CODEX ALIMENTARIUS COMMISSION

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Agenda Item 4d **NFSDU/42 CRD6**

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

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ESSENTIAL COMPOSITION REQUIREMENTS FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN (HELD AT STEP 7)

Comments by Australia, AOAC/ISO/IDF and IFT

AUSTRALIA

Definition of 'drink/product for young children with added nutrients' and 'drink for young children'

Australia supports Option 1 (Recommendation1, Appendix 1) i.e. the removal of the square brackets and retaining the bolded text as follows:

> *Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children* ***which may contribute to the nutritional needs of young children***[1]
>
> [1] *In some countries these products are regulated as breast-milk substitutes.*

We consider the purpose of the definition is to provide clarity and understanding of the product(s) intended to be captured by the Standard, and also to clearly differentiate these products from other drinks or products for young children (e.g. milk). Clear categorisation of standardised products is important to ensure the correct application of standards by government regulators and industry and the quality and integrity of products for consumers.

We consider the definition should reflect the agreed principles of:

i. Contribution to the nutritional needs of young children where the nutrient is widely inadequate; and/or

ii. Contribution of adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children; and/or

iii. The nutritional quality and integrity of product to ensure nutritional safety.

Australia considers these products as having a nutritional 'supplementary' role and therefore support inclusion of the bracketed text (or something similar) to indicate the role and purpose of the product.

Nitrogen to protein conversion factor

Australia supports retaining the NCF of 6.25 for Follow-up Formula for older infants and 'Drink/Product for young children with added nutrients' and 'Drink for young children' (Recommendation 2, Appendix I).

The current specifications in Sections A and B of the draft revised Standard for Follow-up Formula are based on NCF of 6.25. Any change to the NCF would require re-opening the minimum and maximum protein levels within the draft revised Standard as well as consideration of the other macronutrient levels in order to meet the energy requirement. Other protein related requirements would also need re-consideration which will impact the timely progression of the revised standard.

Australia notes the JEMNU conclusions are based on a 'very low to moderate' certainty of evidence for the NCFs derived in the report. Given the potential implications of a change to the NCF, this should be an important part of CCNFSDU's consideration.

AOAC, ISO AND IDF

Comments of AOAC, ISO and IDF on the Measurement of Sweet Taste in Follow-Up Formula

Executive Summary

In 2019, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed to revise the Codex Standard (CXS) for follow-up formula (FUF; Section B: drink/product for young children with added nutrients/drink for young children i.e. FUF 12-36 months), specifying that "for products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose." Based on this specification and the requirement for Codex Standards to include a reference to a suitable method of analysis for checking the compliance with the standard as stated in the CODEX Procedural Manual, CCNFSDU referred the matter to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for guidance on internationally validated methods to measure sweetness of carbohydrate sources for these products.

In 2021, during its 41st session, CCMAS agreed to inform CCNFSDU that **there are no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision.** This discussion addressed both analytical and sensory methods**.**

The below comment was provided to CCMAS by AOAC, ISO and IDF in a specific Conference Room Document (CRD 05). The information is also captured below for the benefits of the CCNFSDU delegates.

Currently, there are no analytical methods to determine sweet taste of carbohydrate sources relative to lactose for regulatory compliance of FUF. There are several official methods/standards for analyzing individual carbohydrates or sugar profile in foods, but these methods determine carbohydrate composition and not sweet taste.

While sweet taste can be determined by standard sensory analysis methods, no sensory intensity reference value for sweetness of carbohydrate sources can be defined as an indicator for sweetness in FUF. This is true for two important reasons. First, it is impossible to define an accurate sweetness reference value. Second, it is impossible to selectively measure perceived sweetness of carbohydrate sources in FUF due to the taste perception of other ingredients in the FUF matrix. Also, processing effects (e.g. thermal treatment) may modulate perceived sweetness of the finished product.

Recommendations to CCNFSDU following CCMAS information

The draft Codex Standard for FUF foresees requirements related to sweetness in Point 3.1 (footnote 5) and in Point 3.2.4 (Optional Ingredients) of Section B. However, as indicated by CCMAS and our findings there are no internationally validated methods to enforce these proposed specifications. It is therefore not recommended to include any requirement related to "sweetness" or "sweet taste" in a revised Codex standard on FUF.

Therefore, we recommend that CCNFSDU remove these provisions. If they were to be maintained in part or integrality, and/or if the term sweetness is used, we also recommend for the information provided by CCMAS - **there are no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision -** to be captured in the Standard as such, to clarify that there are no methods to control compliance.

