

# 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](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 4a

NFSDU/42 CRD4

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

Forty-second Session

Virtual

19 - 25 November and 1 December 2021

### PROPOSED DRAFT REVISED STANDARD FOR FOLLOW UP FORMULA FOR OLDER INFANTS AND DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN: REMAINING SECTIONS (AT STEP 4)

*Comments by the European Union, Kenya and Rwanda*

#### EUROPEAN UNION

##### *European Union Competence*

##### *European Union Vote*

This document provides specific comments on each recommendation made by the eWG Chairs in document CX/NFSDU 19/41/5.

#### **Recommendation 3 (Purity requirements)**

The EU agrees with the proposal to retain the provisions relating to purity requirements of the current Follow-up Formula Standard for both follow-up formula for older infants and for [name of product] for young children.

#### **Recommendation 4 (Vitamin Compounds and Mineral Salts)**

The EU in general agrees with the proposed approach to retain provisions 3.4.2.1 and 3.4.2.2 of the current Follow-up Formula Standard for follow-up formula for older infants.

However, when it comes to the exact wording, the EU kindly notes that Sections 3.3.1 and 3.3.2 would need to be renumbered in the provision in accordance with the final structure of the revised Standard and that the provision could reference the title of CXG 10-1979 (i.e. *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children*) as is the case in the Standard for Canned Baby Foods and in the Standard for Processed Cereal based Foods for Infants and Young children.

In terms of [name of product] for young children, in addition to the comments made above, the EU supports the proposal to retain only provision 3.4.2.1 of the current Follow-up Formula Standard considering that a maximum level for sodium has not been set for such products and therefore provision 3.4.2.2 is not relevant.

#### **Recommendation 5 (Consistency and Particle Size)**

The EU in general agrees with the recommendation to retain provision 3.5 in the current Follow-up Formula Standard relating to consistency and particle size for both follow-up formula for older infants and for [name of product] for young children.

However, in order to be in line with the wording used in the more recently revised Infant Formula Standard the EU would suggest a small change to the proposed texts as follows:

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles and suitable for adequate feeding of older infants.

When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles and suitable for adequate feeding of young children.

#### **Recommendation 6 (Specific prohibitions)**

The EU agrees with the Chairs` recommendation.

### **Recommendation 7 (Food additives – permissions for food additives)**

The EU agrees with the recommendation to retain the current permissions for food additives (excluding flavourings) in the current Follow-up Formula Standard for both follow-up formula for older infants and [name of product] for young children.

### **Recommendation 8 (Food additives-administrative changes)**

The EU supports Recommendation 8a, i.e. the administrative changes i – iii, and the alignment of the names of food additives in the current Follow-up Formula Standard with those in the GSFA.

As regards Recommendation 8b, the EU notes that “Packaging gases” is a functional class recognized both at the EU and Codex level. Therefore, and also in line with the IF Standard, the functional class “Packaging gases”, together with the provisions for INS 290 carbon dioxide and INS 941 nitrogen, should be included in the Food Additive section as per the approach taken in the Infant Formula Standard.. The EU is of the view that “Packaging gases” shall not be retained in Section 7 (Packaging).

### **Recommendation 9 (Carry-over of food additives)**

In line with the endorsed principle that foods intended for infants and/or young children shall be prepared without food additives whenever possible, the EU supports option 2, i.e. the adoption of the text from the Infant Formula Standard and Standard for Processed Cereal- based Foods for Infants and Young Children for both follow-up formula for older infants and [name of product] for young children. This would reflect Section 4.3 of the GSFA wherein follow-up formulae is listed among the foods for which the carry-over of food additives is not acceptable.

Option 1 is not preferred as the reference to the whole Section 4 of the Preamble to the GSFA includes Section 4.1 and Section 4.3 that are mutually exclusive. A reference to Section 4.3 could be considered after the alignment has been finalized (as it refers to additive provisions listed in Tables 1 and 2 of the GSFA).

### **Recommendation 10 (Flavourings)**

The EU welcomes the Chair’s recommendation to include the JECFA numbers in addition to the name of the flavouring substance in the standard. This inclusion should help in better identifying and characterising the flavouring substances in the standard. The JECFA numbers for flavouring substances are essentially equivalent to the INS numbers for food additives and indicate that there are JECFA evaluations and specifications for them. The EU can also accept the inclusion of a reference to the Guidelines for the Use of Flavourings (CXG 66-2008) in accordance with the Codex Procedural Manual.

However, the EU notes that infants and young children is a particularly vulnerable population group with regard to taste, as during the early life period taste preferences are formed, that can determine dietary preferences throughout life. Such taste preferences can lead to preferences for certain foods that are not in line with dietary recommendations, which in turn increases the risk for (early) development of (childhood) overweight and obesity and related non-communicable diseases. Globally, the EU is among the regions with the highest rates of childhood obesity. Taste preferences can be set by recurring exposure to certain foods and flavours. The EU is therefore concerned that allowing flavourings to be added to follow-up formula for older infants and to [name of the product] for young children could negatively influence the normal development of taste preferences that are established when infants and young children are provided with an appropriate, recommended diet. Follow-up formula for older infants and [name of the product] for young children are products that are typically consumed very frequently, normally on a daily bases. Given this very frequent exposure, it is very likely that those food categories strongly influence the development of taste preferences later in life. The EU currently does not have specific provisions for flavourings intended for infants and young children. Taking into account the rational above, the EU could support the Chair’s proposal provided a footnote that would allow national and regional authorities to restrict or prohibit the use of the flavourings listed under sections 4.5 is added to those provisions.

