

# CODEx ALIMENTARIUS COMMISSION



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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

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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 (CXS 72-1981)

*Comments of ISDI*

#### ISDI - International Special Dietary Foods Industries

##### Executive Summary

This document complements CRD 3 prepared by the United States of America and 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 40<sup>th</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in November 2018.<sup>1</sup> These methods are intended to replace and complement current Type II reference methods, which may be outdated and/or were not validated on all types of infant formula.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 enable them 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 minerals and trace elements (e.g., calcium, magnesium, phosphorus, potassium, sodium, copper, iron, manganese, and zinc), vitamin K, and folic acid 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 minerals and trace elements (**AOAC 2015.06 / ISO 21424 | IDF 243**) to CCMAS for review and endorsement with the recommendation of a Type II method.
- ISDI supports the recommendation to request 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, as well as either retain the existing methods, make any necessary changes to the Type, or revoke any methods which do not meet these specifications. ISDI's recommendations for necessary changes are noted below in Table 1.
- ISDI supports the recommendation to confirm that the method for vitamin K (**AOAC 2015.09 / ISO 21446**) determines the analyses consistent with the form in CXS 72-1981 and Infant Formula provisions in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG-10) and, if so, refer the method to CCMAS for review and endorsement as Type II. As there are no current Codex Type II methods for the determination of vitamin K in infant formula within CXS 234-1999, no additional changes are needed.
- ISDI supports the recommendation to confirm that the method for folic acid (**AOAC 2011.06**) determines the analyses consistent with the form(s) in CXS 72-1981 and infant formula provisions in

<sup>1</sup> NFSDU/40 CRD/3 <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-40%252FCRD%252FCRD3%2B%2528prepared%2Bby%2BUSA%2529.pdf>

CXG-10 and, if so, refer the method CCMAS for review and endorsement as Type II. ISDI's recommendations for necessary changes to existing methods in CXS 234-1999 are noted below in Table 1.

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

Commodity	Provision	Method	Principle	Proposed Type
Infant formula	Calcium	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		ISO 8070   IDF 119	Flame atomic absorption spectrophotometry	# III
		AOAC 985.35	Flame atomic absorption spectrometry	III
		AOAC 984.27	ICP emission spectroscopy	III
	Copper	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		AOAC 985.35	Flame atomic absorption spectrophotometry	# III
		AOAC 984.27	ICP emission spectroscopy	III
	Iron	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		AOAC 985.35	Flame atomic absorption spectrometry	III
		AOAC 984.27	ICP emission spectroscopy	III
		AOAC 999.11   NMKL 139	AAS after dry ashing	# III
	Magnesium	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		ISO 8070   IDF 119	Flame atomic absorption spectrophotometry	# III
		AOAC 985.35	Flame atomic absorption spectrometry	III
		AOAC 984.27	ICP emission spectroscopy	III
	Manganese	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		AOAC 985.35	Flame atomic absorption spectrometry	# III
		AOAC 984.27	ICP emission spectroscopy	III
	Phosphorus	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		AOAC 984.27	ICP emission spectroscopy	III
		AOAC 986.24	Spectrophotometry (molybdovanadate)	# III
	Potassium	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		ISO 8070   IDF 119	Flame atomic absorption spectrophotometry	# III
		AOAC 984.27	ICP emission spectroscopy	III
	Sodium	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		ISO 8070   IDF 119	Flame atomic absorption spectrophotometry	# III
		AOAC 984.27	ICP emission spectroscopy	III
	Zinc	<b>AOAC 2015.06 / ISO 21424   IDF 243</b>	<b>ICP mass spectrometry</b>	<b>II</b>
		AOAC 985.35	Flame atomic absorption spectrometry	# III
		AOAC 984.27	ICP emission spectroscopy	III
Vitamin K	<b>AOAC 2015.09 / ISO 21446</b>	<b>HPLC</b>	<b>II</b>	
Folic acid	<b>AOAC 2011.06</b>	<b>LC-MS/MS</b>	<b>II</b>	
	AOAC 992.05 / EN 14131	Microbioassay	# III	
	J AOAC Int. 2000:83; 1141-1148	Optical Biosensor Immunoassay	IV	
	J Chromatogr. A., 928, 77-90, 2001	HPLC, incorporating immunoaffinity clean-up and conversion to 5-methyltetrahydrofolate	IV	