CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CX/NFSDU 16/38/2**

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

Thirty-eighth Session

Hamburg, Germany
5-9 December 2016

Matters Referred by the Codex Alimentarius Commission and/or Other Subsidiary Bodies

A. DECISIONS OF THE 39TH SESSION OF THE COMMISSION (CAC39)

MATTERS FOR INFORMATION

Standards and Related Texts Adopted at Step 8, Step 5/8 and Step 5[1]

1. CAC39 adopted the following:

- Additional or revised nutrient reference values for labelling purposes in the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) except the NRV for Vitamin E which was adopted at Step 5 noting that any request for scientific advice from JEMNU should be sent through CCNFSDU.[2]
- Amendment to the Annex of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) to add a definition for RASBS. The definition was adopted with modifications recommended by CCEXEC[3].
- Amendment to Section 10, methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants* (CODEX STAN 72-1981).

2. CAC39 adopted the methods of analysis as endorsed by CCMAS[4]

Amendments to the Procedural Manual[5]

3. CAC39 agreed to adopt the amendment proposed by CCMAS and endorsed by CCGP to the section on methods of analysis and sampling of the Format for Codex Commodity Standards (Section II: Elaboration of Codex Commodity Standards). The revised section requires that commodity standards includes the following wording: *"For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of analysis and sampling (CODEX STAN 234-1999) relevant to the provisions in this standards, shall be used.".*

4. The amendment would not imply the automatic removal of methods of analysis and sampling currently contained in Codex standards. The removal of methods of analysis and sampling from commodity standards would be done as the review and updating of CODEX STAN 234-1999 progress and inconsistencies and other pending issues are resolved.

5. The Committee **is invited to note** the above decisions. The NRV for Vitamin E will be considered under agenda item 4a.

MATTERS FOR ACTION

New Work[6]

6. CAC39 approved new work on a Guideline for Ready-to-Use Therapeutic Foods (RUTF).

7. The Committee **is invited to consider** the new work under agenda item 8.

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[1] REP15/CAC, paras 13, 23-30, Appendix III
[2] REP16/CAC, paras 40 – 44 (reproduced in Appendix I to this document)
[3] REP16/EXEC, para.17
[4] REP16/CAC, para. 46-47
[5] REP16/CAC, Appendix II, REP16/MAS Appendix II
[6] REP16/CAC, paras 102-107, Appendix VI

Consistency of the Risk Analysis Texts across Relevant Committees[7]

8. CAC39 endorsed the recommendations of CCGP[8] that CCNFSDU should revise the text on nutritional risk analysis[9] and consider how to include JEMNU as a primary source of scientific advice.

9. The Committee **is invited to consider** this request.

B. MATTERS ARISING FROM SUBSIDIARY BODIES AS RELATED TO THE WORK OF CCNFSDU

MATTERS FOR INFORMATION

The 37th Session of the Committee on Methods of Analysis and Sampling (CCMAS37)

Methods of analysis for provisions in the Standard for Infant Formula and Formulas for special Medical Purposes Intended for Infants[10]

10. CCMAS endorsed the methods of analysis for Vitamin A, total nucleotides, pantothenic acid and iodine as Type II, and the methods of analysis for chromium, selenium and molybdenum as Type III. These methods were adopted by the CAC39 for inclusion in CODEX STAN 234-1999 (See table in Appendix II).

11. The Committee is **invited to note** the above.

48th Session of the Committee on Food Additives (CCFA48)

Alignment of provisions in GSFA with the Standard for Infant Formula and Formulas for Special Medical Purposes for Infants (CODEX STAN 72-1981)[11]

12. CCFA48 agreed to inform the Committee of the alignment of the provisions for carrageenan (INS 407), citric and fatty acid esters of glycerol (INS 472c) and starch sodium octenyl succinate (INS 1450) in the GSFA with the *Standard for Infant Formula and Formulas for Special Medical Purposes for Infants.*

Process for submission of data in the Priority List of Substances proposed for evaluation by JECFA[12]

13. CCFA48 agreed that CCNFSDU needed to confirm the technological need of food additives intended for use in infant formula prior to the inclusion in the CCFA priority list.

14. CCFA agreed that (i) for CCFA48, the request for CCNFSDU confirmation of the technological justification for gellan gum (INS 418) would be requested through the matters referred document prepared by the Codex Secretariat (see the request in para. 19 below), and (ii) for future requests, it will be the sponsors' responsibility to obtain CCNFSDU confirmation before submitting the request to CCFA.

