Agenda Item 4a
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA:
DRAFT SCOPE, DESCRIPTION AND LABELLING FOR FOLLOW-UP FORMULA FOR OLDER INFANTS
Comments of Ecuador, Indonesia, Kenya, Mali, Senegal, HKI, IBFAN, WPHNA

ECUADOR

English

(i) General comments
Ecuador thanks to the Codex Committee on Nutrition and Food for Special Regimes for the opportunity to comment on the Standard for follow-up formula (CXS 156-1987): draft scope, description and labelling for follow-up formula for older infants.


Likewise, it is important to consider the informative note from WHO and UNICEF regarding the cross-promotion of breast milk substitutes for the discussion of this section.¹

(ii) Specific comments
Ecuador agrees with all the amendments made by CCFL45 to sections 9.22, 9.3 and 9.4.1 and 9.4.2.

Regarding section 9.6.4, during the 40th meeting, the prohibition of cross-promotion between the different product categories were agreed upon. However, no consensus was reached as to what term to use: "label" or "labelling". Considering that the permanence of this prohibition is not a matter of discussion at the 41st meeting, Ecuador asks that the concepts of labeling and labelling be reviewed from the GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CXS 1-1985):

“Label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food.

“Labelling” includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

In accordance with the International Code of Marketing of Breast Milk Substitutes and because it is the most comprehensive term, Ecuador considers appropriate the use of the term “labelling”. Thus, compliance with the promotion prohibition is facilitated.

Spanish

(i) Comentarios generales
Ecuador agradece al Comité del Codex sobre Nutrición y Alimentos para Regímenes Especiales la oportunidad de emitir comentarios a la Norma para preparados complementarios (CXS 156-1987): proyecto de ámbito de aplicación, descripción y etiquetado para los preparados complementarios para lactantes de más edad.

¹ https://www.who.int/nutrition/publications/infantfeeding/information-note-cross-promotion-infant-formula.pdf?ua=1

Asimismo, Ecuador considera importante que para la discusión de esta sección se tome en cuenta la nota informativa de la OMS y Unicef respecto a la promoción cruzada de sucedáneos de la leche materna.²

(ii) Comentarios específicos

Ecuador está de acuerdo con todas las enmiendas hechas por CCFL45 a las secciones 9.22, 9.3 y 9.4.1 y 9.4.2.

Respecto a la sección 9.6.4, durante la reunión 40°, se acordó la prohibición de promoción cruzada entre las distintas categorías de productos. Sin embargo, no se llegó a un consenso respecto a qué término utilizar: “label” o “labelling”. Considerando que la permanencia de la prohibición no es motivo de discusión en la reunión 41, Ecuador pide que se revisen los conceptos de “label” y “labelling” de la NORMA GENERAL PARA EL ETIQUETADO DE LOS ALIMENTOS PREENVASADOS (CXS 1-1985):

“Etiqueta”, cualquier marbete, rótulo, marca, imagen u otra materia descriptiva o gráfica, que se haya escrito, impreso, estarcido, marcado, marcado en relieve o en heucograbado o adherido al envase de un alimento.

“Etiquetado”, cualquier material escrito, impreso o gráfico que contiene la etiqueta, acompaña al alimento o se expone cerca del alimento, incluso el que tiene por objeto fomentar su venta o colocación.

En concordancia con el Código Internacional de Comercialización de Sucedáneos de la Leche Materna y debido a que es un término más comprensivo, Ecuador considera “apropiado el uso del término “labelling”. De tal manera que, se facilite el cumplimiento de la prohibición de promoción de sucedáneos de la leche materna al público en general.

INDONESIA

Indonesia wishes to thank New Zealand for preparing CRD on the Review of The Standard for Follow-Up Formula. Following Indonesia comments on CL 2019/77/OCS-NFSDU and CRD prepared by New Zealand, Indonesia proposes to modify last sentence in sub section 9.6.4 as follows:

Products shall be distinctly labelled is 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 [label/labelling] of the product. Other product categories (products other than breastmilk substitute) should not have the same brand name and label design as follow-up formula for older infants.

KENYA

Issue: 9.6.4 Products shall be distinctly 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 colors used, to enable consumers to make a clear distinction between them, {Cross promotion between product categories is not permitted on the [label/labelling] of the product.}

Comment: Kenya takes note of the discussions and conclusion by CCFL45 and CAC42 on this issue. We particularly note that though the request by CCNFSDU was on the square brackets, i.e. choice between label and labelling, CCFL45 also raised key issue related to the term cross promotion and its likely use extending beyond the scope of Codex standards. The intention of this sentence was informed by ensuring promotion and marketing of BMS are controlled to the extent possible within the spirit and intent of International Code and its resolutions. CCNFSDU agreed (REP 19/NFSDU Para 39) to consider the WHO International Code of Marketing of Breastmilk Substitutes, the Global Strategy for Infant and Young Child Feeding and relevant WHA resolutions in the clause of labelling rather than the clause scope. Cross promotion is described and discouraged in the Global Strategy for Infant and Young Child Feeding and thus the need to maintain this statement. Kenya therefore supports the intent of the clause while appreciating there may be need to introduce a definition to add clarity on the term.

