

[Revised] 15 October 2019

Review of the Standard for Follow-up Formula (CXS 156-1987): Proposed draft follow up formula for older infants and [product] for young children¹

ISDI reply to Circular Letter (CL 2019/78-NFSDU) at STEP 3

Recommendation 1

That CCNFSDU agree to the following text:

*⁴⁾ Lactose should be the preferred carbohydrates in [name of product] based on milk protein. **[For products not based on milk protein glucose polymers should be the preferred carbohydrates used.]***

Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.

ISDI Comment

ISDI partially supports recommendation 1 and appreciates the proposed wording. ISDI would like to suggest an addition to the text as follows: *⁴⁾ Lactose should be the preferred carbohydrates in [name of product] based on milk protein. **[For products with reduced lactose and products not based on milk protein, glucose polymers should be the preferred carbohydrates used.]** Mono- and disaccharides, other than lactose, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose should not be added.*

ISDI proposes this additional wording because there are currently milk-based [name of product] for young children with reduced lactose on the market.

Recommendation 2

That CCNFSDU considers whether the sentence ***[Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]]*** should be retained under 3.2.1 Optional ingredients to capture the intent that no such substances or ingredients should be added to these products or be deleted.

ISDI Comment

ISDI is of the view the sentence ***[Substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]]*** should be deleted.

The paragraphs 3.2.1 of the "optional ingredients" section deal with the addition of ingredients or substances to achieve a "particular nutrition purpose" in relation to beneficial effect. This is the purpose of their addition. The added text in square brackets is at odds with this since imparting or enhancing a sweet taste is not a nutritional purpose.

As stated by the eWG's Chair in conclusion for the recommendation 1 above, "Compositional requirements in a

¹ For the background information, please refer to CX/NFSDU 19/41/5.

standard should be science based and enforceable". Optional ingredients or substances added must be safe and suitable for the target population according to the general principles established in the revised text. Codex standard must reflect state of the art science at the time it is set or revised.

If an optional ingredient or a substance added for nutritional purpose would bring mono and di-saccharides, other than lactose, they shall not exceed 2.5 g/100kcal (0.60 g/100kJ), therefore limiting sweet taste.

ISDI would like to take the opportunity to address the comments made in the eWG (included in section 2 of the Agenda Paper – CX/NFSDU 19/41/5).

Sweeteners including steviol glycosides (INS 960) are not authorized as an additive for use in foods for infants and young children as per GSFA (CODEX STAN 192-1995, revision 2018), nor are any other additives with a functional class of sweetener. ISDI believes that the existing processes are effective at controlling which ingredients or substances are used.

Flavouring substances are products that are added to food to impart, modify, or enhance the flavour of food and are chemically-defined substances either formed by chemical synthesis, or obtained from materials of plant or animal origin as defined in Guidelines for the Use of Flavourings (CXG 66-2008).

The use of flavouring substances is governed by the Follow-up Formula Standard (CODEX STAN 156-1987, under revision) with the positive list of permitted substances including specific limits, where applicable (Natural Fruit Extracts, Vanilla extract, Ethyl vanillin, Vanillin). Any other flavouring substances are prohibited for use in foods for infants and young children.

Recommendation 3

a) Follow-up formula for older infants:

That CCNFSDU agree to the following text for 'Purity Requirements' for follow-up formula for older infants; All ingredients shall be clean, of good quality, safe and suitable for ingestion by **[older] infants** ~~from the 6th month on and young children~~. They shall conform with their normal quality requirements, such as colour, flavour and odour.

b) [Name of product] for young children:

That CCNFSDU agree to the following text for 'Purity Requirements' for [name of product] for young children; All ingredients shall be clean, of good quality, safe and suitable for ingestion by ~~infants from the 6th month on and~~ young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

ISDI Comment

ISDI supports recommendation 3.

Recommendation 4

a) Follow-up formula for older infants:

That CCNFSDU agree to the following text for 'Vitamin Compounds and Mineral Salts' for follow-up formula for older infants;

Vitamin compounds and mineral salts

Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the [Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children](#) approved by the Codex Alimentarius Commission (CXG 10-1979).

The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.1.

b) [Name of product] for young children:

That CCNFSDU agree to the following text for 'Vitamin Compounds and Mineral Salts' for [name of product] for young children;

Vitamin compounds and mineral salts

Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the [Advisory List for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children](#) approved by the Codex Alimentarius Commission (CXG 10-1979).

~~The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6~~

ISDI Comment

ISDI supports recommendation 4a. However, concerning recommendation 4b, ISDI would like to reiterate its previous concern that CCNFSDU did not establish a maximum for sodium to ensure nutritional integrity for [name of product] for young children.

If limit for sodium would be established, ISDI supports to maintain the statement [the amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6].

