CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 11a **CX/NFSDU 15/37/10 (Rev)**

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

Thirty-seventh Session

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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)

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 CCNFSDU (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 09/32/26). In 2009, 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). These methods were adopted by the Codex Alimentarius Commission in 2009, include various Type I, II, 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 To date, some methods referenced in CODEX STAN 72-1981 and CODEX STAN 234-1999 are outdated and/or not validated for infant formula. Further, for some required nutrients and many optional ingredients, Codex Official Reference Methods are lacking (i.e. myo-inositol and nucleotides).

3. Eight methods of analysis for nutrients in infant formula (vitamin B12, myo-Inositol, chromium, selenium, molybdenum, nucleotides, vitamins A and E, fatty acid profile, iodine, and pantothenic acid) have been validated in infant formula 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 have also been adopted by the International Organization for Standardization (ISO) and International Dairy Federation (IDF) as ISO/IDF standards and publication of the ISO standards is expected by November 2015.

PROPOSAL AND RATIONALE

4. The Committee is requested to consider submitting the following eight methods of analysis for nutrients in infant formula (vitamin B12, myo-Inositol, chromium, selenium, molybdenum, nucleotides, vitamins A and E, fatty acid profile, iodine, and pantothenic acid) 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 nutrients in infant formula and have been validated in infant formula.

5. The Committee is requested to consider recommending to CCMAS that methods in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) that may be replaced by the eight AOAC official methods in Table 1 (below) and are not validated for infant formula (e.g. AOAC 992.17 Pantothenic Acid) be removed or reclassified.

6. Table 1 presents the eight AOAC Official methods of analysis for nutrients validated in infant formula. These same methods are also provided as ISO/IDF standards.

TABLE 1. AOAC Official Methods validated in Infant Formula with ISO/IDF References

Commodity	Provision	Method	Principle	Proposed Type†
Infant Formula	Vitamin B12	AOAC 2011.10 ISO/DIS 20634	High Performance Liquid Chromatography (HPLC)	II
Infant Formula	Myo-Inositol	AOAC 2011.18 ISO/DIS 20637	Liquid Chromatography (LC) -pulsed amperometry	II
Infant Formula	Chromium	AOAC 2011.19 ISO/DIS 20649 | IDF 235	Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)	II
Infant Formula	Selenium	AOAC 2011.19 ISO/DIS 20649 | IDF 235	ICP-MS	II
Infant Formula	Molybdenum	AOAC 2011.19 ISO/DIS 20649 | IDF 235	ICP-MS	II
Infant Formula	5'-Mononucleotides	AOAC 2011.20 ISO/DIS 20638	LC	II
Infant Formula	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate), Total Vitamin E (dl-α-Tocopherol and dl-α-Tocopherol Acetate)	AOAC 2012.10 ISO/DIS 20633	HPLC	II
Infant Formula	Total Fatty Acid Profile	AOAC 2012.13 ISO/DIS 16958 | IDF 231	Gas Chromatography	II
Infant Formula	Iodine	AOAC 2012.15 ISO/DIS 20647 | IDF 234	ICP-MS	II
Infant Formula	Pantothenic Acid	AOAC 2012.16 ISO/DIS 20639	Ultra HPLC-MS/MS	II

† A Type II method is the one designated Reference Method where Type I methods do not apply. It should be selected from Type III methods (one which meets the criteria required by the CCMAS for methods that may be used for control, inspection or regulatory purposes). It should be recommended for use in cases of dispute and for calibration purposes. (*Principles for the Establishment of Codex Methods of Analysis*, Codex Alimentarius Commission Procedural Manual, 23rd ed., Joint FAO/WHO Food Standards Programme, FAO, Rome 2015.)

REFERENCES

Sullivan, D. Infant formula and adult/pediatric nutritional methods approved first action using the AOAC voluntary consensus standards process. J AOAC Int. 2012 95(2):1-4.

Gill BD, Indyk HE, Blake CJ, Konings EJ, Jacobs WA, Sullivan DM. Evaluation Protocol for Review of Method Validation Data by the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals Expert Review Panel. J AOAC Int. 2015 98(1):112-5

AOAC Official Method℠ 2011.10 **Vitamin B12** in Infant Formula and Adult Nutritionals (http://stakeholder.aoac.org/SPIFAN/2011.10.pdf)

ISO/DIS 20634:2015 - Infant formula and adult nutritionals -- Determination of **vitamin B12** by reversed phase high performance liquid chromatography (RP-HPLC)

AOAC Official Method℠ 2011.18 **Myo-Inositol** (Free and Bound as Phosphotidylinositol) in Infant Formula and Adult Nutritionals (http://stakeholder.aoac.org/SPIFAN/2011.18.pdf)

ISO/DIS 20637:2015 - Infant formula and adult nutritionals -- Determination of **myo-inositol** by liquid chromatography and pulsed amperometry

AOAC Official Method℠ 2011.19 **Chromium, Selenium and Molybdenum** in Infant Formula and Adult Nutritional Products (http://stakeholder.aoac.org/SPIFAN/2011.19.pdf)

ISO/DIS 20649 | IDF 235:2015 - Infant formula and adult nutritionals -- Determination of **chromium, selenium and molybdenum** by inductively coupled plasma mass spectrometry (ICP-MS)

AOAC Official Method℠ 2011.20 5'-**Mononucleotides** in Infant Formula and Adult/Pediatric Nutritional Formula (http://stakeholder.aoac.org/SPIFAN/2011.20.pdf)

ISO/DIS 20638:2015 - Infant formula -- Determination of **nucleotides** by liquid chromatography

AOAC Official Method℠ 2012.10 Simultaneous Determination of 13-cis and all-trans **Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate), and Total Vitamin E (dl-α-Tocopherol and dl-α-Tocopherol Acetate)** in Infant Formula and Adult Nutritionals (http://stakeholder.aoac.org/SPIFAN/2012.10.pdf)

ISO/DIS 20633:2015 - Infant formula and adult nutritionals -- Determination of **vitamin E and vitamin A** by normal phase high performance liquid chromatography

AOAC Official Method℠ 2012.13 Determination of Labeled **Fatty Acids** Content in Milk Products and Infant Formula (http://stakeholder.aoac.org/SPIFAN/2012.13.pdf)

ISO/DIS 16958 | IDF 231:2015 - Milk products and infant formulae -- Determination of **fatty acid content** - Capillary gas chromatographic method

AOAC Official Method℠ 2012.15 Total **Iodine** in Infant Formula and Adult/Pediatric Nutritional Formula (http://stakeholder.aoac.org/SPIFAN/2012.15.pdf)

ISO/DIS 20647 | IDF 234:2015 - Infant formula and adult nutritionals -- Determination of total **iodine** by inductively coupled plasma mass spectrometry (ICP-MS)

AOAC Official Method℠ 2012.16 **Pantothenic Acid** (Vitamin B5) in Infant Formula and Adult/Pediatric Nutritional Formula (http://stakeholder.aoac.org/SPIFAN/2012.16.pdf)

ISO/DIS 20639:2015 - Infant formula and adult nutritionals -- Determination of **pantothenic acid** by ultra-performance liquid chromatography and tandem mass spectrometry method (UHPLC-MS/MS)