



Agenda Item 4b
18/40/5

CX/NFSDU

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Fortieth Session
Berlin, Germany
26 – 30 November 2018

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

ISDI comments on Agenda Item 4b
CX/NFSDU 18/40/5

SCOPE, LABELLING, DEFINITIONS AND STRUCTURE

1.4.1 Scope: Follow-up formula for older infants

1.4.1.1 Section 1.1

Recommendation 1:

That CCNFSDU agree to the following text for Section 1.1 of the Scope (for follow-up formula for older infants):

- 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.

ISDI comment

ISDI supports this recommendation.

1.4.1.2 Section 1.2

Recommendation 2:

That CCNFSDU agree to the following text for Section 1.2 of the Scope (for follow-up formula for older infants):

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

ISDI comment

ISDI supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants.

1.4.1.3 Section 1.3

Recommendation 3:

That CCNFSDU agree to the following text for Section 1.3 of the Scope (for follow-up formula for older infants):

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

ISDI comment

ISDI supports this recommendation and favours the word “shall” instead of “should” as this is more consistent with the terminology used in the labelling section of the Standard.

1.4.2 Scope: [Name of product] for young children

1.4.2.1 Section 1.1

Recommendation 4:

That CCNFSDU agree to the following text for Section 1.1 of the Scope (for [name of product] for young children):

- 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.

ISDI comment

ISDI supports this recommendation.

1.4.2.2 Section 1.2

Recommendation 5:

That CCNFSDU agree to the following text for Section 1.2 of the Scope (for [name of product] for young children):

- 1.2** This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for [name of product] for young children.

ISDI comment

ISDI supports the statement proposed for section 1.2, but would like to highlight that analytical requirements are related to composition, quality and safety – similar to contaminants.

1.4.2.3 Section 1.3

Recommendation 6:

That CCNFSDU agree to the following text for Section 1.3 of the Scope (for [name of product] for young children):

- 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard ~~[should/ shall]~~ be presented as [name of product] for young children.

ISDI comment

ISDI supports this recommendation and favours the word “shall” instead of “should” as this is more consistent with the terminology used in the labelling section of the Standard.

1.5.1 Follow-up formula for older infants

Recommendation 7:

That CCNFSDU agree to the following definition for follow-up formula for older infants:

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

ISDI comment

ISDI supports the following definition:

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

ISDI considers that the wording “as a substitute for breast milk” is not suitable in the definition of Follow up Formula for older infants.

ISDI takes note of the discussions at CCNFSDU39 and the analysis of the eWG Chair.

- With regard to the word “especially”, ISDI is of the opinion that it is appropriate to retain the word. Older infants have particular nutritional requirements and this product aims to address these.

Follow-up formula for older infants remains a “food for special dietary uses” in line with the GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (CODEX STAN 146-1985) that describes “Foods for Special Dietary Uses (FSDU) are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.”

ISDI would like to highlight that the last revised Standard for infant formula and formula for special medical purposes intended for infants (Codex STAN 72-1981, rev.2007) and the Guidelines on formulated complementary foods for older infants and young children (CAC/GL 8-1991, rev. 2013) stipulate these products are “specially manufactured” and “specifically formulated” respectively. Both are Foods for Special Dietary Uses and the terminology “specially manufactured”/ “specifically formulated” refers to the nutritional requirements provided by these products.

- With regard to the reference ‘substitute for breast milk’, ISDI notes that CX STAN 72-1981 defines infant formula as a breast-milk substitute and states that “No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.”

Follow-up formulas do not constitute the sole source of nutrition. They are intended for use as a liquid part of a progressively diversified diet for older infants. Therefore, these products do not satisfy, by themselves, the nutritional needs of the older infant.

ISDI notes that the requirements not to discourage breastfeeding are stipulated in section 9.6 (Additional Labelling Requirements).

1.5.2 [Name of product] for young children

Recommendation 8:

That CCNFSDU agree to the following definition for [name of product] for young children, and make a decision on whether to retain or delete the text contained within [] :

[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~~.

ISDI comment

ISDI supports this Recommendation even though it remains of the opinion that the word “specially” should be retained.

ISDI welcomes the deletion of “as a breast milk substitute” in the sentence.