15. The Committee is **invited to note** the above information.

MATTERS FOR ACTION

37th Session of the Committee on Methods of Analysis and Sampling (CCMAS37)

Protein Conversion factors[13]

16. CCMAS37 agreed that it was not in a position to reply to the questions posed by CCNFSDU37 as the determination of conversion factors was in the remit of CCNFSDU.

17. This matter was also discussed in CAC39. An excerpt of the discussion is reproduced in Appendix I to this document.

Examination of "ELISA G12" as a potential method for inclusion in the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979)[14]

18. CCMAS37 agreed that the two methods (R5 and G12) are not comparable, that comparability data for the two methods were not available, and mixed matrices are not included in the scope of either of the methods obtained during their validation.

19. The Committee is **invited to consider** the replies from CCMAS.

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[7] REP16/CAC, para. 179
[8] REP16/GP, para. 55
[9] Codex Procedural Manual, Section IV: Risk Analysis: *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses*
[10] REP16/MAS, para. 30 – 39 and 44
[11] REP16/FA, para. 76
[12] REP16/FA, paras 119-120
[13] REP16/MAS, paras 12-13
[14] REP16/MAS, para. 23

Methods of analysis for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants[15]

20. CCMAS37 while endorsing methods of analysis for provisions in the above-mentioned standard, requested CCNFSDU to consider the following:

Chromium, selenium and molybdenum*:* review the proposed numeric values for method criteria.

Vitamin B12 – clarify whether the existing method in CODEX STAN 234-1999, AOAC 986.23 (measures total Vitamin B12 as cyanocobalamin), is still fit for purpose. If the method is still fit for purpose, this method would become Type III.

Myo-inositol – confirm that AOAC 2011.18 and ISO 20637 determine the forms to be measured according to CODEX STAN 72-1981 for myo-inositol. The AOAC 2001.18 and ISO 20637 determine free and bound myo-inositol as phosphatidylinositol, but it is unclear if this is the definition (inclusion of free and bound) in CODEX STAN 72-1981. Provided that the definition and the scope of the methods harmonize, CCMAS recommended endorsement of AOAC 2001.18 and ISO 20637 as Type II.

Vitamin E – confirm the scope of AOAC 2012.10 and ISO 20633 is in line with the provision for the isomers of Vitamin E in CODEX STAN 72-1981. The methods do not discriminate both d and dl-alpha-tocopherol, neither do the currently endorsed methods (i.e. AOAC 992.03 and EN 12822) and Vitamin E are listed in the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* with sources listed as D-alpha-tocopherol, DL-alpha-tocopherol, D-alpha-tocopheryl acid succinate, DL-alpha-tocopheryl polyethylene glycol 1 000 succinate. However, in CODEX STAN 72-1981 the footnote only refers to d-alpha-tocopherol. Provided the provision and the scope of the methods harmonize, CCMAS recommends endorsement of AOAC 2012.10 and IOS 20633 as Type II.

Other general considerations – CCMAS noted that composition provisions in CODEX STAN 72-1981 were expressed on the basis of 100 kcal and 100 kJ, but that the methods results would be expressed in mg/kg or µg/kg, and recommended that CCNFSDU consider including a formula for conversion of units in the Standard as described in Appendix II to provide clarity to analysts.

21. The Committee is **invited to consider the recommendations** from CCMAS (also see Appendix II).

48th Session of the Committee on Food Additives (CCFA48)

Gellan gum (INS 418)[16]

22. CCFA48 requested CCNFSDU to confirm the technological need of gellan gum (INS 418) in infant formula, formula for special medical purposes for infants, and follow-up formula.

23. The Committee is **invited to consider** this request.

Flavourings[17]

24. CCFA48 agreed to recommend to CCNFSDU to consider revising the text pertaining to flavourings in the following standards to ensure consistency with the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008): The Annex of CX/FA 15/47/20 would inform the Committee's work on the revision.

- *Standard for Canned Baby Foods* (CODEX STAN 73-1981)
- *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981)
- *Standard for Follow-up Formula* (CODEX STAN 156-1987).

