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Agenda Item 10 **CRD47**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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Dresden, Germany

REPORT OF THE IN-SESSION WORKING GROUP ON METHODS OF ANALYSIS IN THE STANDARD FOR INFANT FORMULA (CXS 72-1981) AND STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

(Prepared by the In-Session Working Group chaired by the United States of America and the European Union)

Methods of Analysis in the CXS 234-1999 for Use with the Standard for Infant Formula (CXS 72-1981) and the Standard for Follow-Up Formula (CXS 156-1987)

Introduction

On October 2, 2024, CCNFSDU44 agreed to an in-session Working Group (WG), chaired by the USA and working in English, Spanish, and French. The focus of the in-session working group was to discuss several methods of analysis proposed by AOAC International, C&G, ICC, IDF, ISDI and ISO to CCNFSDU. This proposal was contained in CRD05 Rev. The objective of the working group was to review and consider the proposal and develop recommendations to CCNFSDU44 regarding the methods. The WG had the following terms of reference:

- To consider proposals for analytical methods published in CRD5 Rev for provisions in CXS 72-1981, CXS 156-1987, and CXG 23-1997 for inclusion in the Standard on Recommended Methods of Analysis and Sampling (CXS 234-1999).
- To provide recommendations to CCNFSDU44 regarding the suitability of the methods for submission to CCMAS for review.

The Committee discussed the following:

1. Updating the method for the determination of insoluble, soluble, and total dietary fibre to AOAC 2022.01/ICC Standard 191/AACC 32-61.01 in CXS 234-1999.
2. Methods of analysis for the determination of nutrients in infant formula (CXS 72-1981 Section A) and follow-up formula (CXS 156-1987 Section A)

Discussion and recommendations regarding the method for dietary fibre

Discussion

The in-session working group Chair introduced the proposal from AOAC to update AOAC 2011.25/AACC 32-50.01 with AOAC 2022.01/ICC Standard 191/AACC 32-61.01 in CXS 234-1999 as a Type I method for the measurement of insoluble, soluble, and total dietary fibre. A summary of the discussion was as follows:

- A member organization expressed concerns that the new method would increase the quantity and types of fibre measured which may include fibres not aligned with the Codex definition of dietary fibre which includes physiological effect of benefit to health.
- AOAC and ICC clarified that the method under consideration would rectify significant flaws that have been identified in the older method (AOAC 2011.25/AACC 32-50.01). AOAC explained that it has already replaced AOAC 2011.25/AACC 32-50.01 with the new method. The new method (AOAC 2022.01/ICC Standard 191/AACC 32-61.01) allows for separation of oligosaccharides from polysaccharides.
- The Chair clarified that neither the method under consideration nor the method previously updated to measure total dietary fibre (AOAC 2017.16/ICC Standard 185/AACC-23-60.01) would determine physiological benefits. They added that the new method (AOAC 2022.01/ICC Standard 191/AACC 32-61.01) identifies differences between molecular weights of compounds, allowing for separation of dietary fibre types.
- Several members acknowledged that while the method captures fibres that are not defined as dietary fibres in their national legislation, they support a recommendation to CCNFSDU44 to request that CCMAS

endorse the updated method.

- A member organization indicated that it could support referring the method to CCMAS provided a footnote was included to clarify that the method measures some substances that are not considered dietary fibre by some national authorities.

Recommendation

- The in-session working group requests that CCNFSDU request CCMAS to:

    1. Endorse AOAC 2022.01/ICC Standard 191/AACC 32-61.01 as Type I for the determination of insoluble and soluble dietary fibres of higher and lower molecular weight in food that may or may not contain resistant starches. When listed in CXS 234-1999 the method should contain a footnote as follows: Isolated, purified, and synthetic fibres captured by AOAC 2022.01/ICC Standard 191/AACC 32-61.01 that do not meet the Codex definition of dietary fibre in the Guidelines on Nutrition Labeling (CXG 2-1985) should be subtracted from the final measurement.
    2. Revoke AOAC 2011.25/AACC 32-50.01 for use with the same provision.