Recommendation 5**a) Follow-up formula for older infants:**

That CCNFSDU agree to the following text for 'Consistency and Particle Size' for follow-up formula for older infants;

Consistency and particle size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

b) [Name of product] for young children:

That CCNFSDU agree to the following text for 'Consistency and Particle Size' for [name of product] for young children;

Consistency and particle size

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles.

ISDI Comment

ISDI supports recommendation 5.

Recommendation 6**a) Follow-up formula for older infants:**

That CCNFSDU agree to the following text for 'Specific Prohibitions' for follow-up formula for older infants;

Specific prohibitions

The product and its components shall not have been treated by ionizing radiation.

b) [Name of product] for young children:

That CCNFSDU agree to the following text for 'Specific Prohibitions' for [name of product] for young children;

Specific prohibitions

The product and its components shall not have been treated by ionizing radiation.

ISDI Comment

ISDI supports recommendation 6.

Recommendation 7
a) Follow-up formula for older infants: That CCNFSDU agree to retain the permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard (CXS 156-1987), for follow-up formula for older infants, noting these will be replaced by a reference to the corresponding sections of the GSFA following the completion of the alignment work.
b) [Name of product] for young children: That CCNFSDU agree to retain the permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard (CXS 156-1987), for [name of product] for young children, noting these will be replaced by a reference to the corresponding sections of the GSFA following the completion of the alignment work.

Recommendation 8
a) That CCNFSDU agree to administrative changes i – iii, and to aligning the names of food additives in the current Follow-up Formula Standard with those in the GSFA (see Appendix II for administrative changes)
b) That CCNFSDU consider if ‘Packaging gases’ should be included in the Food Additive section and listed under the appropriate functional class, noting also Recommendation 13 to retain them in Section 7 Packaging.

ISDI Comment

ISDI supports recommendations 7.

ISDI supports recommendations 8a). With respect to recommendation 8b) ISDI strongly prefers for ‘Packaging gases’ to be included in the Food Additive section under the appropriate functional class. ISDI is of the view that they do not also need to be retained in Section 7 Packaging but can accept them being listed in both places as is the case in the infant formula standard.

Recommendation 9	
a) Follow-up formula for older infants: Please indicate your preference of the two options and provide justification for your response	
Option 1: reference Section 4 of the Preamble of the GSFA (CXS 192-1995)	Option 2: Adopt the text from the Infant Formula Standards and the Standard for Processed Cereal-based foods for Infants and Young Children for the carry-over of food additives and nutrient carriers.
b) [Name of product] for young children: Please indicate your preference of the two options and provide justification for your response	
Option 1: reference Section 4 of the Preamble of the GSFA (CXS 192-1995)	Option 2: Adopt the text from the Infant Formula Standards and the Standard for Processed Cereal-based foods for Infants and Young Children for the carry-over of food additives and nutrient carriers.

ISDI Comment

ISDI supports option 2 as it may offer improved clarity within the Standard i.e. to adopt the text from the Infant Formula Standards and the Standard for Processed Cereal-based foods for Infants and Young Children for the carry-over of food additives and nutrient carriers.

Recommendation 10
<p>a) <i>Follow-up formula for older infants:</i></p> <p>That CCNFSDU agree to the following text for follow-up formula for older infants:</p> <p>4.5 Flavourings</p> <p>Natural Fruit Extracts: GMP</p> <p>Vanilla extract: GMP</p> <p>Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml</p> <p>Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml</p> <p><i>[The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)]</i></p>
<p>b) <i>[Name of product] for young children:</i></p> <p>That CCNFSDU agree to the following text for [name of product] for young children:</p> <p>4.5 Flavourings</p> <p>Natural Fruit Extracts: GMP</p> <p>Vanilla extract: GMP</p> <p>Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml</p> <p>Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml</p> <p><i>[The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)]</i></p>

ISDI Comment

ISDI supports recommendation 10.

Recommendation 11
<p>a) <i>Follow-up formula for older infants:</i></p> <p>That CCNFSDU agree to the following text for 'Contaminants' for follow-up formula for older infants;</p> <p>CONTAMINANTS</p> <p>The products covered by this Standard shall comply with the Maximum levels of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).</p> <p>The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.</p>
<p>b) <i>[Name of product] for young children:</i></p> <p>That CCNFSDU agree to the following text for 'Contaminants' for [name of product] for young children;</p>

CONTAMINANTS

The products covered by this Standard shall comply with the Maximum levels of the [General Standard for Contaminants and Toxins in Food and Feed \(CXS 193-1995\)](#).

The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.

ISDI Comment

ISDI supports recommendation 11.