Agenda Item #2: Matters Referred to the Committee by the Codex Alimentarius Commission and Other Subsidiary Bodies

Codex Committee on Methods of Analysis and Sampling (CCMAS41)

Methods to measure sweetness in Drink/Product for young children with added nutrients / Drink for young children

Introduction

In 2019, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed to revise the Codex Standard (CXS) for follow-up formula (FUF; Section B: drink/product for young children with added nutrients/drink for young children i.e. FUF 12-36 months), specifying that "carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose" for products based on non-milk protein. The AOAC INTERNATIONAL (AOAC) delegation intervened to express doubt about the ability to analytically measure and enforce a requirement for sweet taste objectively. Indeed, the CODEX Procedural Manual includes the requirement for Codex Standards to include a reference to a suitable method of analysis for checking the compliance with the standard. CCNFSDU41 agreed and referred the matter to the Codex Committee on Methods of Analysis and Sampling (CCCMAS) for guidance.

CCNFSDU41 agreed to ask CCMAS41 whether there were internationally validated methods to measure sweetness of carbohydrate sources for these products.

To assist CCMAS in its guidance, AOAC INTERNATIONAL formed the AOAC Ad Hoc Expert Panel on Sweetness in November 2020 with participation of the International Standardization Organization (ISO/TC

34/ SC 12 – Sensory analysis) to assess the landscape of methods of analysis for determining sweet taste of carbohydrate sources in FUF 12-36 months. The International Dairy Federation was also consulted. The findings and recommendations were presented to CCMAS in CRD 05.

Findings from AOAC, IDF and ISO

Standards for Analytical Methods to Determine Carbohydrate Compositions in Foods, but Not Sweet Taste

To the best of our knowledge, there are no stand-alone analytical methods for determining the sweet taste of carbohydrates in FUF or other foods.

An abundance of analytical methods for quantitating carbohydrates in foods has been reported in the literature. Most state-of-the-art methods use well-accepted analytical instruments to selectively determine a single carbohydrate or multiple carbohydrates simultaneously (i.e. sugar profile methods that generally include two or more of the most common mono- and disaccharides – glucose, fructose, galactose, lactose, sucrose, and maltose) in ingredients and finished products. Specifically, chromatographic methods like high-performance anion-exchange chromatography with pulsed amperometric detection and high- performance liquid chromatography with tandem mass spectrometric, evaporate light-scattering, or refractive index detection continue to be developed and optimized to extend their applicability to various complex food matrices while providing good accuracy and precision, high sensitivity and resolution, and required LOD and LOQ. Alternative, highly specific, enzyme-based methods are also well established and validated for the measurement of individual sugars or groups of sugars.

Although we were unable to find any official methods of analysis for quantitating carbohydrates in FUF specifically, we identified several sugar profile methods for milk/milk product and infant formula (ISO 22184|IDF 244), foods of low/high protein or sugar matrices (AOAC 2018.16), fruit/fruit juices (AOAC 971.18), cereals (AOAC 982.14), milk chocolate (AOAC 980.13), and instant coffee (AOAC 995.13, ISO 11292). In addition to the sugar profile methods, there are official methods for quantitating individual carbohydrates, including lactose in raw/processed milk (AOAC 2006.06; ISO 22662|IDF 198:2007) and powdered infant formula (AOAC 2020.01). Lastly, there are also official methods for quantitating complex carbohydrates in relevant foods. These include fructans in foods and animal feeds (AOAC 999.03, 2018.07) and pediatric nutritional and infant formulas (AOAC 2016. 14, AOAC 2016.06, ISO 22579 | IDF 241) as well as galactooligosaccharides in foods/cereals/dairy products (AOAC 2021.01).

There are no methods of analysis or provision for carbohydrates in FUF in CXS 234-1999. However, there are several for carbohydrate ingredients and foods. These include Codex Type II methods for sucrose in fruit juices and nectars (EN 12630, IFU Method No. 67 (1996), NMKL 148 (1993)); fructose and glucose in sugars (fructose) (ISO 10504:1988); lactose in sugars (lactose) (ICUMSA GS 4/3-3 (1994)); and lactose in dried milk, dried ice-mixes and processed cheese (ISO 5765-1/2 | IDF 079-1/2:2002). Additionally, CXS 234-1999 includes Codex type III methods for glucose and fructose in fruit juice and nectars ((EN 12630, IFU Method No 67 (1996), NMKL 148 (1993)); and carbohydrates in Foods for Special Dietary Uses (Method described in CAC/VOL IX-Ed.1, Part III).

Indeed, the results of the analytical methods mentioned above do not indicate the sweet taste of individual carbohydrate sources for FUF products. Sweet taste can only be determined by standard sensory analysis methods.

Standards for Sensory Analysis Methods

Sensory evaluation in the food industry aims at understanding the perceptual impact generated by a molecule, an ingredient, or a final product. Among existing methodologies, Quantitative Descriptive Profile is a test in which sensory attributes of a product are determined, and the perceived intensity of each attribute is quantified on an intensity scale by a trained panel of human taste-testers as described in ISO standards [1-2]. This sensory methodology is general to any food-related stimuli and perception and can be applied to measure the sweetness of any carbohydrate source as well as FUF.