² https://www.who.int/nutrition/publications/infantfeeding/information-note-cross-promotion-infant-formula.pdf?ua=1
La présentation de ce document de travail a suscité des questions, commentaires, observations et contributions ci-après :

Au paragraphe 9.1.2, le Mali soutient la suppression des crochets autour de "régionaux". Le produit doit être désigné par les termes « Préparation de suite pour nourrissons du deuxième âge » tels que définis dans la section 2.1, ou par toute autre désignation appropriée décrivant la véritable nature du produit, conformément aux usages nationaux [ou régionaux].

Au paragraphe 9.1.3 Le Mali soutient la suppression des crochets autour de * à côté du mot "protéines" dans le texte.

Au paragraphe 9.2.2 Le Mali soutient la suppression du texte barré. "Les ingrédients d'origine animale ou végétale ainsi que les additifs alimentaires doivent être désignés par un nom spécifique. En outre, des catégories fonctionnelles appropriées pour ces ingrédients et additifs peuvent également figurer sur l'étiquette. Le numéro SIN des additifs alimentaires peut aussi être mentionné, à titre facultatif."

Au paragraphe 9.3 Déclaration de la valeur nutritive Le Mali soutient les changements proposés. Les renseignements d'ordre nutritionnel figurant sur l'étiquette [des préparations de suite pour nourrissons du deuxième âge] doivent comporter les éléments d'information ci-après, qui doivent être indiqués dans l'ordre suivant :

a) la valeur énergétique, exprimée en kilocalories (kcal) et/ou en kilojoules (kJ), et le nombre de grammes de protéines, de glucides et de lipides fournis par 100 grammes ou par 100 millilitres ml de l'aliment tel qu'il est vendu, [ainsi que] par 100 millilitresml de l'aliment prêt à l'emploi, lorsqu'il est préparé conformément aux instructions figurant sur l'étiquette ;

b) la quantité totale de chaque vitamine et sel minéral spécifiés au paragraphe 3.1.3 de la section A, ainsi que tout autre ingrédient spécifié au paragraphe 3.2 de la section A, par 100 grammes ou par 100 millilitresml de l'aliment tel qu'il est vendu, ainsi que par 100 millilitresml de l'aliment prêt à l'emploi, lorsqu'il est préparé conformément aux instructions figurant sur l'étiquette ; en outre, la déclaration des éléments nutritifs sous a) et b) par 100 kilocalories (kcal) (ou par 100 kilojoules (kJ)) est autorisée

Au paragraphe 9.4 Datage et instructions d'entreposage, le Mali soutient la suppression du paragraphe 9.4.1 et l'ajout de la phrase en gras « Le datage et les instructions d'entreposage doivent être conformes à la section 4.7.1 de la Norme générale pour l'étiquetage des denrées alimentaires préemballées."

Au paragraphe 9.4.2, le Mali soutient la suppression du texte barré ;

Au paragraphe 9.6.2.5 Le Mali soutient la suppression du crochet qui est sûrement une omission car il était déjà convenu de le supprimer ;

Au paragraphe 9.6.4, le Mali accepte le texte tel que proposé, tout en privilégiant le terme « Etiquetage » en lieu et place « d'étiquette. »

En ce qui concerne le texte entre crochets [étiquette / étiquetage], le Mali soutient le terme étiquetage. Sur la base des recherches concernant la promotion croisée, il est claire que le terme "étiquetage" devrait être utilisé dans le texte, car les pratiques de promotion croisée s'étendent et sont spécifiquement conçues par les fabricants pour s'étendre au-delà de l'étiquette.

**SENEGAL**

Le Sénégal soutient le texte tel que présenté et convenu à la réunion du CCNFSDU en 2018 tout en gardant le terme « étiquetage » en lieu et place de «étiquette. » (en référence à la définition des ces termes dans le document CXS 1-1985).

Ainsi, la phrase devrait se lire comme suit : « La promotion croisée entre les catégories de produits n'est pas autorisée sur l'étiquette / l'étiquetage du produit. »

**Commentaire :** Comme déjà discuté, la promotion croisée qui pose problème, peut négativement affecter la santé des nourrissons du deuxième âge. Le texte actuel tel que proposé, devrait être maintenu aussi, la définition adoptée par l'AMS 63.14 et la 69.9 pourrait être incluse en tant que note de bas de page au texte 9.6.4, auquel elle fait référence.
SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

9.3.1
Helen Keller International supports the deletion of the square brackets around the * adjacent to protein in this text.

9.2.2 List of ingredients
Helen Keller International supports the deletion of the text marked with strikethrough.

9.3 Declaration of Nutritive Value
a) b) c)
Helen Keller International supports these proposed changes.

We note 2 editorial errors:

1. **9.3 a)**: There is a spacing issue on the second line which should read ‘grams of protein’.
2. **9.3 c)**: There is a spacing issue and missing bracket.