The proposed texts read as follows:

#### **a) Follow-up formula for older infants:**

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

#### **4.5 Flavourings [ <sup>1)</sup>]**

Natural Fruit Extracts: GMP

Vanilla extract: GMP

Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml

Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml

**[The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)]**

**[<sup>1)</sup> National and/or regional authorities may restrict or prohibit the use of the listed flavourings]**

**b) [name of product] for young children**

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

**4.5 Flavourings [ <sup>1)</sup>]**

Natural Fruit Extracts: GMP

Vanilla extract: GMP

Ethyl vanillin [(JECFA no. 893)]: 5 mg/100 ml

Vanillin [(JECFA no. 889)]: 5 mg/ 100 ml

**[The flavourings used in products covered by this standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008)]**

**[<sup>1)</sup> National and/or regional authorities may restrict or prohibit the use of the listed flavourings]**

**Recommendation 11 (Contaminants)**

The EU agrees with the Chairs` recommendation to adopt the “Contaminant” provision of the more recently revised Infant Formula Standard for both follow-up formula for older infants and [name of product] for young children.

**Recommendation 12 (Hygiene)**

The EU agrees with the Chairs` recommendation to adopt the “Hygiene” provisions within the Infant Formula Standard for both follow-up formula for older infants and [name of product] for young children.

As regards the proposal to reference two additional Codex documents (Codex Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods (CXC 40-1993) and the Codex Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods (CXC 23-1979)), the EU notes that follow-up formulae are mainly marketed in powder form on the EU market, but there are products available in ready-to-drink form too. Such products can be considered as canned ready-to-feed follow-up formula based on the CODEX definition of canned foods i.e. “commercially sterile food in hermetically sealed containers”. Therefore, in case the Committee prefers to reference the two additional texts, the EU can accept it.

**Recommendation 13 (Packaging)**

The EU agrees with the recommendation to adopt the packaging provisions in the current Follow-up Formula Standard for both follow-up formula for older infants and [name of product] for young children.

As noted under Recommendation 8b the EU considers that “Packaging gases” should be included in the Food Additive section and listed under the appropriate functional class. Thus, the EU does not support retaining Packaging gases in Section 7 (Packaging).

However, if, in addition to their inclusion in the Food Additive section, there is a strong preference to retain Packaging gases (i.e. nitrogen and carbon dioxide) in Section 7, the EU could accept it, provided a reference to the Food Additives section is made in the last sentence of Section 7.1 as follows:

“...; nitrogen and carbon dioxide may be used as a packing media, i.e. as food additives (packaging gases), in line with Section 4 of this standard.”

**Recommendation 14 (Fill of containers)**

The EU agrees with the recommendation to adopt the “fill of containers” provisions in the current Follow-up Formula Standard for both follow-up formula for older infants and [name of product] for young children. The also agrees with the revised level of 5 oz.

**Recommendation 15 (Method of analysis and sampling)**

The EU agrees with the recommendation to adopt the “Method of analysis and sampling” provisions in the current Follow-up Formula Standard for both follow-up formula for older infants and [name of product] for young children.

## KENYA

| <b>Recommendations</b>   | <b>Comment</b>  | <b>Rationale (where necessary)</b>   |
|--------------------------|---|--|
| <b>Recommendation 1</b>  | Kenya supports the adoption of the text in square brackets  | The use of glucose polymers will ensure that the products are not sweetened beyond what would ordinarily be when lactose is the main sugars  |
| <b>Recommendation 2</b>  | Kenya support the adoption of the text  | This will avoid use of free sugars in these products which have the potential of influencing the taste of the young children   |
| <b>Recommendation 3</b>  | Kenya Supports adoption of the recommendation   |  |
| <b>Recommendation 4</b>  | Kenya Supports adoption of the recommendation including reference to sodium in both products for older infants and young children | The sodium expression in these products is based on total sodium (including those from ingredients) and not just the added sodium. This note will guide the users of the standard while testing for sodium content in the products.                          |
| <b>Recommendation 5</b>  | Kenya Supports adoption of the recommendation   |  |
| <b>Recommendation 6</b>  | Kenya Supports adoption of the recommendation   |  |
| <b>Recommendation 7</b>  | Kenya Supports adoption of the recommendation   |  |
| <b>Recommendation 8</b>  | Kenya Supports adoption of the recommendation   |  |
| <b>Recommendation 9</b>  | Kenya Supports option 1 in both products  | It would be appropriate to make reference to the section of 4 of preamble and not borrowing the text from the preamble. This will ensure appropriate alignment of the standard to GSFA including when (or if) minor amendments may be introduced in the GSFA |
| <b>Recommendation 10</b> | Kenya Supports adoption of the recommendation   | Reference to the guidelines to the use of flavourings is an important aspect and aligned to the procedural requirement   |
| <b>Recommendation 11</b> | Kenya Supports adoption of the recommendation   | This is consistent to requirement of the procedural manual   |
| <b>Recommendation 12</b> | Kenya Supports adoption of the recommendation   | Additional referencing will guide manufacturers who may wish to produce products of low acids either canned or otherwise   |
| <b>Recommendation 13</b> | Kenya Supports adoption of the recommendation   | We appreciate the two gases (nitrogen and carbon dioxides) are allowed for use as packaging gas under GMP within CXS 192-1995.   |
| <b>Recommendation 14</b> | Kenya Supports adoption of the recommendation   |  |
| <b>Recommendation 15</b> | Kenya Supports adoption of the recommendation   | This is consistent to requirement of the procedural manual   |

