CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 4.1, 6.1, 8, 9 **CRD28**

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

Forty-fourth Session

Dresden, Germany

(Comments by European Union)

AGENDA ITEM 4.1 GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVS-R FOR PERSONS AGED 6 –36 MONTHS (AT STEP 7)

European Union Competence
European Union Vote

The European Union (EU) would like to thank Ireland, USA and Costa Rica for their work on document CX/NFSDU 24/44/4, Part A.

The EU supports recommendation i.. The EU supports the definition of Adequate Intake derived from the FAO/WHO expert group updating the nutrient intake values for infants and young children for calcium, vitamin D, and zinc to be included in the revised General Principles, as described in Appendix I.

The EU does not support recommendation ii.. The EU prefers option 1, as for example, in the EU such a combined NRV-R value likely would be used for labelling of Processed Cereal Based Foods and Baby Foods. The majority of consumption of such products lies at the beginning of the age range and not at the end. Therefore, a value derived from option 1 would be more appropriate for this situation. Furthermore, in jurisdictions where labelling is provided per fixed quantities, e.g. per 100 g or ml, and not per portion, even if a lower quantity of a nutrient is contained per 100 g, after selecting either option 1 or 2, young children would consume higher amounts of this food, bigger portion sizes, due to higher energy requirements, and would therefore consume in absolute amounts also higher amounts of the nutrients as compared to older infants.

The EU does not support recommendation iii.. The EU considers that no clarification is needed on how these combined NRVs-R for persons aged 6–36 months should be used as the preamble of the *Draft general principles for establishing nutrient reference values for persons aged 6 to 36 months* already provide the needed explanations (emphasis added):

> *[…]* ***These values may be used in the labelling of pre-packaged foods for special dietary uses (FSDU) intended for persons aged 6–36 months*** *to help consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products.* ***Governments are encouraged to use the NRVs-R****, or alternatively, consider the suitability of the general principles below including the level of evidence required, and additional factors specific to a country or region in establishing their own NRVs-R. […].”*

The EU considers that this text clarifies that governments can choose the appropriate NRV value for their national situation and legislative context, to “*help consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products.*” As the case may be, this could be the value for 6-12 months, for 12-36 months, or for 6-36 months. The EU supports, as highlighted in the contributions to previous EWG consultations, that text is added to CXG 2-1985 that clarifies that the use of NRVs-R for persons aged 6–36 (6-12 months, 12-36 months, 6-36 months) is limited to labelling of foods covered by

- the Standard for Processed Cereal-Based Foods for Infants and Young Children CXS 74-1981,
- the Standard for Canned Baby Foods CXS 73-1981*,
- the Guidelines on Formulated Complementary Foods for Older Infants and Young Children CAC/GL 8-1991,
- the Standard for Follow-up Formula CXS 156-1987.

AGENDA ITEM 6.1 GUIDELINE FOR THE PRELIMINARY ASSESSMENT TO IDENTIFY AND PRIORITIZE NEW WORK FOR CCNFSDU

Mixed Competence
Member States Vote

The European Union and its Member States (EUMS) would like to thank Germany and Canada for preparing the Draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU.

General comments

The EUMS note that some committees have developed or are in the process of developing their own approach and tailored criteria for managing work priorities.

While the EUMS greatly appreciate the efforts of all committees engaging in work management enhancement processes, the EUMS would like to recall its view, that a more detailed overview of all existing procedures in committees and a centralised access to all existing prioritisation criteria and methodologies would be beneficial for Members wishing to propose new work that addresses their needs in Codex.

For that purpose, all prioritisation mechanisms and other work practices that have been developed on this issue should be collated in one single place. Such place could be the practical guidance for new work proposals that the Codex secretariat has been tasked to draft.[1]

Specific comments

Concerning the introduction of the numerical rating system, while the EUMS have a neutral stance on it, would like to stress that it must ensure an appropriate overall assessment. The meaning of the "neutral" rating is not entirely clear and it seems complicating the proposed rating system.

The EWG consultation document aimed to improve alignment with the prioritization mechanisms of other committees (i.e. CCFL and CCFH). The EUMS note that the CCFL draft prioritization mechanism includes only a qualitative assessment (CL 2024/29-FL) and that it seems also an appropriate approach.

