

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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Agenda Item 1/13 (CRD 7)

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

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

*Comments on CRD 7 by ISDI*

#### Executive Summary

This document outlines the positions of the International Special Dietary Foods Industries (ISDI) regarding the proposal to replace and complement methods of analysis for nutrients in infant formula, which are listed in CXS 234-1999, referenced in CXS 72-1981, and will be considered during the 41<sup>st</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in November 2019. These methods are intended to replace and complement current Type II reference methods, which may be outdated and/or were not validated on all types of infant formula.

These new methods have been developed through the Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) project, which is managed by AOAC INTERNATIONAL (AOAC), and endorsed by the International Organization for Standardization (ISO) and International Dairy Federation (IDF) as ISO or ISO/IDF Standards. It is proposed that these new methods be adopted as Codex Type II Methods to be utilized as needed for the purposes of dispute resolution internationally.

#### ISDI Positions

Below are ISDI positions regarding the proposal to replace and complement methods of analysis for the determination of nutrients in infant formula. These new methods reflect the most recent scientific methods of analysis for thiamine, riboflavin, niacin, vitamin B6, choline, carnitine, fructans, beta carotene, lycopene, and biotin in infant formula and all methods have been validated in infant formula. Table 1 illustrates how these methods should be listed in CXS 234-1999.

- ISDI supports the recommendation to refer the method for thiamine (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), and vitamin B6 (AOAC 2015.14 / ISO DIS 21470) to CCMAS for review and endorsement with the recommendation of a Type II method.
- ISDI supports the recommendation to refer the method for choline and carnitine (AOAC 2015.10 / ISO DIS 21468) to CCMAS for review and endorsement with the recommendation of a Type II method.
- ISDI supports the recommendation to refer the method for fructans (fructooligosaccharides and/or inulin) (AOAC 2016.14 / ISO DIS 22579 | IDF 241) to CCMAS for review and endorsement with the recommendation of a Type II method.
- ISDI supports the recommendation to refer the method for beta-carotene and lycopene (AOAC 2016.13 / ISO DIS 23443) to CCMAS for review and endorsement with the recommendation of a Type II method.
- ISDI supports the recommendation to refer ISO DIS 23305 to CCMAS for review and endorsement with the recommendation of a Type II method.
- ISDI supports requesting that CCMAS review the existing Type II and Type III methods listed in CXS 234-1999 to determine if the methods meet the specifications in CXS 72-1981 and, based on that review, either retain the existing methods, make any necessary changes to the Type, or revoke any methods which do not meet the specifications. ISDI's recommendations for necessary changes are noted below in Table 1.

**TABLE 1.** AOAC Official Methods validated in Infant Formula

Commodity	Provision	Method	Principle	Proposed Type
Infant Formula	Thiamine	<b>AOAC 2015.14 / ISO DIS 21470</b>	<b>Enzymatic digestion and LC-MS/MS</b>	<b>II</b>
		EN 14122	HPLC with pre- or post-column derivatization to thiochrom	# III
		AOAC 986.27	Fluorimetry	III
	Riboflavin	<b>AOAC 2015.14 / ISO DIS 21470</b>	<b>Enzymatic digestion and LC-MS/MS</b>	<b>II</b>
		EN 14152	HPLC	# III
		AOAC 985.31	Fluorimetry	III
	Niacin	<b>AOAC 2015.14 / ISO DIS 21470</b>	<b>Enzymatic digestion and LC-MS/MS</b>	<b>II</b>
		EN 15652	HPLC	# III
		AOAC 985.34	Microbioassay and turbidimetry	III
	Vitamin B6	<b>AOAC 2015.14 / ISO DIS 21470</b>	<b>Enzymatic digestion and LC-MS/MS</b>	<b>II</b>
		AOAC 2004.07 / EN 14164	HPLC	# III
		AOAC 985.32	Microbioassay	III
		EN 14166	Microbioassay	III
	Choline	<b>AOAC 2015.10 / ISO DIS 21468</b>	<b>LC-MS/MS</b>	<b>II</b>
		AOAC 999.14	Enzymatic Colorimetric Method with limitations on applicability due to choline and ascorbate concentration	# III
	Carnitine	<b>AOAC 2015.10 / ISO DIS 21468</b>	<b>LC-MS/MS</b>	<b>II</b>
	Fructans	<b>AOAC 2016.14 / ISO DIS 22579   IDF 241</b>	<b>Enzymatic digestion with HPAEC-PAD</b>	<b>II</b>
Beta Carotene	<b>AOAC 2016.13 / ISO DIS 23443</b>	<b>UHPLC-UV</b>	<b>II</b>	
Lycopene	<b>AOAC 2016.13 / ISO DIS 23443</b>	<b>UHPLC-UV</b>	<b>II</b>	
Biotin	<b>AOAC 2016.02 / ISO 23305</b>	HPLC-UV	II	
	EN 15607	HPLC-fluorescence	III	