25. This Committee is **invited to consider** the above request.

[15] REP16/MAS, paras 30 - 44
[16] REP16/FA, para. 120 and Appendix XIV
[17] REP16/FA, para.152

Appendix I

NRV – Vitamin E (REP16/CAC, paras 40 – 44)

Malaysia, supported by Indonesia, proposed to return the NRV for Vitamin E to Step 3 until the work on the related conversion factor was finalised. These delegation delegations pointed out that there were divergent views and lack of consensus in CCNFSDU on whether to identify all forms of Vitamin E isomers or only alpha-tocopherols as exhibiting Vitamin E activity. They noted that work should proceed in a logical order and that the first part of the task should be to adopt the conversion factor for the vitamin before proceeding to adopt the NRV for Vitamin E. Returning the NRV to Step 3 would allow discussion on the NRV to be carried out in parallel with the discussion on the conversion factor. These delegations further proposed that JEMNU should be requested to look at the NRV for Vitamin E and its conversion factor.

Two observers also noted that the proposed NRV for Vitamin E was not based on the latest science; that Vitamin E was made up of eight isomers not only alpha tocopherol; and that the NRV should be higher than the proposed 9 mg level.

The Representative of FAO clarified that FAO would welcome requests for scientific advice, but that requests to JEMNU should come from the relevant technical committee.

The chairperson of CCNFSDU clarified that at the last session of the Committee, the NRV had been extensively discussed and that CCNFSDU had agreed to submit the NRV for adoption while noting reservations from three countries. CCNFSDU had also agreed to postpone discussion on the conversion factor and dietary equivalents. However, noting the concerns expressed and that the conversion factor should be agreed first before finalising the NRV, the Chairperson proposed that the NRV be adopted at Step 5 as a compromise. The next session of CCNFSDU would then consider Vitamin E dietary equivalents and conversion factor and in this context could consider if there was an effect on the NRV value.

Conclusion

The Commission adopted the NRV for Vitamin E at Step 5 noting that any request for scientific advice from JEMNU should be sent through CCNFSDU.

Protein conversion factors (REP16/CAC, paras 184 – 190)

The Commission noted the reply from CCMAS that it was not in a position to reply to the question posed by CAC38 on the appropriate protein conversion factors for soy products as this was in the remit of other Codex committees; and noted that it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversions factors.

Some members, while not opposed to the idea to request FAO/WHO to convene a panel to review the scientific literature, cautioned that such a request would have to take into account the overall scientific advice needs, budgetary constraints being faced and a need to prioritize work.

The Representative of FAO noted the request for FAO and WHO to convene an expert panel to review available literature in order to assess the scientific basis for protein conversion factors. However, she noted that given the current workload of FAO and WHO and the resource constraints, the proposed work could not be considered at this stage. She underlined that work could be considered at a later stage if the scope and the expected impact could be better defined.

One delegation not in support of the need for scientific review in particular noted that the FAO/WHO/UNU expert consultation, Protein and Amino Acid Requirements in Human Nutrition was a fairly recent report and therefore a review was not warranted at this stage.

An observer further noted that the standard conversion factor 6.25 was currently in use without any negative impact on human health and nutrition and that the use of this factor should be more appropriately re-evaluated in the appropriate technical committee.

One delegation noted that CCNFSDU would be considering the conversion factor within the context of its work, and that this matter could be addressed there.

Conclusion

The Commission noted the interest for a scientific review. Consideration could be given to convene an expert panel at a later stage with a more defined scope in light of the need for prioritisation of work on scientific advice and financial constraints.

APPENDIX II

Methods of analysis – matters for consider/reply from CCMAS37

Chromium, selenium and molybdenum

The Committee did not endorse the methods as Type II as proposed by CCNFSDU as there were concerns that these methods (requiring expensive instrumentation) were recommended for dispute settlement. The current methods in CODEX STAN 234-1999 were considered by some delegations as equally suitable for use. It was clarified that the newer methods had been extensively validated specifically for infant formula, were more sensitive, precise and necessary for use to ensure the nutritional safety of the products. In order to provide flexibility to countries in the selection of methods, it was agreed to recommend numeric values for method criteria for the determination of chromium, selenium and molybdenum for consideration by CCNFSDU.

The Committee noted that the method criteria developed indicated that none of the current methods in CODEX STAN 234-1999, nor the newer proposed methods would meet the criteria, although the newer AOAC/ISO/IDF methods were closest to meeting the performance criteria, specifically the minimum limit in column 2, and to inform CCMAS whether it had interpreted the limits in the related provisions correctly. If the values are correct then CCNFSDU should note that none of the methods (newly endorsed or existing) meet the numeric values for method criteria. If the values are incorrect then CCNFSDU should provide CCMAS advice on the correct values and how to proceed.

