CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Thirty-seventhth Session
Budapest, Hungary, 22 – 26 February 2016

(information prepared by vice-chair of Endorsement WG)

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

Plain Text = Methods and provisions as presented from CCNFSDU 16/37/3 Appendix IV
BOLD = As currently listed in CODEX STAN 234-1999
Strike Through/Underline = proposed edits to Appendix IV Table and to CODEX STAN 234-1999

Commodity	Provision	Method	Principle	Type
Infant Formula	Vitamin B12	AOAC 2011.10 ISO 20634	HPLC	II
Infant Formula	**Vitamin B12**	**AOAC 986.23** **Total B12 as cyanocobalamin**	**Turbidimetric**	**III**
Infant	Myo-Inositol	AOAC 2011.18	LC-pulsed amperometry	II

Formula		ISO 20637		
Infant Formula	Chromium	AOAC 2011.19 ISO 20649 | IDF 235	ICP-MS	II
Infant formula	**Chromium (Section B of STAN 72 only)**	**EN 14082**	**Graphite furnace atomic absorption after dry ashing**	**III**
Infant formula	**Chromium (Section B of STAN 72 only)**	**EN 14083**	**Graphite furnace AAS after pressure digestion**	**III**
Infant formula	**Chromium (Section B of STAN 72 only)**	**AOAC 2006.03**	**ICP emission spectroscopy**	**III**
Infant Formula	Selenium	AOAC 2011.19 ISO 20649 | IDF 235	ICP-MS	II
Infant formula	**Selenium**	**AOAC 996.16 or AOAC 996. 17**	**Continuous hydride generation Flame atomic absorption spectrometry (HGAAS)**	**III**
Infant formula	**Selenium**	**EN 14627**	**Hydride generation atomic absorption spectrometry (HGAAS)**	**III**
Infant formula	**Selenium**	**AOAC 2006.03**	**ICP emission spectroscopy**	**III**
Infant Formula	Molybdenum	AOAC 2011.19 ISO 20649 | IDF 235	ICP-MS	II
Infant formula	**Molybdenum (Section B of STAN 72 only)**	**EN 14083**	**Graphite furnace AAS after pressure digestion**	**III**

Infant formula	**Molybdenum (Section B of STAN 72 only)**	**AOAC 2006.03**	**ICP emission spectroscopy**	**III**
Infant Formula	Total nucleotides	AOAC 2011.20 ISO 20638	LC	II
Infant Formula	Total Vitamin E (dl-α-Tocopherol and dl-α-Tocopherol Acetate)	AOAC 2012.10 ISO 20633	HPLC	II
Infant formula	**Vitamin E**	**AOAC 992.03** **Measures all rac-vitamin E (both natural + supplemental ester forms) aggregated and quantified as α-congeners**	**HPLC**	**III**
Infant formula	**Vitamin E**	**EN 12822** **(Measures Vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual tocopherol congeners (α, β, γ, δ).**	**HPLC**	**III**
Infant Formula	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate),	AOAC 2012.10 ISO 20633	HPLC	II
Infant formula	**Vitamin A**	**EN 12823-1 (all-trans-retinol and 13-cis-retinol)** **Vitamin A (both natural + supplemental ester forms) aggregated and quantified as individual retinol isomers (13 - cis and all-trans)**	**HPLC**	**III**

Infant Formula	Fatty acids (including trans fatty acids)	AOAC 2012.13 ISO 16958 | IDF 231	Gas Chromatography	II
Infant formula	**Fatty acids (including trans fatty acid)**	**AOAC 996.06**	**Gas chromatography**	**III**
Infant formula	**Fatty acids (including trans fatty acid)**	**AOCS Ce 1h-05**	**Gas chromatography**	**III**
Infant formula	**Total fat**	**AOAC 989.05** **ISO 8381|IDF 123**	**Gravimetry (Röse-Gottlieb)**	**I**
Infant formula	**Total fat** **for milk-based infant formula** **(Products not completely soluble in ammonia)**	**ISO 8262-1 |IDF 124-1**	**Gravimetry (Weibull-Berntrop)**	**I**
Infant Formula	Iodine	AOAC 2012.15 ISO 20647 | IDF 234	ICP-MS	II
Infant formula	**Iodine** **(for milk-based formula)**	**AOAC 992.24**	**Ion-selective potentiometry**	**III**
Infant Formula	Pantothenic Acid	AOAC 2012.16 ISO 20639	UHPLC-MS/MS	II

