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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
(41st Session)

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Düsseldorf, Germany

European Union Comments on

Agenda item 4 d)

Review of the Standard for Follow-Up Formula (CODEX STAN 156-1987) at Step 3

(CX/NFSDU 19/41/5)

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 1 (Dextrose equivalent)

The EU supports the inclusion of a maximum limit of the DE for glucose polymers for products not based on milk protein with an additional clarifying 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 ***that consist of D-glucose units linked primarily by α-1-4 bonds and that have a dextrose equivalent (D.E.) of less than 15*** *should be the preferred carbohydrates used.] [~~For products not based on milk protein, carbohydrate sources (like starch) with an average DE of 15 should be used. OR For products not based on milk protein, a combination of carbohydrate sources giving an average dextrose equivalent not higher than DE15 (corresponding to the relative sweetness of lactose), should be preferred.] (for consideration by the EWG on follow-up formula)~~*
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.

The EU notes that [name of product] for young children is not necessary to satisfy the nutritional requirements of young children when compared with other foods that may be included in their normal diet. Therefore, it is important to ensure that the sweet taste of [name of product] for young children not based on milk protein is limited to avoid the development of taste preferences that are unfavourable and that could lead to the development of overweight and obesity later in life and associated increased risk for developing non-communicable diseases.
Relative 'sweetness' is a characteristic of a food as well as a characteristic of an ingredient that can be objectively measured. The sweetness level of [name of product] for young children is influenced by the sweetness level of its ingredients and their concentration. As ingredients play a role in influencing the final sweetness level of a product, the EU considers that the sweetness level of ingredients should be limited. In general, the relative sweetness of glucose syrups or maltodextrins as ingredients increases with increasing DE.
The EU is of the view that introducing a maximum limit of the DE for glucose polymers that are used as source of available carbohydrates in products not based on milk protein can contribute to ensure that products not based on milk protein are not sweeter than products based on milk protein, for which lactose is the preferred carbohydrate. The table below (H. Douglas Goff, Richard W Hartel, Ice Cream, 7th Edition, 2013 Edition, Springer, ISBN-13: 978-1461460954) illustrates this approximation.

Ingredient	Average molecular weight	Relative sweetness[a]	Total solids (%)	Relative freezing point depression[b]	Maximum total sugar supplied[c] (%)
Dextrose	180	74	92	1.90	40
Fructose	180	173	100	1.90	40
Sucrose	342	100	100	1.00	100
Lactose	342	16	100	1.00	d
Maltose	342	32	100	1.00	40
Honey	~270	75	74	1.46	45
Invert sugar	~270	95	77	1.12	30
High fructose corn syrup					
90%	180	125	77	1.88	50
55%	185	98	77	1.85	50
42%	190	86	71	1.80	50
High maltose corn syrup					
55 DE	411	55	81	0.83	40
Corn syrups					
64 DE	298	68	82	1.15	25–50
42 DE	428	48	80	0.80	25–50
36 DE	472	42	80	0.72	25–50
32 DE	565	40	80	0.61	25–50
20 DE	900	23	80	0.38	e
Maltodextrins					
15 DE	1,200	17	95	0.29	e
10 DE	1,800	11	95	0.19	e
5 DE	3,600	6	95	0.10	e

[a]Sweetness relative to sucrose on an as is or product basis
[b]Factor to estimate freezing point depression relative to solids equal in weight to sucrose
[c]Percent of sugar on a sweetness basis generally acceptable from a quality viewpoint
[d]Lactose provides low sweetness, but amount is limited by tendency to crystallize
[e]Lower DE corn starch products build body and provide bulk rather than sweetness

The DE can be assessed on an ingredient check base and therefore enforced. The EU has included in its regional legislation a limit on DE for glucose syrups used in the manufacturing of infant and follow-on formula. Assessment of compliance can be achieved by assessing compliance of the ingredients used for manufacture.

Recommendation 2 (3.2.1.-Optional ingredients)

The EU supports the retention of the sentence 'substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]' under 3.2.1 Optional ingredients. However, the EU suggests adding the word "ingredients" as the latter term is broader covering all ingredients with sweetening properties whilst the term "substance" is usually associated with chemically defined substances as additives (i.e. sweeteners and flavour enhancers). Thus the sentence would read '*ingredients or substances shall not be added with the purpose of imparting or enhancing a sweet taste of [name of product]'*.

The EU notes that due to sugar reduction policies, there is currently considerable momentum to develop non-sugar ingredients that impart or enhance sweet taste that may not necessarily and in all cases be classified as additives. It is expected that the number of such ingredients will increase in the future. While such substances may be used to reduce sugar intakes in

adults, for the age group of infants and young children, their use may negatively influence the development of healthy taste preferences and should therefore be addressed in the standard.

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 *[[1)]]*
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)]

[[1)] 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 *[[1)]]*
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)]

[[1)] 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.