 1-1985**), the Guidelines on Nutrition Labelling (**CXG 2-1985**) and the Guidelines for Use of Nutrition and Health Claims (**CXG 23-1997**) apply to [name of the product] for young children. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation.

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 **[name of the 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 ~~for regional~~ usage.

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

- a) If [name of animal] milk is the only source of protein[*], the product may be labelled '**[name of the product] for young children** based on [name of animal] milk [protein]'.
- b) If [name of plant] is the only source of protein[*], the product may be labelled '**[name of the product] for young children** based on [name of plant] [protein]'.
- c) **If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled 'Follow-up Formula for Older Infants Based on [name of animal] milk protein and [name of plant] protein' or '[name of the product] for young children based on [name of plant] protein and [name of animal] milk protein'.**

* For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options.

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

9.2 List of Ingredients

9.2.1 A complete list of **all** 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. **In addition, appropriate functional classes for these ingredients and additives may be included on the label. The food additives INS number may also be optionally declared ~~the INS number.~~**

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 g or per 100 ml of the food as sold **as well as** per 100 ml 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 g or per 100 ml 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.
- c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

~~9.4.1 (i) The “Best Before Date” or “Best Quality Before Date” shall be declared by the day, month and year except that for products with a shelf-life of more than three months, [at least] the month and year [shall be declared] [The day and year shall be declared by uncoded 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).]~~

~~(ii) In the case of products requiring a declaration of month and year only, the date shall be introduced by the words “Best before end insert date; or “Best Quality before end insert date].~~

The date marking and storage instructions shall be in accordance with section 4.7.1 of the General Standard for the Labelling of Prepackaged Foods.

4.7.1 If not otherwise determined in an individual Codex standard, the following date marking shall apply, unless clause 4.7.1 (vii) applies:

(i) When a food must be consumed before a certain date to ensure its safety and quality the “Use-by Date” or “Expiration Date” shall be declared.

(ii) Where a “Use-by Date” or “Expiration Date” is not required, the “Best-Before Date” or “Best Quality Before Date” shall be declared.

IBFAN considers that the use of “Best Before Date” or “Best Quality Before Date” is not appropriate for follow-up formulas for older infants. The CXS 1-1985 states that when a food must be consumed before a certain date to ensure its **safety and quality** “Use-by Date” or “Expiration Date” should be used. IBFAN considers that a follow-up formula should not be consumed after the expiration date, since there is no guarantee of the compliance with the required nutritional content of the standard, nor its microbiological and other quality and safety requirements. Since follow-up formula is intended for older infants from 6 to 12 months these precautions must be in place for this vulnerable population

~~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.

9.5 Information for use

9.5.1 **Ready to use products in liquid form should be used directly. Concentrated liquid products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use.** Products in powdered form must contain a statement that the product is not sterile and preparation instructions must include that the product be reconstituted with safe water at 70 degrees centigrade according to the (WHO/FAO (2007) guidelines, “Safe preparation, storage and handling of powdered infant formula (http://apps.who.int/iris/bitstream/handle/10665/43659/978924_1595414_eng.pdf?sequence=1)

and WHA resolutions WHA 58.32 (2005) and 61.20 (2008) as well as the Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008), which provides relevant recommendations for the labeling of powdered infant formula and follow-up formula.

~~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 [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.

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.

9.5.6 The label of **[name of the product] for young children** shall include a statement that the product **is not suitable for infants under the age of 12 months**, and **may** be used as part of a diversified diet..

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 "Breastmilk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk;

c) a statement that the product should only be used on advice of an **independent** health worker as to the need for its use **including that the product is not suitable for infants under the age of 12 months** and the proper method of use.

(d) the statement; 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding'.

9.6.2 The label **shall have no pictures of infants, young children and women nor any other picture, text or representation**, including pictures of feeding bottles, that could undermine or discourage breastfeeding.

9.6.2.1 idealize the used of **[name of the product] for young children;**

9.6.2.2 suggest use for infants under the age of 12 months (including references to milestones and stages);

9.6.2.3 recommend or promote bottle feeding;

9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is similar, 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 ~~or regional~~ regulatory authorities.

9.6.3 The terms "humanized", "maternalized" or other similar terms that compare the product to breastmilk shall not be used.

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, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them. Cross promotion between product categories is not permitted on the labelling of the product.