Recommendation 12**a) Follow-up formula for older infants:**

That CCNFSDU agree to the following text for 'Hygiene' and consider whether the additional references in [] are necessary for follow-up formula for older infants;

HYGIENE

It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the [General Principles of Food Hygiene \(CXC 1- 1969\)](#), and other relevant Codex texts such as the [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children \(CXC 66-2008\)](#)

[the [Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods \(CXC 40-1993\)](#) and the [Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods \(CXC 23-1979\)](#)]

The products should comply with any microbiological criteria established in accordance with the [Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods \(CXG 21-1997\)](#).

b) [Name of product] for young children:

That CCNFSDU agree to the following text for 'Hygiene' and consider whether the additional references in [] are necessary for [name of product] for young children;

HYGIENE

It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the [General Principles of Food Hygiene \(CXC 1- 1969\)](#), and other relevant Codex texts such as the [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children \(CXC 66-2008\)](#)

[the [Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods \(CXC 40-1993\)](#) and the [Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods \(CXC 23-1979\)](#)]

The products should comply with any microbiological criteria established in accordance with the [Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods \(CXG 21-1997\)](#).

ISDI Comment

ISDI would recommend that reference to [General Principles of Food Hygiene \(CXC 1- 1969\)](#), and other relevant Codex texts such as the [Code of Hygienic Practice for Powdered Formulae for Infants and Young Children \(CXC 66-2008\)](#) is made. ISDI believes that the reference to the [Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods \(CXC 40-1993\)](#) and the [Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods \(CXC 23-1979\)](#) do not bring any additional value to the text.

In case the Committee prefers to reference the two additional texts, the section should read as follows:

It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the General Principles of Food Hygiene (CXC 1-1969), and other relevant Codex texts such as the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CXC 66-2008) **and in the case of liquid formula that has been commercially sterilised the appropriate sections of [the Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40-1993) and the Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23-1979)]**. The products should comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997).

Recommendation 13

a) Follow-up formula for older infants:

That CCNFSDU agree to the following text for 'Packaging' for follow-up formula for older infants;

Packaging

The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as a packing media.

The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

b) [Name of product] for young children:

That CCNFSDU agree to the following text for 'Packaging' for [name of product] for young children;

Packaging

The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as a packing media.

The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

ISDI Comment

ISDI prefers that the packaging gases are only listed in the additives section to avoid repetition but can accept them being listed here as well as is the case in the Infant Formula Standard.

Recommendation 14

a) Follow-up formula for older infants:

That CCNFSDU agree to the following text for 'Fill of containers' for follow-up formula for older infants;

Fill of containers

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5 ½ - 9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

b) [Name of product] for young children:

That CCNFSDU agree to the following text for 'Fill of containers' for [name of product] for young children;

Fill of containers

In the case of products in ready-to-eat form, the fill of container shall be:

- (iv) not less than 80% v/v for products weighing less than 150 g (5 ½ oz.);
- (v) not less than 85% v/v for products in the weight range 150-250 g (5 ½ - 9 oz.); and
- (vi) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

ISDI Comment

ISDI supports recommendation 14.

Recommendation 15

a) Follow-up formula for older infants:

That CCNFSDU agree to the following text for Methods of analysis and sampling for follow-up formula for older infants;

Methods of analysis and sampling

For checking the compliance with this Standard, the methods of analysis contained in the [Recommended Methods of Analysis and Sampling \(CXS 234-1999\)](#) relevant to the provisions in this standard, shall be used.

b) [Name of product] for young children:

That CCNFSDU agree to the following text for Methods of analysis and sampling for [name of product] for young children;

Methods of analysis and sampling

For checking the compliance with this Standard, the methods of analysis contained in the [Recommended Methods of Analysis and Sampling \(CXS 234-1999\)](#) relevant to the provisions in this standard, shall be used.

ISDI Comment

ISDI supports recommendation 15.

ISDI Comment on Appendix II

ISDI would like to take the opportunity to comment on the [Appendix II of the Agenda Paper \(CX/NFSDU 19/41/5\)](#).

- 1) In regard to 322 Lecithin, ISDI would like to note that the correct INS number is 322(i).

INS 322 encompasses both INS 322(i) and 322(ii). However, only INS 322(i) has a JECFA monograph and safety evaluation. Additionally, the GSFA specifies that INS 322(i) Lecithin is permitted in FC 13.1.2. Therefore, this entry in the commodity standard should be for INS 322(i) Lecithin as shown below:

322(i)	Lecithin	0.5 g
--------	----------	-------

- 2) Concerning, 301 Sodium ascorbate, ISDI would like to note that Sodium ascorbate is a source of sodium. For older infants, it should have the accompanying sodium note as in the current standard. Practically, this should be shown as follows in the table:

301	Sodium ascorbate	Within the limits for sodium in Section 3.1*
-----	------------------	--

*Applicable to Follow-up Formula for Older Infants only.