## RWANDA

| Section  | Comments   | Rationale   |
|--|--|---|
| <b>Recommendation 1</b>                          | Rwanda supports text proposed by the Chair   | Rwanda agrees that compositional requirements in a standard should be science based and enforceable. Rwanda notes that dextrose equivalent (DE) is difficult to enforce. In addition, exclusion of Sucrose and fructose will control energy intake and limit sweetness addiction for young children   |
| <b>Recommendation 2</b>                          | Rwanda supports retaining the sentence in square bracket   | It is necessary to retain the text in square brackets to facilitate enforcement of this section   |
| <b>Recommendation 3a)<br/>Recommendation 3b)</b> | Rwanda <b>accepts the removal of the brackets [older] to retain the term “older”</b> in recommendation 3a) and <b>retain the term “young children”</b> in recommendation 3b) to differentiate the age range appropriately  | Rwanda agrees with the Purity Requirements as they are identical to the those in the Infant Formula Standard, with the clarification of the age range   |
| <b>Recommendation 4</b>                          | Rwanda supports recommendation (4a).<br><br>Rwanda also supports recommendation 4b) to remove the statement on limits of sodium derived from vitamin and mineral ingredients as CCNFSDU did not establish a maximum for sodium for young children  | Rwanda supports recommendation 4  |
| <b>Recommendation 5</b>                          | Rwanda supports the views of EWG on recommendation 5a) to read “When prepared according to the directions of use, the product shall be free of lumps and of large, coarse particles <b>and suitable for adequate feeding of [older infants]</b> ” in order to be specific on suitability for only older infant as they are prone to the effect of larger particle.<br><br>Rwanda agrees with the chair 's proposal on recommendation 5b) | Rwanda thanks the EWG and supports the recommendation 5   |
| <b>Recommendation 6</b>                          | Rwanda supports the proposed text on Recommendation 6  | Rwanda agrees with recommendation 6   |
| <b>Recommendation 7</b>                          | Rwanda agrees with the chair's proposal for recommendation 7a ) and b) .   | Changes will only be adopted when the alignment work of GSFA is completed   |
| <b>Recommendation 8</b>                          | Rwanda agrees with the chair's proposal for recommendation 8a ) and b) .   | Changes will only be adopted when the alignment work is completed   |
| <b>Recommendation 9</b>                          | Rwanda supports the option 1 for both recommendation <b>9a) and b)</b>   | This is because there was an incorrect reference to Section 4.1 of the GSFA in the current Follow-up Formula Standard and referencing the entire Section 4 of the Preamble of the GSFA to ensure the complementarity of both section 4.1 and 4.3. This option also follows the referencing principle of the existing Codex texts rather than repeat requirements in commodity standards |

|                          |   |   |
|--------------------------|---|---|
| <b>Recommendation 10</b> | Rwanda agrees with the text proposed in recommendation (10a) and (10b)  | Rwanda agrees with recommendation (10a) and (10b), without further comments   |
| <b>Recommendation 11</b> | Rwanda supports the proposed text for both Recommendation 11a) and 11b)   | Rwanda agrees with recommendation 11a) and 11b) with no additional comments   |
| <b>Recommendation 12</b> | Rwanda agrees with Recommendations 12 a) and 12 b) and supports retaining the text in square brackets to cater for all forms of follow up formula for older infant and [Name of product] for young children             | Rwanda supports recommendation 12 without additional comments   |
| <b>Recommendation 13</b> | Rwanda agrees with Recommendations 13 a) and 13 b) to keep the packaging gases in the section under packaging rather than their inclusion in Section 4 Food Additives as this would be misleading to the standard users | Rwanda supports the recommendation 13 a) and 13b)   |
| <b>Recommendation 14</b> | Rwanda agrees with Recommendations 14 a) and 14 b) regarding the fill of containers for the proposed Standard for Follow-up Formula for Older Infants and [Name of Product] for young children.                         | Rwanda agrees with the recommendation 14 with no additional comments  |
| <b>Recommendation 15</b> | Rwanda agrees with the proposal in recommendation 15a) and 15b)   | Rwanda supports recommendation 15a) and 15b) as the method CXS 234-1999 covers for Foods for Special Dietary Uses hence applicable in these products (Follow-up formula for older infants and [Name of product] for young children) |