

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 11

NFSDU/39 CRD/14

Original language only

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

Thirty-ninth Session

Berlin, Germany
4 - 8 December 2017

OTHER BUSINESS AND FUTURE WORK

Comments of the United States of America

UNITED STATES

Methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)*

Prepared by the United States of America

INTRODUCTION

1. The *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)* was revised in 2007. At the 30th session of the CCFNSDU (2008), the electronic working group (eWG) on methods of analysis for infant formulae recommended that the Committee periodically review the methods in the infant formula list in the *Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999)* to keep them updated (ALINORM 09/03/26). In 2009, 2016 and 2017, the Codex Committee on Methods of Analysis and Sampling (CCMAS) endorsed the status of several methods of analysis of nutrients in CODEX STAN 72-1981 based on the best available methods in matrices at the time (ALINORM 09/32/23 paras. 45-71; REP16/MAS para 30-39 and 44, Appendix II; REP17/MAS paras. 19-20, Appendix II Part 2). These methods were adopted by the Codex Alimentarius Commission in 2009, 2016 and 2017, including various Type I, I, III and/or IV methods, and are included in the *Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999)*.

BACKGROUND

2. To date, some methods referenced in CODEX STAN 72-1981 and CODEX STAN 234-1999 remain outdated and/or are not validated for infant formula. Further, for some required nutrients and many optional ingredients, Codex Official Reference Methods are lacking.

3. During its 37th Session, CCMAS endorsed methods for Vitamin A, Total Nucleotides, Pantothenic Acid and Iodine as Type II and a method for Chromium, Selenium and Molybdenum as Type III (REP16/CAC paras 46-47). All of these methods were adopted by the Codex Alimentarius Commission (CAC) during its 39th Session. CCMAS also endorsed methods for Vitamin B12 and Fatty Acids as Type II but asked CCFNSDU to clarify whether the existing Type II methods for these nutrients should be retyped as Type III (REP16/MAS para 33 and 38). CCMAS also asked CCFNSDU to confirm whether the scope and forms to be measured by the methods for Vitamin E and Myo-inositol (REP16/MAS para 37 and 35) are the same as in CODEX STAN 72-1981.

4. During its 38th Session, CCFNSDU clarified the existing Type II methods for Vitamin B12 and Fatty Acids should be retyped as Type III and confirmed the scope and forms to be measured by the methods for Vitamin E and Myo-inositol are the same as in CODEX STAN 72-1981. CCFNSDU also referred a method for Vitamin C to CCMAS for technical review and typing. During its 38th Session, CCMAS reviewed the method and endorsed it as Type II. All of these methods were adopted and/or retyped by CAC during its 40th Session.

4. Methods of analysis for Biotin, Vitamin D, and Chloride in infant formula have now been validated by a collaboration of international experts (through the AOAC INTERNATIONAL-led Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN)). The AOAC INTERNATIONAL has adopted and published these methods in the Journal of AOAC INTERNATIONAL. These internationally accepted methods are in the

process of being adopted by the International Organization for Standardization (ISO) as an ISO Standard. The proposed methods are outlined in Table 1.

PROPOSAL AND RATIONALE

5. The Committee is requested to consider submitting the methods for Biotin, Vitamin D, and Chloride to CCMAS for technical review, typing, endorsement, and inclusion in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) in Part A, section "Foods for Special Dietary Uses," with the description "Infant Formula." These methods reflect the most recent scientific method of analysis for these nutrients in infant formula and have been validated in infant formula.

6. The Committee is requested to consider recommending to CCMAS that the methods for Biotin, Vitamin D, Chloride be introduced in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) and that existing methods may be replaced by the AOAC official method in Table 1 (below) and methods not validated for infant formula be removed or reclassified.

7. Table 1 presents the AOAC Official methods of analysis for Biotin, Vitamin D, and Chloride in infant formula. These methods are also being developed as ISO or ISO/IDF Standards.

TABLE 1. AOAC Official Method validated in Infant Formula

Commodity	Provision	Method	Principle	Proposed Type
Infant Formula	Biotin	EN 15607	HPLC	# III
		AOAC 2016.02	HPLC	II
	Vitamin D	AOAC 992.26	HPLC	III
		EN 12821	HPLC	# III
		AOAC 995.05	HPLC	III
		AOAC 2016.05 ISO DIS 20636	LC-MS	II
	Chloride	AOAC 986.26	Potentiometry	III
		AOAC 2016.03 ISO DIS 21422 IDF 242	Potentiometry	II