

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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Organization

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

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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 United States of America)

EXECUTIVE SUMMARY

An in-session physical working group (PWG) was held on the 25th of November 2019 during the CCNFSDU meeting.

The WG considered the following Terms of Reference established by the Committee:

- Whether AOAC Method 2009.01 for the determination of total dietary fiber in foods and food ingredients should be replaced by AOAC Method 2017.16 (see [CRD 6](#)),
- Whether the methods for Vitamin K in FUF currently in CXS 234-1999 (AOAC 999.15 / EN 14148) should be replaced by the methods endorsed as Type II methods for infant formula (i.e., AOAC 2015.09 / ISO 21446) (see [CX/NFSDU 19/41/2](#) paragraph 14b),
- Whether the currently used microbiological methods for nicotinamide, niacin, pantothenic acid, pyridoxine, cobalamin and vitamin D (see Appendix II of [CX/NFSDU 17/39/2 Rev 1](#)) be retained or not,
- Whether the Committee concurs with the reclassification of AOAC 2011.14 / ISO 15151 | IDF 229 as Type III method for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc (see [CX/NFSDU 19/41/2](#) paragraph 13), and consider establishing numerical method performance criteria for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc, and identify appropriate methods that meet the criteria;
- Whether the methods AOAC 2015.14/ISO DIS 21470 (certain B-vitamins), AOAC 2015.10/ISO DIS 21468 (choline and carnitine), AOAC 2016.13 / ISO 23443 (β -carotene and lycopene) and ISO DIS 23305 (biotin) may be referred to CCMAS for endorsement with the recommendation of a Type II method (see [CRD 7](#)).

Additional rationale supporting each method is provided below. Table 1 presents the summary of the recommended changes for minerals and vitamin K.

INTRODUCTION

The *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) was revised in 2007. At the 30th CCNFSDU Session in 2008, the electronic Working Group (eWG) on methods of analysis for infant formula recommended the Committee to periodically review the infant formula methods listed in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) to keep them updated (ALINORM 09/03/26). Since 2009, the Codex Committee on Methods of Analysis and Sampling (CCMAS) has endorsed the status of several methods of analysis for nutrients in CXS 72-1981 based on the best available methods in matrices at the time (ALINORM 09/32/23 paras. 45-71). These methods have been adopted by the Codex Alimentarius Commission, including various Type I, II, III and/or IV methods, and are included in CXS 234-1999.

DIETARY FIBER

The working group discussed whether AOAC Method 2009.01 for the determination of total dietary fiber in foods and food ingredients should be replaced by AOAC Method 2017.16.

An observer presented the modified AOAC Method 2017.16 which updates the current AOAC Method 2009.01 for the determination of total dietary fiber in foods and food ingredients. The observer explained that the updated method corrects for errors in measurement of carbohydrate fractions in the 2009.01 method, reduces the incubation period from 16 to 4 hours, and requires the same equipment and financial resources as with the earlier version. Final AOAC validation of this method is expected in early 2020.

Several members of the working group noted that modified AOAC Method 2017.16 was in use in their countries and reported positive experiences with the method. The EU noted that they did not want to delay the referral to CCMAS however noted that they would continue to review the method as CCMAS reviews it. They expressed concerns over measurement of dietary fibers which have undetermined health benefits and noted the need to consult with member states. The observer noted that neither the current or modified analytical method address the physiological benefit. However, continuing to use AOAC Method 2009.01 will result in misleading labeling as the method inaccurately measures carbohydrate fractions. The working group agreed to refer the modified AOAC Method 2017.16 to CCMAS for review. At that time, the current Type 1 should be replaced and the existing method not retyped.

VITAMIN K (AOAC 2015.09 / ISO 21446)

The working group discussed whether the methods for Vitamin K in FUF currently in CXS 234-1999 (AOAC 999.15 / EN 14148) should be replaced by the methods endorsed as Type II methods for infant formula (i.e., AOAC 2015.09 / ISO 21446) (see [CX/NFSDU 19/41/2](#) paragraph 14b). The working group agreed to replace the methods for Vitamin K for FUF currently in CXS 234-1999 with the Type II methods for infant formula in order to align the Vitamin K methods used for FUF and infant formula standards.

MICROBIOLOGICAL METHODS (Type III) for nicotinamide, niacin, pantothenic acid, pyridoxine, cobalamin, and vitamin D.