Method	Provision	**Principle**	LOD	LOQ		RSD_R(%)	Recovery	Specification in Standard	
AOAC 2011.10 ISO 20634	Vitamin B12	HPLC		0.8 ug/kg		3.54% - 19.5% Average 6.64%		Min 0.1 ug/100kcal	GUL 1.5 ug/100 kcal
AOAC 2011.18 ISO 20637	Myo-Inositol	LC-pulsed amperometry				1.5% - 5.1%		Min 4 ug/100kcal	GUL 40 ug/100 kcal
AOAC 2011.19 ISO 20649 | IDF 235	Chromium	ICP-MS		Powder 100 ng/g	Liquid 20 ng/g	9.3%		Min 1.5 ug/100kcal	GUL 10 ug/100 kcal
AOAC 2011.19 ISO 20649 | IDF 235	Selenium	ICP-MS		Powder 50 ng/g	Liquid 10 ng/g	6.5%		Min 1 ug/100kcal	GUL 9 ug/100 kcal
AOAC 2011.19 ISO 20649 | IDF 235	Molybdenum	ICP-MS		Powder 100 ng/g	Liquid 20 ng/g	5.3%		Min 1.5 ug/100kcal	GUL 10 ug/100 kcal
AOAC 2011.20 ISO 20638	5'-mononucleotides	LC				4.4% - 5%		Min XX ug/100kcal	GUL XX ug/100 kcal
AOAC 2012.10 ISO 20633	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate), Total Vitamin E (dl-α-Tocopherol and	HPLC						Min 60 ugRE/100kcal * 1ug RE = 3.33 IU vitamin A	Max 180 ugRE/100 kcal GUL 5 mg α-TE/100kcal (1 mg α-TE (alpha-tocopherol equivalent) =

	dl-α-Tocopherol Acetate)						Min 0.5 mg α-TE/100kcal	1 mg d-α-tocopherol)
AOAC 2012.13 ISO 16958 | IDF 231	Total Fatty Acid Profile	Gas Chromatography						
AOAC 2012.15 ISO 20647 | IDF 234	Iodine	ICP-MS		25-50 ug/kg	5.4% - 11.5%		Min 10 ug/100kcal	GUL 60 ug/100 kcal
AOAC 992.07* AOAC 2012.16 ISO 20639	Pantothenic Acid	UHPLC-MS/MS					Min 400 ug/100kcal	GUL 2000 ug/100 kcal

Notes from CAC/GL10-1979 "ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN" and from CODEX STAN 72-1981 "STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS"

Nucleotides
Referred to as nucleotides in GL 10 1979, but as Total Nucleotides in STAN 72-1981. In GL 10 there are 7 compounds listed, 3 being disodium salt (Uridine, Guanosine, Inosine), 2 where the neutral compound is also listed. Therefore producing 5 free compounds (Uridine, Guanosine, Inosine, Adenosine, Cytidine), which are the same 5 compounds listed in AOAC 2011.20 Table 2011.20A (*Adenosine 5′-monophosphate, Cytidine 5′-monophosphate, Guanosine 5′-monophosphate, Inosine 5′-monophosphate Uridine 5′-monophosphate*)

Inositol
Referred to Inositol in GL 10, Myo-Inositol (=meso-Inositol) is listed in GL 10, with Myo-Inositol listed in STAN 72-1981, but no indication of free or bound.

Vitamin B12
Referred to Vitamin B12 in GL10, with Cyanocobalamin and Hydroxo-cobalamin listed in GL10 as sources. Vitamin B12 is listed in STAN 72-1981,

Pantothenic Acid
Pantothenic is listed as heading in GL10, with the following approved sources Calcium-D-pantothenate , Sodium-D-pantothenate , D-Panthenol , DL-Panthenol and Pantothenic Acid is listed in STAN 72-1981.

Vitamin A
Vitamin A is listed in GL10, with sources listed as all trans Retinol, Retinyl acetate, Retinyl palmitate. Vitamin A is listed in STAN 72-1981 with the footnote that reads *"1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity."*

Vitamin E
Vitamin E is listed in GL10, with sources listed as D-alpha-Tocopherol, DL-alpha-Tocopherol, D-alpha-Tocopheryl acetate, DL-alpha-Tocopheryl acetate, D-alpha-Tocopheryl acid succinate, DL-alpha-Tocopheryl acid succinate, DL-alpha-Tocopheryl polyethylene glycol 1000 succinate. Vitamin E is listed in STAN 72-1981 with the following footnote "*1 mg α-TE (alpha-tocopherol equivalent) = 1 mg d-α-tocopherol*".

Fatty Acids
Fat, Total Fat and Fatty Acids are not listed in GL10. Total Fat is listed in STAN 72-1981 with the following footnotes:

Commercially hydrogenated oils and fats shall not be used in infant formula.

Lauric and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3 % of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in infant formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).