Discussion and recommendations regarding methods of analysis in the CXS 72-1981, Section A and CXS 156-1987, Section A

Discussion

The in-session working group Chair introduced the proposal from AOAC, ISO, IDF, and ISDI. The Chair explained that AOAC proposed extending methods for infant formula to follow-up formula in CXS 234 to assess compliance with provisions in Section A of CXS 156-1987 and be referred to CCMAS for endorsement and an appropriate method for determining crude protein in follow-up formula. In addition, AOAC, ISO, IDF, and ISDI proposed to revoke several of the older methods for vitamin A and iodine as they are no longer fit for purpose and to retype the old method for pantothenic acid to a Type III. A summary of the discussion follows:

- One member sought clarification on revoking the older methods for vitamin A and requested that the older methods be retyped instead.
- The Chair proposed that the in-session working group recommend to CCNFSDU to also request CCMAS retype the old vitamin A methods to type III and type IV as appropriate to retain them, and if they cannot be re-typed, to revoke the old methods. No objections were raised to this proposal.
- Regarding the method for folic acid in infant formula (CXS 72-1981, Section A), the Chair and Codex Secretariat explained that the proposal was to add the identical ISO 20631 to the AOAC 2011.06 method that was already listed in CXS 234-1999.

Recommendation

- The in-session working group recommends that CCNFSDU request CCMAS to:

    1. Endorse the methods listed in Table 1 of Appendix 1 as Type II/Type III methods for the determination of the following nutrients in infant formula (CXS 72-1981, Section A) and follow-up formula (CXS 156-1987, Section A) (see Appendix 1, Table 1):

        Vitamin E, vitamin D, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, folic acid, vitamin C, biotin, iron, calcium, phosphorus, magnesium, sodium, chloride, potassium, manganese, selenium, copper, zinc, total nucleotides, choline, myo-inositol, L-carnitine, total amino acids, tryptophan, total fatty acids

    2. Revoke AOAC 992.24 for iodine in follow-up formula (CXS 156-1987, Section A) (see Appendix 1, Table 1).
    3. Retype AOAC 974.29, AOAC 992.04, and AOAC 992.06 for vitamin A in follow-up formula (CXS 156-1987, Section A) to type III or type IV as appropriate; if they cannot be retyped, revoke the methods (see Appendix 1, Table 1).
    4. Retype AOAC 992.07 for pantothenic acid in follow-up formula (CXS 156-1987, Section A) (see Appendix 1, Table 1).
    5. Endorse the method for crude protein in follow-up formula (CXS 156-1987, Section A) in CRD 05 Rev as a Type I method (see Appendix 1, Table 2).

Methods of assessing the sweetness of carbohydrate sources in the standard for follow-up formula (CXS 156-1987)

Introduction

The in-session Working Group, working in English, French, German and Spanish, was held on the 2nd of October 2024 during the 44th session of the CCNFSDU. The ToR of the in-session working group is the following:

- To consider the method of assessing the sweetness of carbohydrate sources in CXS 156-1987 and to provide recommendations to CCNFSDU44 to refer the method for submission to CCMAS for review, if appropriate.

Discussion and recommendation

The in-session WG recommended the following further refinements to the recommendation of the EWG, also in light of the comments expressed at the Plenary:

- to change the entry of the "provision" to include "**sweetness** of carbohydrates";
- to reduce the double concentration (~~17.5 g~~) to the single concentration (**8.75 g**);
- to change the entry of the "provision" to include "sweetness of carbohydrates (**products** based on non-milk protein)";
- to change the entry of the "principle" to "Sensory **panel** ~~test~~".

There was overall support for the revised recommendation of the EWG, namely to submit it to CCMAS.

Members opposing highlighted:

- that the method would not allow to test for compliance;
- concern on the validity of the method to test compliance with the standard;
- that considerable resources would be needed to implement the method, particularly in some parts of the world.

Members supporting stressed that:

- the arguments related to resource capacities are raised only here, while many Codex methods are resource intensive and this argument could be us for other methods;
- as no better method was proposed so far, this method should be forwarded to CCMAS;
- the proposed ISO standard gives an example for use, which exactly captures the intended purpose for measuring compliance with footnote 4[1];
- there is a benefit to have a globally harmonised method for testing compliance of footnote 4;
- there is a need to proceed with the issue, since extensive discussions took place already.

Observers expressed divergent views such as that:

- it is important to proceed with the method to help better enforcement in order to protect children;
- it is critical that sweetness is controlled because taste preference is established at young age, and therefore enforcing footnote 4 is important;
- the feasibility of the standard as well as the need to spend additional time in CCNFSDU/CCMAS was questioned.