ISDI supports the following definition:

[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~~.

- With respect to the word “specially”, ISDI takes note of the discussions at CCNFSDU39.

Young children have particular nutritional requirements and this product contributes to these.

The [Name of product] for young children remains a “food for special dietary uses” in line with the GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (CODEX STAN 146-1985) that describes “Foods for Special Dietary Uses (FSDU) are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such.”

ISDI would like to highlight the eWG that the last revised Standard for infant formula and formula for special medical purposes intended for infants (Codex STAN 72-1981, rev.2007) and the Guidelines on formulated complementary foods for older infants and young children (CAC/GL 8-1991, rev. 2013) stipulate these products are “specially manufactured” and “specifically formulated” respectively. Both are Foods for Special Dietary Uses and the terminology “specially manufactured”/ “specifically formulated” refers to the nutritional requirements provided by these products.

- With regard to the reference ‘substitute for breast milk’, ISDI 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 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 or breast milk and it does not constitute the sole source of nutrition. 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 **28 micronutrients**. There are also differences between both products in terms of the mandatory requirements for macronutrients.

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).
- would contravene the purpose of the WHO Code on Marketing of Breast-milk Substitutes.

1.6 LABELLING

1.6.1 Follow-up formula for older infants

1.6.1.1 Introductory paragraph

Recommendation 9:

That CCNFSDU agree to the following text for introductory paragraph to the Labelling Section for follow-up formula for older infants:

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 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.]~~

ISDI comment

ISDI supports this recommendation.

ISDI notes that the text in 'strikethrough' is addressed in the Codex Guidelines for Use of Nutrition and Health Claims (CAC-GL 23-1997). These guidelines are referenced in this recommendation and therefore this text should not be repeated.

1.6.1.2 Additional labelling requirements

Recommendation 10:

That CCNFSDU agree to the following text for Section 9.6 for follow-up formula for older infants and that the Committee consider the text presented within the individual provisions within square brackets, or with strikethrough.

[9.6 Additional Labelling Requirements

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

- a) the words "important notice" or their equivalent;
- b) the statement "Breast-milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast-milk;
- c) a statement that the product should only be used on advice of an ~~[independent]~~ health worker as to the need for its use ~~[including any exception to the age of introduction of 6 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 and women nor any other picture[,] or text[,] which idealizes the use of follow up formula. The label shall have no pictures images, text or other representation that might:

9.6.2.1 idealize the used of follow-up formula for older infants;

9.6.2.2 suggest 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 breast-milk,~~ or suggests that the product is nearly equivalent to or superior to breast-milk;

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

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

9.6.4 Products 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.]]

ISDI comment

ISDI takes note of the discussions at CCNFSDU39 and supports most of the proposed wording.

ISDI strongly opposes the following requirements:

- 9.6.2.2: the phrase "(including references to milestones and stages)" should be deleted
- 9.6.2.5: the phrase "(or anything that may be construed as an endorsement)" should be deleted

ISDI's proposed texts

- 9.6.2.2 should read *“suggest use for infants under the age of 6 months.”*
- 9.6.2.5 should read *“convey an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional authority”*

Rationale

The paper prepared the eWG Chair further noted that some modifications to the provisions may be required to ensure that Section 9.6 should not be more stringent than that required on the label of infant formula.

ISDI is of the opinion that the above modifications address this point.

1.6.2 [Name of product] for young children

1.6.2.1 Introductory paragraph

Recommendation 11:

That CCNFSDU agree to the following text for introductory paragraph to the Labelling Section for [Name of product] for young children:

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.~~

ISDI comment

ISDI supports the proposed text for the introductory paragraph to the Labelling section, including a reference to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997).

ISDI notes that the text in 'strikethrough' is addressed in the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). These guidelines are referenced in this recommendation and therefore this text should not be repeated.

ISDI supports that nutrition and health claims are permitted for [name of product] for young children and proposes the following paragraph:

The requirements of the *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to [name of product] for young children. Nutrition and Health claims may be permitted provided, in the case of health claims, that they have been demonstrated in rigorous studies with adequate scientific standards.