A well-designed sensory analysis helps ensure objective results on perceived intensity of each attribute. First, trained taste panelists are recruited according to their acuity in detecting and recognizing basic tastes and other specific sensory attributes depending on the targeted product category. Second, evaluation performed in sensory booths prevents human testers from interacting and influencing each other's judgments. Third, randomized and balanced order of product presentation allows for statistical suppression of carry-over effects (i.e. influence of one stimulus on perception of next evaluated stimuli). Finally, the number of stimuli evaluated in a single session is defined per product category to avoid sensory fatigue and saturation.

Even with a well-designed study and training to limit variability between individual panelists' responses, it is still impossible to define a reference sweetness intensity value as a quality control indicator for each carbohydrate source relative to lactose that is identical over time and across global taste panels. This is because variability exists inherently in sensory response due to physiological and psychological differences

between individuals such as differences in sweet perception threshold, hunger, and mood [3]. Additionally, the perceived sweetness of a carbohydrate source dissolved in aqueous solution at a given concentration does not indicate equivalent sweetness for the same carbohydrate at the same concentration in a finished product. Indeed, manufacturing processes (e.g. thermal processing) and other ingredients in the finished product can modulate the sweetness of carbohydrates. Examples include sourness of organic acid, bitterness of peptides, flavouring odour, and recipe texture through physicochemical, physiological and/or perceptual interactions [4-7].

In summary, existing sensory methodologies can be used to measure sweetness. However, no sensory intensity reference value for sweetness of carbohydrate sources can be defined as an indicator for sweetness of FUF because:

- Inherent psychological and physiological differences between trained taste panelists prohibit the development of an accurate sweetness reference value that can be globally harmonized across food companies and is stable over time;
- The selective measurement of perceived sweetness of carbohydrate sources as an indicator for sweetness of FUF is impossible because matrix and processing effects modulate perceived sweetness in the finished product.

Conclusions

As informed by CCMAS, there are no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision.

A range of analytical methods is available to determine carbohydrate composition. In contrast, sensory methods can determine a perceived sweetness of an ingredient or product. However, it is impossible to define a reference sweetness intensity value as a quality control indicator for a carbohydrate source relative to lactose sweetness in FUF.

Considering the need for fit for purpose testing procedures to enable verification of compliance with specifications to support international trade, it is not recommended to include any requirement related to "sweetness" or "sweet taste" in a revised Codex standard on FUF.

We recommend that CCNFSDU remove the following provisions:

1. From Point 3.1 (footnote 5) in Section B:
   1.1. "~~**For products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose**~~**"**
2. From Point 3.2.4 (Optional Ingredients): **"**~~**Ingredients shall not be added with the purpose of imparting or enhancing a sweet taste**~~**"**.

If, however, there is a need to establish additional requirements beyond those already drafted[1], considerations should be given on the availability of analytical methods for regulatory compliance verification.

If the above requirements recommended for deletion are maintained in part or integrality, and/or if the term sweetness is used, we also recommend for the information provided by CCMAS - **there are no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision -** to be captured in the Standard as such, to clarify that there are no methods to control compliance.

[1] Without the sweetness/sweet taste references in 3.1 (Footnote 5) and 3.2.4 (Optional Ingredients), the current draft revised Standard Section B on Drink/Product for young children with added nutrients or Drink for young children establishes the following requirements and principles relevant for this discussion:

- A maximum for available carbohydrates of 12.5 g /100 kcal*
  **For the product as defined in Section 2.1 with a protein level below 3.0 g/100 kcal a maximum level of available carbohydrates up to 14 g/100 kcal (3.3 g/100 kJ) may be permitted by competent national and/or regional authorities.*
- Lactose is the preferred source of carbohydrate
- Maximum limit of mono and disaccharides excluding lactose at 2.5g/100Kcal
- Sucrose and/or fructose should not be added.
- The additive categories of sweeteners and flavour enhancers are prohibited
- In addition to the compositional requirements listed under 3.1.3 Section B, other ingredients or substances may be added to the product as defined in Section 2.1 where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.
- When any of these ingredients or substances is added, the product as defined in Section 2.1 shall contain sufficient amounts to achieve the intended effect.

References

1. ISO 13299:2016. Sensory Analysis – Methodology – General guidance for establishing a sensory profile.

2. ISO 6658:2017. Sensory analysis – Methodology – General guidance.

3. Trius-Soler, Marta, et al. "Effect of physiological factors, pathologies, and acquired habits on the sweet taste threshold: A systematic review and meta-analysis." Comprehensive Reviews in Food Science and Food Safety 19.6 (2020): 3755-3773.