Recommendation

The in-session WG recommends that the Committee considers referring the following method to CCMAS for endorsement and inclusion in the *Recommended Methods of Analysis and Sampling* CXS 234-1999:

[1] footnote 4 of 3.1.c) of Section B) of *Standard for follow-up formula for older infants and product for young children* (CXS 156 -1987): „Lactose should be the preferred carbohydrate in the product as defined in Section 2.1 based on milk protein. 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"

Commodity	Provision	Method	Principle	Type
Foods for special dietary uses				
Follow-up formula, Section B: Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children	Sweetness of carbohydrates (products based on non-milk protein)	ISO 5495 The relative sweetness of a carbohydrate ingredient shall be measured by comparing a sample solution prepared with 8.75 ~~17.50~~ g carbohydrate in 100 ml water* with a reference solution of 8.75 ~~17.50~~ g lactose in 100 ml water* at 20 to 22°C. When the carbohydrate ingredient solution is rated sweeter than the lactose solution by a trained sensory panel**, the carbohydrate source does not comply with the provision.	Sensory panel ~~test~~	IV

* neutral, tasteless, still, odourless and preferably with low mineral content

** ISO 8586 – Sensory analysis – General guidelines for the selection, training and monitoring of selected assessors and expert sensory assessors; and ISO 3972 + Cor. 1 – Sensory analysis – Methodology – Method of investigating sensitivity of taste shall be used for the selection, training and qualification of sensory assessors

For the implementation of the standard ISO 5495 the following default values for α-risk, β-risk and p_d should be applied to achieve minimal statistical precision:

- α-risk: 0.05[2],
- β-risk: 0.05[3],
- p_d : 50%[4].

[2] If α-risk is 0.05, there is a 5% likelihood of inaccuracy
[3] If β-risk is 0.05, there is a 5% likelihood of inaccuracy
[4] p_d, the proportion of the population of subjects who are able to distinguish between the two samples

APPENDIX 1

Table 1

Commodity	Provision	Method	Principle	Type
Follow-up formula	Vitamin A	AOAC 2012.10 / ISO 20633	HPLC-UV	II
		~~AOAC 992.04~~	~~HPLC~~	~~II~~
		~~AOAC 992.06~~	~~HPLC~~	~~III~~
		~~AOAC 974.29~~	~~Colorimetry~~	~~IV~~
	Vitamin E	AOAC 2012.10 / ISO 20633	HPLC	II
	Vitamin D	AOAC 2016.05 / ISO 20636	LC-MS	II
	Thiamine	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Riboflavin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Niacin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Vitamin B_6	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
	Vitamin B_{12}	AOAC 2011.10 / ISO 20634	HPLC	II
		AOAC 2014.02	LC-UV	III
	Pantothenic acid	AOAC 2012.16 / ISO 20639	UHPLC-MS/MS	II
		AOAC 992.07	Microbioassay	~~II~~ III
	Folic Acid	AOAC 2011.06 / ISO 20631	LC-MS/MS	II
	Vitamin C	AOAC 2012.22 / ISO 20635	HPLC-UV	II
	Biotin	AOAC 2016.02 / ISO 23305	HPLC-UV	II
	Iron	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Calcium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Phosphorus	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Magnesium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Sodium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Chloride	AOAC 2016.03 / ISO 21422 | IDF 242	Potentiometry	II
	Potassium	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Manganese	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Iodine	AOAC 2012.15 / ISO 20647 | IDF 234	ICP-MS	II
		~~AOAC 992.24~~	~~Ion selective potentiometry~~	~~II~~
	Selenium	AOAC 2011.19 / ISO 20649 | IDF 235	ICP-MS	II
	Copper	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Zinc	AOAC 2015.06 / ISO 21424 | IDF 243	ICP-MS	II
		AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
	Total nucleotides	AOAC 2011.20 / ISO 20638	LC	II
	Choline	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
	Myo-inositol	AOAC 2011.18 / ISO 20637	LC-pulsed amperometry	II
	L-carnitine	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
	Total amino acids (excluding taurine and tryptophan) for use according to section 3.1.3 (a) notes 2) and 3) of CXS 156-1987	AOAC 2018.06 / ISO 4214 | IDF 254 /AACC 07-50.01	UHPLC-UV	II
	Tryptophan	AOAC 2017.03	HPLC	II
	Total fatty acids	AOAC 2012.13 / ISO 16958 | IDF 231	Gas chromatography	II
Infant formula	Folic acid	AOAC 2011.06/ISO 20631	LC-MS/MS	II

Table 2

Commodity	Provision	Method	Principle	Type
Follow-up formula	Crude protein	ISO 8968-1 | IDF 20-1	Titrimetry (Kjeldahl)	I