- The valid role of health and nutrition claims has been recognized by national legislation in a number of countries.
- Certain health and nutrition claims on labels for foods intended for healthy young children are already allowed in a number of countries.
- Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) already lays down detailed instructions to ensure that the claims made for the foods are substantiated.
- The Global Strategy for Infant and Young Child Feeding¹ states, "Mothers ... should be supported to optimize their infants' nutrition." Nutrition and health claims on [Name of Product] for Young Children are a sensible way to encourage optimized nutrition for young children who are not breast-fed.
- Young children need nutrient dense foods to meet their unique nutrient and energy requirements. Most adult food is not able to provide such density.

¹ http://www.who.int/nutrition/topics/global_strategy/en/

- Furthermore, young children consume a diverse diet of foods, many of which can bear nutrition and health claims, and [name of product] for young children should be similarly allowed to include nutrition and health claims.
- It is crucial that parents and caregivers are able to make appropriate and informed choices about feeding their young children. Parents and caregivers need access to science- and evidence-based information and statements about the role of nutrients in the growth and development of their young children to support their nutrition decisions.
- When making a food choice, parents and caregivers often compare the label of foods used by general population with products which are classified by Codex as Foods for Special Dietary Uses. Foods used by general population are not specially formulated for young children and are not subject to additional safety criteria. However, the label of foods used by general population often carry nutrition and health claims and these claims could lead parents and caregivers to believe that these foods are superior. This could potentially lead to unhealthy food choices for young children and create unequal conditions for competition.

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1.6.2.2 Name of Product

Recommendation 12:

That CCNFSDU agree to the following text for The Name of Product Section 9.1 for [Name of product] for Young Children:

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 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 {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 '[Name of 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 Product] for Young Children Based on [name of plant] {protein}{'.

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'.**

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

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

ISDI comment

ISDI supports this recommendation.

1.6.2.3 List of Ingredients

Recommendation 13:

That CCNFSDU agree to the following text for the List of Ingredients (provision 9.2.1) for [name of product] for young children, and further discuss the bold text within provision 9.2.2, noting the recommendation to realign with the Infant Formula Standard:

9.2 List of Ingredients

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

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives.

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].

ISDI comment

ISDI supports this recommendation. However section 9.2.2. addresses how some ingredients ought to be labelled. ISDI believes the labelling of these ingredients is captured in the Codex General Standard for the labelling of prepackaged foods (CODEX STAN 1-1985) and therefore does not need to be repeated.

1.6.2.4 Declaration of Nutritive Value

Recommendation 14:

That CCNFSDU agree to the following text for the Declaration of Nutritive Value for [name of product] for young children:

9.3 Declaration of Nutritive Value

The declaration of nutrition information for [name of product] for young children shall contain the following information which should be in the following order:

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

ISDI comment

ISDI supports this recommendation.

1.6.2.5 Date marking and storage instructions

Recommendation 15:

That CCNFSDU agree to the following text for Date Marking and Storage Instructions for [name of product] for young children:

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>”.

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated # {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.

ISDI comment

ISDI supports this recommendation.

1.6.2.6 Information for Use

Recommendation 16:

That CCNFSDU agree to the following text for Instructions for Use for [name of product] for young children:

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 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.~~
- 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 this recommendation.

However, ISDI suggests to:

Slightly modify 9.5.3, to read “The label shall carry clear instructions illustrating the method of preparation. Use of graphics is permitted and encouraged for multi-step instructions”.

Remove “and “ in in 9.5.4. to read:

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

ISDI recommends that the section 9.5.6. is cross-referenced in section 9.6. [Additional labelling requirements] and reads as follows:

[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] diet.]
“and that it is not formulated as a substitute for breast milk and is not suitable as a sole source of nutrition”.

This additional wording: “*and that it is not formulated as a substitute for breastmilk and is 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*’ (Ref: Section 3.1 CODEX STAN 1-1985; Labelling of Prepackaged Foods)

1.6.2.7 Additional labelling requirements

Recommendation 17:

That CCNFSDU agree to the following text for the Additional Labelling requirements for [name of product] for young children and that the Committee further considers whether the text presented within square brackets in provision 9.6.2 be retained with or without the text with strikethrough:

9.6 Additional Labelling Requirements

[9.6.1] The label of [name of product] for young children shall have no 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.}]

[9.6.2] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes**[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used].**

ISDI comment

ISDI supports this recommendation and refers to recommendation 16 whereby ISDI suggests to reference section 9.5.6. into this section. Therefore, a new section 9.6.3 would read as follows: [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] diet.] “*and that it is not formulated as a substitute for breast milk and is not suitable as a sole source of nutrition*”.