While CCNFSDU reviews the numeric values for method criteria, CCMAS has endorsed the proposed methods as Type III and maintained the typing of the existing methods in CODEX STAN 234-1999.

Performance criteria for elemental methods (for consideration by CCNFSDU)

Provision	ML (minimum µg/kg)	ML (minimum µg/100kcal)	Applicable range (µg/kg)	LOD (µg/kg)	LOQ (µg/kg)	Precision RSDR (%)	Recovery (%)
Selenium	6	1	10-500	4	10	<15	90-110
Chromium	9	1.5	20-1600	7	20	<15	90-110
Molybdenum	9	1.5	20-1000	7	20	<15	90-110

Numeric criteria were developed based on Standard Method Performance Requirements (SMPR) were developed for methods of analysis: AOAC 2011.19|ISO 20649|IDF 235

Numeric criteria are referenced to “ready-to-feed” formula.

None of the methods currently listed in CODEX STAN 234 meet the numeric criteria

Plain text = Methods and provisions as proposed by CCNFSDU37
BOLD = As currently listed in CODEX STAN 234-1999 (at the time of endorsement at CCMAS37)
Strike Through/Underline = Proposed edits to methods proposed by CCNFSDU37 and/or to CODEX STAN 234-1999

STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981) - METHODS OF ANALYSIS

Commodity	Provision	Method	Principle	Type	Endorsement status /request
Infant Formula	Vitamin B12	AOAC 2011.10 **|** ISO 20634	HPLC	II	Endorsed
		AOAC 986.23 Total B12 as cyanocobalamin	**Turbidimetric**	~~**II**~~ **III**	Is this method still fit for purpose
Infant Formula	Myo-Inositol	AOAC 2011.18 **|** ISO 20637	LC-pulsed amperometry	II	Confirm that the method determines the forms to be measured (endorsed)
Infant Formula	Chromium	AOAC 2011.19 **|** ISO 20649 | IDF 235	ICP-MS	~~II~~ III	endorsed
	Chromium (Section B of CODEX STAN 72 only)	**EN 14082**	**Graphite furnace atomic absorption after dry ashing**	**II**	
		EN 14083	**Graphite furnace AAS after pressure digestion**	**III**	
		AOAC 2006.03	**ICP emission spectroscopy**	**III**	
Infant Formula	Selenium	AOAC 2011.19 **|** ISO 20649 | IDF 235	ICP-MS	~~**II**~~ **III**	endorsed
		AOAC 996.16 or AOAC 996. 17	**Continuous hydride generation Flame atomic absorption spectrometry (HGAAS)**	**III**	
		EN 14627	**Hydride generation atomic absorption spectrometry (HGAAS)**	**II**	
		AOAC 2006.03	**ICP emission spectroscopy**	**III**	

Infant Formula	Molybdenum	AOAC 2011.19 **|** ISO 20649 | IDF 235	ICP-MS	~~**II**~~ **III**	endorsed
	Molybdenum (Section B of CODEX STAN 72 only)	**EN 14083**	**Graphite furnace AAS after pressure digestion**	~~**III**~~ **II**	
	Molybdenum (Section B of CODEX STAN 72 only)	**AOAC 2006.03**	**ICP emission spectroscopy**	**III**	
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 20633	HPLC	II	Confirm whether the scope is in line with the provision for the isomers of Vit E (endorsed)
	Vitamin E	**AOAC 992.03 Measures all rac-vitamin E (both natural + supplemental ester forms) aggregated and quantified as α-congeners**	**HPLC**	**III**	
		EN 12822 (Measures Vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual tocopherol congeners (α, β, γ, δ).	**HPLC**	~~**II**~~ **III**	
Infant Formula	~~Total Fatty Acid Profile Fatty acids~~ Fatty acids (including trans fatty acids)	AOAC 2012.13 **|** ISO 16958 | IDF 231	Gas Chromatography	II	endorsed
	Fatty acids (including trans fatty acid)	**AOAC 996.06**	**Gas chromatography**	~~**II**~~ **III**	
		AOCS Ce ~~1h-05~~ 1i-07	**Gas chromatography**	**III**	
	Total fat	**AOAC 989.05 ISO 8381|IDF 123**	**Gravimetry (Röse-Gottlieb)**	**I**	

Infant Formula	Iodine	AOAC 2012.15 **|** ISO 20647 | IDF 234	ICP-MS	II	endorsed
		~~**AOAC 992.24**~~	~~**Ion-selective pontentiometry**~~	**Recommended to be revoked**	Not fit for purpose - revoked