

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 2

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON GENERAL PRINCIPLES

Thirtieth Session

Paris, France, 11 - 15 April 2016

MATTERS REFERRED TO THE COMMITTEE

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

(Amendments to sub-section "Working Instructions for the Implementation of the Criteria Approach in Codex" (Principles for the Establishment of Codex Methods of Analysis))

1. CCMAS37 considered a proposal to amend the sub-section on Working Instructions for the Implementation of the Criteria Approach in Codex of the Principles for the Establishment of Codex Methods of Analysis to indicate that the current procedures for single analytes only, were not always suitable for 'sum of components'.
2. CCMAS37 agreed to amend the General Criteria for the Selection of Methods of Analysis section of the Procedural Manual and to send it to the 30th Session of the Committee on General Principles (CCGP) for endorsement and adoption by the 39th Session of the Commission (ref. REP16/MAS para. 60 and Appendix III).

Amendments to sub-section "Methods of Analysis" (Format for Codex Commodity Standards)

3. CCMAS37 reaffirmed its earlier decision ([REP15/MAS](#), para 111) to have CODEX STAN 234-1999 as the single reference for methods of analysis in Codex standards and recalled the reply of CCGP29 that the amendment to the Procedural Manual to indicate a single reference for methods of analysis was possible, but that CCMAS should prepare the proposed amendments for endorsement by CCGP and adoption by CAC.
4. The Committee agreed to amend the section on methods of analysis and sampling in the Format for Codex Commodity Standards to insert a statement referring methods of analysis and sampling in Codex standards to those listed in CODEX STAN 234-1999 for the provisions relevant to the scope of the standard (ref. REP16/MAS para. 73 and Appendix III).
5. The Committee **is invited** to consider the endorsement of the following amendments to Section II "Elaboration of Codex texts" of the Procedural Manual proposed by CCMAS37:
 - (i) Amendments to sub-section "Working Instructions for the Implementation of the Criteria Approach in Codex" (Principle for the Establishment of Codex Methods of Analysis) (Annex 1, Part 2);
 - (ii) Amendments to sub-section "Methods of Analysis" (Format for Codex Commodity Standards) (Annex 1, Part 2).
6. A full excerpt of CCMAS37 discussion on these matters is presented in Annex 2.

AMENDMENTS TO THE PROCEDURAL
(For endorsement by CCGP and adoption by CAC)

Addition are presented in **bold underlined font**; deletion in ~~strike through font~~

Part 1

Section “Principles for the Establishment of Codex Methods of Analysis” (Section II: Elaboration of Codex Standards and related text)

Sub-section: Working Instructions for the Implementation of the Criteria Approach in Codex

Note 1: These criteria are applicable to fully validated methods except for methods such as PCR and ELISA, which require other set of criteria.

Note 2: The approaches described for developing method performance criteria are intended for single-analyte provisions. The approaches described may not be suitable for provisions involving sum of components.

Part 2

Section “Format for Codex Commodity Standards” (Section II: Elaboration of Codex Standards and related text)

Sub-section: Methods of Analysis and Sampling

This section should contain 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 standard, shall be used.”

~~This section should include, either specifically or by reference, all~~ **The** methods of analysis and sampling considered necessary and should be prepared ~~selected~~ **selected** in accordance with the guidance given in the section on Methods of Analysis and Sampling in the *Relations between Commodity Committees and General Subject Committees*. **Preference should be given to set performance criteria according to the guidance established in the General Criteria for the Selection of Methods of Analysis using the Criteria Approach.** If two or more methods have been proved to be equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives ~~and included in this section either specifically or by reference.~~

EXCERPT OF CCMAS37 DISCUSSION

(Amendments to sub-section “Working Instructions for the Implementation of the Criteria Approach in Codex” (Principle for the Establishment of Codex Methods of Analysis) (REP16/MAS paras 52-63)

CRITERIA APPROACH FOR METHODS WHICH USE A ‘SUM OF COMPONENTS’ (Agenda Item 5)¹

52. The Delegation of the United Kingdom, as chair of both the eWG and pWG, introduced the reports of the eWG and pWG. He reminded the Committee of the decision of CCMAS36 for the work to continue with the mandate as outlined in [CX/MAS 16/37/5](#), paragraph 4. The pWG had looked at examples, and concluded that there was no single mechanism for determining numeric method performance criteria for methods and that performance criteria should be addressed on a case-by-case basis.

53. The Delegation further noted that the current procedures in the Procedural Manual are for single analytes only, and an amendment might be necessary to indicate that the process was not always suitable for ‘sum of components’.

54. The Delegation reported that the pWG had considered the report of the eWG and discussed the way forward. He clarified that the document did not address toxic equivalency factors (TEFs), analyte weighting or situations where maximum levels involve both a single component and multi-component analysis and that the pWG were of the opinion that should the work proceed, then those examples where performance criteria have already been generated should be included.