ISDI highlights that section 9.6 (Additional Requirements) of the current Codex Standard for Follow-up Formula Standard states “*The products covered by this standard are not breast-milk substitutes and shall not be presented as such*”. Although this wording is not captured under revised section 9.6, ISDI proposes that its intent is now captured under 9.5.6 to ensure appropriate use (see ISDI response to Recommendation 16).

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 **28 micronutrients**. There are also differences between products in terms of the mandatory requirements for macronutrients.

This additional wording also ensures that:

- Parents/caregivers are provided with clear and accurate information on nutritional value and composition
- No contravention exists with 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)

ISDI agrees with the removal of language covering “texts, images and colours” in 9.6.2 as this is subjective, open to different interpretations and has significant implications for the facilitation of international trade that would not be consistent with the mandate of Codex. Such texts, images and colours are lawfully registered, legitimate trademarked characteristics and are covered by relevant international obligations pertaining to intellectual property rights. In addition, the ability of consumers to recognize trusted, legitimate brands is important for their identification of safe and suitable products and is essential to prevent adulteration and counterfeiting.

1.7 NAME OF PRODUCT FOR YOUNG CHILDREN

Recommendation 18:

That CCNFSDU consider the following Name of Product (for young children) and further discuss the inclusion of '*formulated*' within this name:

[Formulated] drink for young children

ISDI comment

ISDI support this recommendation.

ISDI supports the wording "formulated" in the name of the product as it clarifies that the product is the result of specific and voluntary effort of the manufacturer to prepare a product for a specific intended use. Formulation refers to the phase of theoretical development of the product preceding the manufacturing itself (e.g. choice of specific ingredients when developing the product recipe).

1.8 STRUCTURE OF THE STANDARD(S)

Recommendation 19.

That CCNFSDU agree to further discuss the structure of the standard(s) at the Committee meeting, noting the preference of the eWG for either one standard with two parts or two separate standards.

ISDI comment

ISDI takes note of the eWG recommendation for CCNFSDU to further discuss the structure of the standard(s) at the Committee meeting, noting the preference of the eWG for either one standard with two parts or two separate standards.

ISDI's preferred option, outlined in CP2 Option 2: two separate standards, one for Follow-up Formula for Older Infants and one for [Name of Product] for young children). Both of these two separate standards should be progressed and be finalised in parallel and take into consideration the following elements:

- CCNFSDU36 agreed there is a recognised point of distinction at 12 months as this well reflects the need to accommodate the changing nutritional requirements of older infants and young children and allow to cater for the role of the different products in the diet.
- Two separate standards, one for Follow-up Formula for Older Infants and one for [Name of Product] for young children) could provide more clarity than option 1 considering Follow-up Formula for Older Infants (FUF) and the [Name of Product] for Young Children are two distinct products.
- There are no procedural implications in accordance with the Codex Alimentarius Commission (CAC36) mandate.
- The time to finalize the work will not be further extended.
- Proceeding with two separate standards will facilitate finalization of the respective standards in a timely manner and also allow for future potential modifications, as needed, to be efficiently addressed.

ISDI supports the recommendation of CCEXEC75 to CCNFSDU².

14. **Conclusion**With regard to references to WHO/WHA documents in the draft CCNFSDU text on follow-up formula, CCEXEC75 provided the following advice intended to assist CCNFSDU in moving forward:
- a. references should be considered on a case-by-case basis;
 - b. references may provide context and additional information to assist members in understanding and use of standards;
 - c. concepts and technical information could be incorporated into the text of the standard itself, rather than referencing sources external to Codex; and
 - d. references must be relevant to the scope of the standard itself, fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.

² http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-702-75%252FReport%252FFINAL%252FREP18_EXEC2e.pdf