The working group discussed whether the currently used microbiological methods for nicotinamide, niacin, pantothenic acid, pyridoxine, cobalamin and vitamin D (see Appendix II of [CX/NFSDU 17/39/2 Rev 1](#)) should be retained or not. There was consensus by members of the working group to retain these methods as they are still in use by many of the members conducting analyses.

MINERALS AND TRACE ELEMENTS (Ca, Mg, P, K, Na, Cu, Fe, Mn, Zn) (AOAC 2015.06 / ISO 21424 | IDF 243) AND CRITERIA APPROACH

The working group discussed that AOAC 2015.06 had been endorsed as the Type II method and that CCMAS endorsed AOAC 2011.14 / ISO 15151 | IDF 229 as Type III method for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc in infant formula. The working group agreed with the endorsement of the Type III methods and recommends adoption of these updates to the infant formula standard to reflect AOAC 2015.06 as the Type II method and AOAC 2011.14/AIO 15151/IDF229 as the Type III method.

The working group discussed the request from CCMAS to consider establishing numerical method performance criteria for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc, and identify appropriate methods that meet the criteria. A member noted that the ICP AES was still used by their country. An observer noted that there is value to the criteria approach and it is best applicable for situations where there is no need for Type II dispute resolution methods. The observer noted that infant formula products are highly regulated, and have very narrow regulatory specifications. The performance criteria approach would allow greater variability in test method results, which would be problematic to this industry. The criteria approach could be considered for Codex Type III methods that are used only for quality control, but there should be caution used.

The working group agreed CCFSDU should request CCMAS to provide an overview of the elements and principles for numerical performance criteria and examples as the committee is open to exploring replacing Type III methods with performance criteria methods. Should the committee choose to move

forward at next year's meeting CCFSDU would need to prioritize which methods would be appropriate for development of these criteria.

NEW METHODS FOR SELECT B VITAMINS¹, CHOLINE AND CARNITINE², FRUCTANS³, B-CAROTENE⁴ ¹⁰, AND BIOTIN

The working group discussed the methods AOAC 2015.14/ISO DIS 21470 (B-vitamins thiamin, riboflavin, niacin, pyridoxine/pyridoxal/pyridoxamine), AOAC 2015.10/ISO DIS 21468 (choline and carnitine), AOAC 2016.14/ISO DIS 22579 / IDF 241 (Fructans AOAC 2016.13 / ISO 23443 (β-carotene) and ISO DIS 23305 (biotin) which CCMAS had also reviewed ([CRD 7](#)). The working group agreed to refer the methods to CCMAS for review, endorsement as Type II, and reclassification of the existing Type II method as a Type III method.

SUMMARY

Many Member Countries and Observer Organizations participated in the in-session WG and came to the following conclusions:

- Refer the dietary fiber AOAC method 2017.16 to CCMAS for classification as a Type I method to replace AOAC 2009.01.
- Replace the methods for Vitamin K for FUF currently in CXS 234-1999 with the Type II methods for infant formula in order to align the Vitamin K methods used for FUF and infant formula standards
- Recommend retaining the existing microbiological methods for nicotinamide, niacin, pantothenic acid, pyridoxine, cobalamin and vitamin D (see Appendix II of [CX/NFSDU 17/39/2 Rev 1](#)) for retention as Type III.
- Recommend adoption of updates to the infant formula standard to reflect AOAC 2015.06 as the Type II method and AOAC 2011.14/ISO 15151/ IDF229 as the Type III method.
- Request CCMAS to provide an overview of the elements and principles for numerical performance criteria and examples as the committee is open to exploring replacing Type III methods with performance criteria methods. Should the committee choose to move forward at next year's meeting CCFSDU would need to prioritize which methods would be appropriate for development of these criteria.
- Recommend the methods AOAC 2015.14/ISO DIS 21470 (B-vitamins thiamin, riboflavin, niacin, pyridoxine/pyridoxal/pyridoxamine), AOAC 2015.10/ISO DIS 21468 (choline and carnitine), AOAC 2016.13 / ISO 23443 (β-carotene) and ISO DIS 23305 (biotin) for review, endorsement as Type II methods and reclassification of existing Type II methods as Type III, if appropriate.

¹ Salvati L. M. et al. J AOAC Int. 2016. 99(3), 776-785

² Ellingson D.J. et al. J AOAC Int. 2016. 99(1), 204-209

³ Brunt J et al. J AOAC Int. 2017. 100(3), 753-767

⁴ Hostetler G.I. J AOAC Int. 2017. 100(3), 768-781