As regards the prioritization criterion "Impact on trade practices", the EUMS would like to suggest the inclusion of the word "regional" in its explanatory description: "Describe how the proposed new work would impact global **or regional** food trade and how this work might harmonize international standards and reduce barriers to fair trade."

Paragraphs 4, 8 and 13a. refer to the assessment submitted by the Member(s), the EUMS suggest considering the re-introduction of the term "**self**

-assessment".

The EUMS welcome that the traffic light system has been removed from the Decision Tree. The EUMS suggest for Step 5 the inclusion an option "no" with the following description "**Propose the Committee to reject or return the proposal to submit additional information (e.g. clarify scope or reconsider the assessment)."**

AGENDA ITEM 8 DISCUSSION PAPER ON USE OF FRUCTANS, BETA-CAROTENE, LYCOPENE IN STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CXS 72-1981)

European Union Competence
European Union Vote

The European Union (EU) thank the United States as chair of the Electronic Working Group (EWG) for the work carried out on this subject and the presentation of the discussion paper.

beta-carotene

The EU does not support recommendation i., the EU does not support that CCNFSDU44 informs CCMAS that beta-carotene is a suitable optional ingredient as defined in CXS 72-1981 and listed in the *Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979), and request CCMAS to endorse AOAC 2016.13 / ISO DIS 23443 (beta carotene and lycopene) for use with beta-carotene in the CXS 72-1981 as a Type II method.

[1] REP22/EXEC2, paragraph 118 (iii)

The EU considers that the Terms of Reference (ToR) of the EWG on item 8 of the agenda for CCNFSDU44 are not met regarding the use of beta-carotene as optional ingredient in CX 72-1981. According to the ToR, the EWG was requested to

> *"Review the use of [...] beta-carotene [...]",*

and to (emphasis added)

> *"Develop recommendations to CCNFSDU44 regarding the **safety** and **suitability** of these ingredients **as optional ingredients** in CXS 72-1981 [...]".*

In CX/NFSDU 24/44/8, the chair of the EWG concluded that beta-carotene is a suitable optional ingredient as defined in CXS 72-1981, that it is listed in the Advisory Lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) (Advisory Lists (CXG 10-1979)), and that CCMAS should therefore be requested to endorse AOAC 2016.13 / ISO DIS 23443 (beta-carotene and lycopene) for use of beta-carotene in the CXS 72-1981 as a Type II method.

The justification provided for this conclusion was the support by 11 (of 13) EWG members who stated that beta-carotene is a safe and suitable ingredient and that it is listed in the Advisory Lists (CXG 10-1979). However, neither CX/NFSDU 24/44/8 nor the EWG Consultation Paper prepared by the USA as EWG Chair as of October 27, 2023, provide any information regarding the safety, suitability and/or benefits of using beta-carotene in infant formula or in formula for special medical purposes (FSMP) for infants. To the EU's understanding, it would have been within the ToR of the EWG to review scientific data on the safety and suitability of beta-carotene for infants. Moreover, as beta-carotene is listed in the Advisory Lists (CXG 10-1979) only as provitamin A, the EWG should have presented data showing that beta-carotene can be efficiently converted into vitamin A in infants and is therefore a safe source of vitamin A.

In the above-mentioned Consultation Paper, it is indicated that beta-carotene (together with lycopene) are the most abundant carotenoids in human milk and that breastfed infants are therefore exposed to beta-carotene, whereas infants who consume infant formula have little or no intake of beta-carotene. However, the presence of a substance in human milk does not provide sufficient cause for this substance to be used in infant formula. Thus, it seems that the fact that beta-carotene is listed in the Advisory Lists (CXG 10-1979) has been taken by the EWG as the only reference for the appropriateness of beta-carotene as an optional ingredient in infant formula.

The EU notes that the current listing of beta-carotene as provitamin A in the Advisory Lists (CXG 10-1979) might be a mistake. The EU considers that it is questionable whether the criteria for including nutrient compounds in the lists (Section 2.1 in CXG 10-1979) have ever been critically reviewed in the case of beta-carotene.

With respect to the criterion 2.1 a) that nutrient compounds must be safe and appropriate for the intended use, the EU is of the opinion that there is a lack of knowledge on the rate of conversion of beta-carotene to vitamin A in infants.