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5. Stevenson RJ, Prescott J, Boakes RA. “Confusing tastes and smells: How odours can influence the perception of sweet and sour tastes.” Chemical Senses 1999 Dec 1;24(6): 627-35.

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IFT

Comments of IFT on the Measurement of Sweet Taste in Follow-Up Formulas

Summary of IFT’s Position

In 2019, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed to revise the Codex Standard (CXS) for follow-up formula (FUF; Section B: drink/product for young children with added nutrients/drink for young children i.e., DFYC 12-36 months), specifying that “for products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose.” Based on this specification and the requirement for Codex Standards to include a reference to a suitable method of analysis for checking the compliance with the standard as stated in the CODEX Procedural Manual, CCNFSDU referred the matter to the Codex Committee on Methods of Analysis and Sampling (CCMAS) for guidance on internationally validated methods to measure sweetness of carbohydrate sources for these products.

In 2021, during its 41st session, CCMAS agreed to inform CCNFSDU that **there are no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision.** This discussion addressed both analytical and sensory methods**.**

IFT agrees with the findings of CCMAS41 that there currently are no validated analytical methods to determine sweet taste of carbohydrate sources relative to lactose for regulatory compliance of FUF or DFYC. Although, there are several official methods/standards for analyzing individual carbohydrates or carbohydrate profile in foods, these methods determine carbohydrate composition and not sweet taste.

Sweet taste can be detected by standard sensory analysis methods [1,2]. Sensory tools are important tools used by industry for optimization of food and beverage products for consumers, including assessment of sweet taste of products. However, there are two limitations to using standard sensory analysis methods. Taste panels are often trained using solutions of single ingredients of increasing concentrations like sucrose or table salt and trained taste panels can be highly reproducible in detecting a particular taste in a simple solution (high precision). However, development of sensory testing has been unable to set universal sensory intensity reference values for sweetness across the complex compositions of food and beverage product systems. A second, critically important limitation is that a sensory specification is not directly related to compositional specifications. Formulated beverages can differ in source materials (e.g., protein source) and methods of manufacture, including the further effects of processing methodology (e.g., thermal treatment) on the chemical and physical nature of ingredients within formulated beverages such as FUF and DFYC. Such differences can alter the perceived taste of ingredients consumed in aggregate as a final product. Comments from AOAC/ISO and IDF detail the complexities and work required for sensory evaluations of food products as well as the lack of globally harmonized methods and assessments across food companies and government regulatory agencies or methods to evaluate whether assessments remain stable over time.

Practically speaking, sensory evaluation tools can provide results on product taste (e.g., sweetness) disconnected from the direct composition and ingredient content that is specified by physical (e.g., weight or %) and chemical analysis [3-6]. For this reason, a product evaluated by a sensory panel for the property of sweetness might be judged as appropriate per the CXS standard when it contained inappropriate ingredient amounts for FUF or DFYC, or conversely, inappropriate when it contained ingredients in the amounts specified by the CSX standard. Such a situation would create a point of contentious confusion in judging whether individual products were in regulatory compliance, which is not consistent with the goal of CODEX.

A further concern is the lack of evidence-based science to support the assumption that exposure to differences in sweet intensity prompt a persistent preference for sweet tastes [6-9]. A presumption that initially prompted the suggestion for the regulation of this food property.

Recommendations to CCNFSDU by IFT in light of information from CCMAS and recent nutritional findings and conclusions of other recognized public health authorities

The draft Codex Standard for FUF foresees requirements related to sweetness in Point 3.1 (footnote 5). However, as indicated by CCMAS, there are no internationally validated methods to enforce these proposed specifications and it would therefore be unreasonable to include any requirement related to "sweetness" or "sweet taste" in a revised Codex standard on FUF or DFYC; or indeed other products.

Given this absence of validated objective methods of ensuring compliance with such requirement, **IFT recommends that CCNFSDU remove this provision from the standard.**

Considering the need for "fit for purpose" testing procedures to enable verification of compliance with specifications to support international trade, it is not recommended to include any requirement related to "sweetness" or "sweet taste" in a revised Codex standard on FUF.

We recommend that CCNFSDU removes the following provisions:

1. From Point 3.1 (footnote 5) in Section B:

    1.1. "~~**For products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred and in no case be sweeter than lactose**~~"

If, however, there is a need to establish additional requirements beyond those already drafted[2], considerations should be given on the availability of analytical methods for regulatory compliance verification.

If the above requirement recommended for deletion is maintained in part or in its entirety, and/or if the term sweetness is used, we also recommend that the conclusion provided by CCMAS - **there are no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision -** to be captured in the Standard to clarify that there are no methods to control compliance.

References

1. ISO. Sensory analysis – Methodology – General guidance. 2017; Vol. 6658.
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