The text should read: ‘In addition, the declaration of nutrients in a) and b) per 100 kilocalories (kcal) (or per 100 kilojoules (kJ)) is permitted.’

9.4 Date Marking and Storage Instructions

9.4.1 Helen Keller International supports the deletion of the text and the replacement text in **BOLD**.

9.4.2 Helen Keller International supports the deletion of the text marked with strikethrough.

9.6 Additional Labelling Requirements

9.6.2.5 Helen Keller International supports the deletion of the square bracket and believes this had already been agreed to and so it appears it is an error.

9.6.4 Helen Keller International would like to retain the second sentence that specifically refers to cross-promotion as this is a highly problematic practice that in the interest of the health of children up to 36 months, must be curbed. However, we understand that this term, without an agreed definition, is viewed as problematic by many country governments in terms of implementation. We have thus closely examined the current text and in the spirit of compromise and believing that it is critical to ensure that the 2019 CCNFSDU meeting focusses on the outstanding and important issues related to [name of product] for young children, we are prepared to accept the deletion of the second sentence, if that is the majority will of member countries.

As currently drafted, the text on cross-promotion in the revised draft Codex Standard on Follow-up Formula as it applies to follow-up formula for older infants in 9.6.4 of the Additional Labelling Requirements reads: “Products shall be distinctly 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 [label/labelling] of the product.”

In addition, the labelling text also refers to the need to comply with the Codex General Standard for the Labelling of Prepackaged Foods CODEX STAN 1-1985 (Rev.1-1991)

This provides clear text under the section on general principles 3.2 that reads: “Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.”
Helen Keller International will therefore, as a compromise, accept that with both the reference to the General Standard and the first sentence of 9.6.4 that the issue of cross promotion could be considered to be adequately covered. Helen Keller International however, urges governments to ensure that cross promotion is 1) comprehensively dealt with in their national regulations and 2) that manufacturers are reminded of the requirement to read 9.6.4 of the Codex draft revised Standard for Follow-up Formula, together with the principles in the General Standard for the Labelling of Prepackaged Foods and immediately refrain from continuing with the practice of cross promotion that undermines breastfeeding and has the potential to harm the health of older infants and young children. It is time for all to put public health before company profit.

**IBFAN - INTERNATIONAL BABY FOOD ACTION NETWORK**

IBFAN 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 A: FOLLOW-UP FORMULA FOR OLDER INFANTS**

1. **SCOPE**

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

1.2 This section of the Standard contains compositional, quality, safety, use, labelling and analytical and sampling requirements for Follow-up Formula for Older Infants.

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

**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 Follow-up formula for older infants means a product, manufactured for use as a breast-milk substitute as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.

2.1.2 Follow-up formula for older infants 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 infant means a person of not more than 12 months of age.

2.2.2 The term older infant means a person from the age of 6 months and not more than 12 months of age.

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 follow-up formula for older infants. 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 Follow-up Formula for Older Infants as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage.

9.1.3 The sources of protein in the product shall be clearly shown on the label.
   
a) If [name of animal] milk is the only source of protein[†], the product may be labelled ‘Follow-up Formula for Older Infants Based on [name of animal] milk [protein].

b) If [name of plant] is the only source of protein[†], the product may be labelled ‘Follow-up Formula for Older Infants 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 ‘Follow-up Formula for Older Infants 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 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:

c) 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.

d) 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.

e) 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/10665/43659/9789241595414_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 follow-up formula for older infants shall include a statement that the product is not suitable for infants under the age of six months shall not be introduced before 6 months of age, is not to be used as a sole source of nutrition and that older infants should receive complementary foods in addition to the product.

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 six 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 not:

9.6.2.1 have 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 or idealize the use of follow-up formula for older infants;

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

9.6.2.3 recommend or promote bottle feeding;

9.6.2.4 undermine or discourage breastfeeding, that makes a comparison to breastmilk, or suggests that the product is similar, equivalent to or superior to breastmilk;

9.6.2.5 convey anything that may be construed as an endorsement by a professional or any other body, other than non promotional certifications 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.

In summary IBFAN notes that the commonly used marketing strategy of cross-branding of products with infant formula through labelling and advertisements is a threat to breastfeeding and infant and child health. This marketing strategy is misleading and confusing and clearly designed to circumvent national regulations that cover the marketing of products for infants and young children. Cross branding on formulas and other products for infants and young children over 6 months increases the risk of infants being fed with inappropriate products that do not meet their nutritional needs. “The practice of cross-promotion of breast-milk substitutes must be curbed.” (WHO/UNICEF INFORMATION NOTE - Cross-promotion of infant formula and toddler milks, WHO, 2018)

WPHNA - WORLD PUBLIC HEALTH NUTRITION ASSOCIATION

WPHNA supports the comment submitted by IBFAN.