The EU notes that carotenoids have so far not been considered as sources of vitamin A in infants, neither in Codex, as reflected in the footnotes to the provisions for vitamin A in the Infant formula and Follow-up formula Standards (CXS 72-1981 and CXS 156-1987):

> *"[…] Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.".*

nor at EU level (EFSA, 2014[2]).

[2] Emphasis added, page 56: "Retinol sources authorised for use in IF and FOF are retinol and two forms of retinyl esters, i.e. retinyl palmitate and retinyl acetate. **Carotenoids are not considered as a source of vitamin A in infants owing to a lack of knowledge on the bioconversion of carotenoids in infants**." and page 56/58: "Recommendations Assuming an average energy intake of an infant below six months of age of 500 kcal/day and taking as a basis the intake levels of vitamin A considered adequate by the Panel for this age group of 350 µg RE/day **based on pre-formed vitamin A intakes from breast milk**, this converts into a required minimum vitamin A content of formula of 70 µg RE/100 kcal. […] The vitamin A activity in IF and FOF **should be provided by retinol or retinyl esters. In view of the existing uncertainties as to the relative equivalence of β-carotene and retinol in infants, any content of carotenes should not be included in the calculation and declaration of vitamin A activity."**
EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 12: 3760, 106 pp.
https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2014.3760

Moreover, the EU considers that there is currently no scientific evidence that beta-carotene as such is needed for growth, development and health by infants in the first months of life.

According to 2.2 of the Advisory Lists (CXG 10-1979),

> *"Nutrient compounds shall be deleted from the lists if they are found to no longer meet these criteria. If a country proposes to add or delete a nutrient compound to/from a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.".*

The EU considers that there is insufficient evidence that beta-carotene is appropriate for the intended use as an optional ingredient/source of vitamin A in infant formula and considers that beta-carotene does not fulfil the criteria for being kept in the Advisory Lists (CXG 10-1979). Therefore, the EWG should clarify these aspects for CCNFSDU 45. Alternatively, we suggest that beta-carotene be removed from the Advisory lists (CXG 10-1979), at least regarding its optional use in infant formula, Sec. A and Sec. B.

In addition, generally, the only specific (nutrient) function in the body for beta-carotene is its action as a precursor of vitamin A. Other functions listed in the EWG Consultation Paper relate to lycopene but are assumed to be also valid for beta-carotene (numerous biological effects in humans, including antioxidant, anti-inflammatory and immunomodulatory properties), such effects are non-specific. The addition of beta-carotene to infant formula has not been scientifically demonstrated to lead to additional health benefits compared with formula to which beta-carotene has not been added.

Fructooligosaccharides (FOS), oligofructose (OF), and oligofructan

The EU does not support recommendation ii., the EU does not support that CCNFSDU44 informs CCMAS that

- fructooligosaccharides (FOS), oligofructose (OF), and oligofructan are nutrient compounds consistent with the provisions established in the Advisory Lists (CAC/GL 10-1979)
- FOS, OF and oligofructan are suitable optional ingredients as defined in CXS 72-1981
- requesting CCMAS to endorse AOAC 2016.14/ISO DIS 22579 | IDF 241 (Fructans) for use with CXS 72-1981 as a Type II method.

The EU considers that the ToR of the EWG are not met with regard to the use, safety and suitability of FOS, OF and oligofructan. The use, safety and suitability of specific fructans as an optional ingredient has not been sufficiently demonstrated.

The EU would like to receive clarification about the terms used, the substances under consideration (Fructooligosaccharides (FOS), oligofructose (OF), and oligofructan) and how they relate to one another. The EU notes that for the substances under consideration, FOS, OF and oligofructan, definitions vary and therefore the EU would like to receive clarification which concrete substances are included in those groups. has been provided. It is not possible to evaluate groups of substances without knowing exactly which substances are included.

The substances included in the groups need to correspond to the substances that are measured by a proposed method. Without clearly defining the substances covered, a suitable method cannot be determined. The EU would like to receive clarification about which substances, e.g. chain-length, are measured by the proposed analytical methods AOAC 2016.14/ISO DIS 22579 | IDF 241 (Fructans). The EU would like to receive clarification about how the proposed method differentiates between e.g. FOS and d fructose, e.g. derived from longer chain molecules such as inulin.