55. The Delegation concluded that guidance was needed from the Committee on whether work should proceed, and if so, what the format of this work would be, i.e. what type of document was needed.

56. There was general agreement that further work was needed, as it was clear that the current procedures were not necessarily fit for purpose. Discussion was held on whether it should be an internal procedure for Codex use, or a Codex guidance directed at governments.

57. There was also support to amend the Procedural Manual to clarify that the procedures were not always suitable for a “sum of components”.

58. Concerns were raised on the complexity of the issue and that the type of document that would result, would not be suitable for inclusion the Procedural Manual.

59. The Secretariat clarified that if the procedure was developed for use by CCMAS and other Codex committees, then it was a procedural matter and it would not be appropriate to have it as a document outside of Codex. This would not preclude governments from consulting the Codex procedure. The Committee should proceed with the work and a decision could be taken a later stage on how to make it available for use in Codex.

Conclusion

60. The Committee agreed to amend the *General Criteria for the Selection of Methods of Analysis* section of the Procedural Manual and to send it to the 30th Session of the Committee on General Principles (CCGP) for endorsement and adoption by the 39th Session of the Commission (Appendix III).

61. The Committee noted that Codex Committees should consider seeking guidance from CCMAS if they wish to develop numeric values for method criteria where a sum of components is required.

62. The Committee agreed to re-establish the eWG led by the United Kingdom and working in English with the following terms of reference:

- develop a document in the style of guidance to Codex committees and CCMAS;
- concentrate on chemical methods of analysis only;
- use CX/MAS 16/37/5 as a starting point, the eWG will continue to develop guidance on how MLs and methods of analysis which involve a sum of components could potentially be converted to method performance criteria;
- note that the guidance, to be used on a case-by-case basis, will contain some of the current potential approaches available;

¹ [CX/MAS 16/37/5](#), Report of the pWG on ‘sum of components’ ([CRD 3](#)); comments of Thailand ([CRD 10](#)); Ecuador ([CRD 12](#)); India ([CRD 14](#)); Chile ([CRD 17](#)).

- include examples of where approaches have already been successfully undertaken and cover methods with TEQs/TEFs, analyte weighting and instances where an ML includes both a single analyte and sum of components; and
- investigate the existence of practical examples of sum of components outside the Codex framework.

63. The next session of the Committee will take a decision on how to take this work forward.

Amendments to sub-section “Methods of Analysis” (Format for Codex Commodity Standards) (REP16/MAS paras 72-74)

REVIEW AND UPDATE OF METHODS IN CODEX STAN 234-1999 (Agenda Item 7)²

Amendment to the Procedural Manual – CODEX STAN 234-1999 as a single source of methods of analysis and sampling for Codex standards

72. The Committee reaffirmed its earlier decision³ to have CODEX STAN 234-1999 as the single reference for methods of analysis in Codex standards and recalled the reply of CCGP29 that the amendment to the Procedural Manual to indicate a single reference for methods of analysis was possible, but that CCMAS should prepare the proposed amendments for endorsement by CCGP and adoption by CAC.

73. The Committee agreed to amend the section on methods of analysis and sampling in the *Format for Codex Commodity Standards* (Procedural Manual) to insert a statement referring methods of analysis and sampling in Codex standards to those listed in CODEX STAN 234-1999 for the provisions relevant to the scope of the standard (Appendix III).

74. The Committee noted that:

- 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 Codex standards would be done as the review and updating of CODEX STAN 234-1999 progressed and inconsistencies and other pending issues requiring action from the Codex Secretariat, Codex committees as well as international standards development organizations were resolved.
- The standards currently being developed by Codex committees would refer to CODEX STAN 234-1999 in the section on methods of analysis and sampling.
- The relevant Codex committees would still continue to identify relevant methods of analysis and sampling plans for endorsement by CCMAS or could request CCMAS to identify appropriate methods of analysis and/or sampling plans for consideration by Codex committees. Thus the practice in place for methods of analysis and sampling would not be affected by this amendment.
- The concerns raised by Observer from IFU to have a single source for methods of analysis would be addressed through a hyperlink to the relevant Codex standards.

² [CX/MAS 16/37/7](#); [CX/MAS 16/37/7 Add.1](#); [CX/MAS 16/37/7 Add.2](#); comments of Kenya ([CRD 9](#)); Thailand ([CRD 10](#)); Israel ([CRD 11](#)); Ecuador ([CRD 12](#)); El Salvador ([CRD 13](#)); India ([CRD 14](#)); Nigeria ([CRD 15](#)); European Union ([CRD 16](#)); Chile ([CRD 17](#)); Ghana ([CRD 23](#)); Switzerland ([CRD 28](#)); IFU ([CRD 29](#)).

³ [REP15/MAS](#), para 111.