

CODEX ALIMENTARIUS COMMISSION



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Agenda Item 3

MAS/37 CRD/27
ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Thirty-seventhth Session
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(Comments prepared by AOAC, IDF, ISO)

CLARIFICATION ON WHY CURRENT STAN 234 TYPE II METHODS FOR INFANT FORMULA HAVE TO BE REPLACED WITH FIT FOR PURPOSE, VALIDATED ANALYTICAL METHODS

Table I gives an overview of current Type II methods for nutrients in infant formula presently under discussion for replacement with proposed new Type II methods in Table 2.

Why do current methods need to be replaced?

1. Current Type II methods are mostly NOT (or for limited matrices) validated for infant formula
2. Concentration levels validated for matrices of current Type II methods are generally much higher than common in infant formula, and accompanying RSDR values too high for most matrices
3. Some of the current Type II methods are not specific enough to reflect the correct levels of the target measurands
4. It should be noted that fatty acid provisions in Infant Formula Standard 72-1981 as listed in Table 1 are covered with the newly proposed ISO 16958 | IDF 231:2015 /AOAC 2012.13

Table 1: Current STAN 234 Type II methods for nutrients in infant formula with key validation data.

provision	Current Type II method	Technique	matrix validated	matrix validated	matrix validated	matrix validated	matrix validated	matrix validated	matrix validated
Vitamin A	EN 12823-1	LC-UV	margarine	milk powder					
mg/kg			7.29	6.53					
RSDR (%)			10	3.4					
Vitamin E	EN 12822	LC-FLU	margarine	milk powder	oat powder				
mg/kg			241	100	2.7				
RSDR (%)			6	7	17				
Vitamin B12	AOAC 986.23	microbiology	Milk-based infant formula, 1988	TECHNIQUE BASED ON NON-SPECIFIC DETERMINATION					
RSDR (%)			12.2-17.1						
Pantothenic acid	AOAC 992.07	microbiology	Milk-based RTF infant formula						
RSDR (%)			10.23						
Cr	EN 14082	AAS	liver pate	apple juice	minced fish	wheat bran	milk powder	composit e diet	
mg/kg			0.037	0.1	0.22	0.021	<DL	0.046	
RSDR (%)			62	42	21	38	48	34	
Mo	EN 14083	GFAAS	bovine liver	baby food	whole meal biscuits				
mg/kg			0.19	0.17	0.07				
RSDR (%)			27	19	53				
Se	EN 14627	HGAAS	whole wheat flour	cellery powder	egg powder	cat fish lyoph.	rice powder	white clover lyoph.	pig kidney
mg/kg			0.051	0.077	0.72	1.8	0.374	7.23	10.5
RSDR (%)			16	12	14	10	12	7.2	6.4
Iodine	AOAC 992.24	ion-selective electrode	TECHNIQUE NOT SUITABLE FOR MEASUREMENT OF TOTAL IODINE						
fatty acids myristic acid, lauric acid linoleic acid alpha-linolenic acid trans fatty acids erucic acid total fatty acids	AOAC 996.06	GC	NO DATA ON TRANS FAT, NOT VALIDATED FOR INFANT FORMULA						
myo-inositol	NA								
nucleotides	NA								

Table 2: Newly proposed Type II methods for nutrients in infant formula. MLT is Multi Lab Testing.

Provision	AOAC Official Method	ISO/IDF Standard	MLT conc	MLT conc	MLT RSDR
			low reconstituted prod	high reconstituted product	
			mg/kg	mg/kg	
Iodine	AOAC 2012.15	ISO 20647 IDF 234:2015	0.0347	0.185	5.4-11.5
Pantothenic acid	AOAC 2012.16	ISO 20639:2015	2.88	8.97	4.1-7.0
Chromium	AOAC 2011.19	ISO 20649 IDF 235:2015	0.016	0.14	5.8-13.4
Molybdenum	AOAC 2011.19	ISO 20649 IDF 235:2015	0.018	0.19	3.0-7.9
Selenium	AOAC 2011.19	ISO 20649 IDF 235:2015	0.023	0.133	2.5-9.3
Vitamin A	AOAC 2012.10	ISO 20633:2015	0.463	0.674	6.5-22.6
Vitamin E	AOAC 2012.10	ISO 20633:2015	13	127	4.2-11.3
Vitamin B12	AOAC 2011.10	ISO 20634:2015	0.002	0.015	3.5-19.5
fatty acids myristic acid, lauric acid linoleic acid alpha-linolenic acid trans fatty acids erucic acid	AOAC 2012.13	ISO 16958 IDF 231:2015	See MAS/37 CRD 6		

Note: All nutrients are validated for the following matrices:

- SRM 1849 (NIST)
- Infant Formula Powder Milk-Based
- Infant Formula Ready to Feed Milk-Based
- Infant Formula Powder Soy-Based
- Infant Formula Powder Hydrolysate Milk-Based
- Infant Formula Powder Hydrolysate Soy-Based
- Infant Formula Powder Elemental (amino acid-based)
- Child Formula Powder
- Adult Nutritional Powder
- Adult Nutritional Powder Low Fat
- Adult Nutritional RTF High Protein
- Adult Nutritional RTF High Fat