



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-third Session

Düsseldorf, Germany

7 – 10 March 2023

### REPORT OF THE IN-SESSION WORKING GROUP ON

#### METHODS OF ANALYSIS IN THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CXS 72-1981)

*Prepared by the in-session working groups co-chaired by the United States of America and the EU*

#### Introduction

The in-session Working Group, working in English, French, and Spanish, was held on the 8<sup>th</sup> March 2023 during the 43<sup>rd</sup> session of the CCFNSDU. The ToRs of the working group were as follows:

1. Analytical methods for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes intended for infants (CXS 72-1981) (CRD04),
2. Consider the request from CCMAS41 relating to the methods for fructans, beta-carotene, and lycopene in infant formulas (CX/NFSDU 23/43/2, para 18 and CRDs10, 20, 23, 25, 36), and
3. Appropriate methods for assessing sweetness of carbohydrates sources in “Drink for young children with added nutrients or Product for young children” (CRDs 11, 16, 18).

#### Discussion and recommendations on the three areas under consideration

1. Analytical methods for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes intended for infants (CXS 72-1981) (CRD04). A summary of the discussion and recommendations is presented below.

The AOAC International presented the methods and rationale for the need for Codex methods for use in infant formula. CXS 72-1981 and CXS 234-1999 references are outdated, not validated, and/or lack Codex Type I or Type II methods; newer methods have been validated.

The in-session WG discussed the proposal to refer the following methods for typing and endorsement to CCMAS: Total Amino Acids (minus Taurine and Tryptophan) (AOAC 2018.06 / ISO 4214 | IDF 254 /AACC 07-50.01) and Tryptophan (AOAC 2017.03) with the recommendation of a Type II method and Vitamin B12 (AOAC 2014.02) with the recommendation of a Type III method.

The in-session WG discussed the rationale for referring the two methods and agreed that there are provisions in CXS 72-1981 which provide the necessary justification for the two proposed methods of analysis and proposed specifying the provisions for which these methods of analysis would be used in the Committee’s referral to CCMAS. Some of the proposed text remain to be discussed at plenary.

#### Recommendation 1

The in-session WG recommends that the Committee refer the following methods to CCMAS for review and endorsement, and inclusion in CXS 234. [which shall be used for assessing compliance with provisions 3.1.3 a, footnotes 3 and 4 of Standard CXS 72-1981 and that those provisions are clearly mentioned in CXS 234 linked with the methods below:]

- Vitamin B12 AOAC 2014.02 (LC-UV) as a Type III method;
- Total Amino Acids (excluding Taurine and Tryptophan) AOAC 2018.06 / ISO 4214 | IDF 254 /AACC 07-50.01 (UHPLC-UV) as a Type II method, for use in 3.1.3 of CXS 72-1981; and
- Tryptophan AOAC 2017.03 (HPLC) as a Type II method, for use in 3.1.3 of CXS 72-1981.

2. Consider the request from CCMAS41 relating to the methods for fructans, beta-carotene, and lycopene in infant formulas (CX/NFSDU 23/43/2, para 18 and CRDs10, 20, 23, 25, 36)

The in-session WG discussed the proposal for CCMAS to endorse methods for fructans, beta-carotene, and lycopene and noted that technical issues prevented adequate review of the CRD.

The in-session WG agreed to establish an eWG to further deliberate on the rationale for CCMAS to endorse the methods of analysis for these nutrients. The in-session WG additionally considered whether determining suitability would be the task of the CCNFSDU. The Chair, with input from the Secretariat, proposed that the eWG, upon completing its review, develop a recommendation to CCNFSDU regarding these nutrients' suitability as optional ingredients.

#### **Recommendation 2**

For methods for fructans, beta-carotene, and lycopene, the in-session WG recommends that the Committee:

- Form an eWG to review fructans, beta-carotene, lycopene in the context of optional ingredients in the infant formula standard and develop a recommendation to CCNFSDU regarding the suitability of these ingredients for optional ingredients in the infant formula standard.

3. Appropriate methods for assessing sweetness of carbohydrates sources in “Drink for young children with added nutrients or Product for young children” (CRDs 11, 16, 18).

The Chair provided background on CCMAS' reply to CCNFSDU and the in-session WG's task to consider the proposed sensory methods for assessing sweetness. An analytical expert provided additional information and context regarding the use of sensory methods for validation of food standards.

The in-session WG noted the discussion about the quality and limitations of sensory methods assessing single-ingredient aqueous solutions as opposed to formulated products with complex matrices. There was further discussion around the proposed method's repeatability on a global level.

The in-session WG noted differing views and agreed to establish an eWG to further consider and review the questions raised.

#### **Recommendation 3**

The in-session WG recommends that the Committee:

- Establish an eWG to review and identify and, if appropriate, recommend methods for referral to CCMAS for endorsement and typing, in particular ISO 5495, for assessing the sweetness of carbohydrate sources in comparison to lactose in “Product for Young Children” [in line with section B footnote 6 for those products with non-milk protein, point 3.1 of the new Standard].
- The approach described in CRD 16 regarding assessment of sweetness by the EU and Switzerland should be taken as a starting point.