The EU notes that the method proposed seems to measure the amount of fructose in the product. However, the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) lists in relation to Carbohydrates (emphasis added):

> "Total carbohydrates[8)]

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

> [8)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinized starches gluten free by nature may be added to infant formula up to 30 percent of total carbohydrates and up to 2 g/100 ml.

> Sucrose, unless needed, and the addition of fructose as an ingredient, should be avoided in infant formula because of potential life-threatening symptoms in young infants with unrecognized hereditary fructose intolerance".

The EU would like to receive clarification how the proposed method can distinguish between fructose added as such or as a component of sucrose, which should be avoided, and fructose added as optional ingredient in the form of FOS, OF and oligofructan.

The EU notes that FOS, OF and oligofructan are heterogenous groups and include a wide variety of inulin-type fructans with variable degrees of polymerisation, this heterogenous group is not sufficiently characterised. The ToR of the EWG refer to "fructans (fructo-oligosaccharides and other relevant fructans in human milk)", however, the EWG Consultation Paper covers substances beyond the terms of reference, the EWG Consultation Paper states that "Unlike HMOs, fructans are not a component of human milk". As fructans investigated in the EWG are not a component of human milk, this group of substances is outside the ToR of the EWG.

The EU notes that the Advisory Lists (CAC/GL 10-1979) refer to nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for infants and young children. "Nutrients" have been defined in the *Codex Guidelines on Nutrition Labelling* (CXG 2-1985) as

> "any substance normally consumed as a constituent of food:
>
> (a) which provides energy; or
>
> (b) which is needed for growth, development and maintenance of life; or
>
> (c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur."

The EU does not consider that FOS, OF and oligofructan meet this above definition and that therefore, the three substances are not eligible to be added to the Advisory Lists (CAC/GL 10-1979).

Furthermore, in order to include nutrient compounds in the Advisory Lists (CAC/GL 10-1979), the criteria for such inclusion need to be met, however, the EU considers that this is not the case for FOS, OF and oligofructan. The following criteria need to be met (emphasis added):

1. Advisory Lists (CAC/GL 10-1979)

> *"Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the lists only if: a) they are* ***shown to be safe and appropriate*** *for the intended use as nutrient sources for infants and young children; […] the fulfilment of the above criteria* ***shall be demonstrated by generally accepted scientific criteria****"*

2. Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)

> *"[…] other ingredients may be added* ***in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies****. […]* ***The suitability*** *for the particular nutritional uses for infants* ***and the safety*** *of these substances* ***shall be scientifically demonstrated****."*

The EU has asked for but not received clarification about evidence of the safety of FOS, OF and oligofructan for infants.

FOS, OF and oligofructan are not found in human milk, therefore FOS, OF and oligofructan are not added to match the composition of human milk. The EU considers that it has not been demonstrated that FOS, OF and oligofructan are needed for growth, development and good health status of infants aged 0 – 6 months. The effects for FOS, OF and oligofructan claimed in the EWG Consultation Paper (to have an influence on the composition of gut microbiota and on stool consistency) alone, even if they would be demonstrated scientifically, do not provide a health benefit. However, a health benefit would need to be substantiated for infants aged 0-6 months in order to be considered as an optional ingredient.

The EU considers that there is no scientific evidence to support that adding FOS, OF and oligofructan is beneficial for infants, that the addition of FOS, OF and oligofructan lead to the formulation being suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.

Finally, the EU notes that the EWG Consultation Paper refers to benefits of human milk oligosaccharides (HMOs), which are different from FOS, OF and oligofructan. However, benefits should be scientifically

demonstrated for the specific compounds that are evaluated to whether they meet the criteria for optional ingredients or not, here FOS, OF and oligofructan.

AGENDA ITEM 9 DISCUSSION PAPER ON METHODS OF ASSESSING THE SWEETNESS OF CARBOHYDRATESOURCES IN THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) supports the recommendation of the Chair and the co-Chair of the EWG to refer the ISO 5495 method, preparation protocol and reference values, as described in the document, for assessing the sweetness of carbohydrate sources in comparison to lactose in “Product for Young Children” in line with the *Standard for follow-up formula for older infants and product for young children* (CXS 156-1987), Section B, point 3.1.3 c) footnote 4, for those products based on non-milk protein, to CCMAS for endorsement and inclusion in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999).