CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 11 **NFSDU/39 CRD/21**

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

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Comments of *International Special Dietary Foods Industries (ISDI)*

Agenda Item 11

Methods of Analysis for Infant Formula

Executive Summary

This document outlines a proposal to replace methods of analysis for nutrients in infant formula which are listed in CODEX STAN 234-1999 and referenced in CODEX STAN 72-1981. They will be considered during the 39th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in December 2017 and are intended to replace current Type II reference methods which may be outdated and/or were not validated on all types of infant formula.

These new standards have been developed through the Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) project, which is managed by AOAC INTERNATIONAL (AOAC), have been adopted as AOAC Official Final Action methods and are in the endorsement process with the International Organization for Standardization (ISO) and International Dairy Federation (IDF) as ISO Standards 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.

Recommendations

ISDI recommends that CCNFSDU39 refer the following methods 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 methods of analysis for biotin, vitamin D and chloride in infant formula and have been validated in infant formula. Table 1 illustrates how these methods should be listed in COEX STAN 234-1999.

- It is recommended that CCNFSDU39 refer the method for Biotin (**AOAC 2016.02**[1] **| ISO/NWIP**) to the Codex Committee on Methods of Analysis (CCMAS) for technical review, typing (e.g., Type II) and endorsement during its 39th Session in May 2018, and in addition recommend that this method becomes and/or replaces the current Codex Type II method (EN 15607) for biotin (in infant formula) in CODEX STAN 234-1999 for the purpose of dispute resolution.
- It is recommended that CCNFSDU39 refer the equivalent methods for Vitamin D (**AOAC 2016.05**[2] **| ISO DIS 20636**) to the Codex Committee on Methods of Analysis (CCMAS) for technical review, typing (e.g., Type II) and endorsement during its 39th Session in May 2018, and in addition recommend that these equivalent methods become and/or replace the current Codex Type II method (EN 12821) for vitamin D (in infant formula) in CODEX STAN 234-1999 for the purpose of dispute resolution.

[1] Joseph G et al. Determination of Total Biotin by Liquid Chromatography Coupled with Immunoaffinity Column Cleanup Extraction: Multilaboratory Testing, Final Action 20016.02. J AOAC Int. 2017 Oct 11. doi: 10.5740/jaoacint.17-0242
[2] Gill BD and Indyk HE. Analysis of Vitamin D_2 and Vitamin D_3 in Infant and Adult Nutritional Formulas by Liquid Chromatography-Tandem Mass Spectrometry: A Multilaboratory Testing Study. J AOAC Int. 2017 Aug 8. doi: 10.5740/jaoacint.17-0149.

- It is recommended that CCNFSDU39 refer the equivalent methods for chloride (**AOAC 2016.03**[3] **| ISO DIS 21422 | IDF 242**) to the Codex Committee on Methods of Analysis (CCMAS) for technical review, typing (e.g., Type II) and endorsement during its 39th Session in May 2018, and in addition recommend that these equivalent methods become the current Codex Type II methods for chloride (in infant formula) in CODEX STAN 234-1999 for the purpose of dispute resolution.

Table 1. Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999)

Commodity	**Provision**	**Method**	**Principle**	**Type**
Infant Formula	Biotin	EN 15607	High Performance Liquid Chromatography	~~**II**~~ **III**
		AOAC 2016.02 | ISO/NWIP	**Liquid Chromatography**	**II**
	Vitamin D	AOAC 992.26	High Performance Liquid Chromatography	III
		EN 12821	High Performance Liquid Chromatography	~~**II**~~ **III**
		AOAC 995.05	High Performance Liquid Chromatography	III
		AOAC 2016.05 | ISO DIS 20636	**Liquid Chromatography – Mass Spectometry**	**II**
	Chloride	AOAC 986.26	Potentiometry	III
		AOAC 2016.03 | ISO DIS 21422 | IDF 242	**Potentiometric Titration**	**II**

[3] Jaudzems GG. Determination of Chloride in Infant Formula and Adult/Pediatric Nutritional Formula by Automated Potentiometry: Single-Laboratory Validation, First Action 2015.08. J AOAC Int. 2015 Sep-Oct;98(5): 1390-4. doi: 10.5740/jaoacint.15-136.