CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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REP 11/MAS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Thirty fourth Session
Geneva, Switzerland, 4-9 July 2011

REPORT OF THE THIRTY SECOND SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Budapest, Hungary
7 – 11 March 2011

Note: This report includes Circular Letter CL 2011/3-MAS.

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CX 4/50.2 **CL 2011/3-MAS**
March 2011

TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme

SUBJECT: **Distribution of the Report of the 32nd Session of the Codex Committee on Methods of Analysis and Sampling (REP11/MAS)**

MATTERS FOR ADOPTION BY THE 34th SESSION OF THE COMMISSION:

Draft Guidelines at Step 8 of the Procedure

1. Draft Revised Guidelines on Measurement Uncertainty (para. 23, Appendix II).

Methods of Analysis and Sampling

2. Methods of Analysis in Codex Standards at different steps, including methods of analysis for natural mineral waters (paras. 25-51, Appendix III)

Governments and interested international organizations wishing to comments on items 1 and 2 above should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Procedural Manual of the Codex Alimentarius Commission), to the above address, before **15 May 2011**.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 32nd Session of the Codex Committee on Methods of Analysis and Sampling are as follows:

Matters for decision by the 34th Session of the Commission:

The Committee:

- Advanced to Step 8 the Draft Revised Guidelines on Measurement Uncertainty (para. 23, Appendix II);
- Endorsed or updated the status of several methods of analysis in Codex standards, including proposed methods of analysis for natural mineral waters (paras. 25-51, Appendix III);
- Agreed to propose new work on principles for the use of sampling and testing in international food trade (para. 71, Appendix IV); and
- Agreed to propose new work on provisions on proprietary methods in Codex standards to be included in the Codex Procedural Manual (para. 78).

Matters referred to other Codex Committees

The Committee:

- Noted that it would be helpful for the Secretariat of the Committee on Sugars to contact the relevant international organisations to collect information on methods of analysis for honey (para. 42); and
- Requested the Committee on Fats and Oils (CCFO) to consider the determination of relative and apparent density in relevant standards and the determination of erythrodiol+uvaol in olive oils (paras. 45-46).

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APPENDICES

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling held its Thirty-Second Session in Budapest, Hungary, from 7 to 11 March 2011, by courtesy of the Government of Hungary. The Session was chaired by Professor Árpád Ambrus, Deputy Director General, Hungarian Food Safety Office. Dr Béla Kovacs, Professor, University of Debrecen, acted as the Vice-Chairperson. The Session was attended by 141 delegates and observers representing 46 Member Countries, one Member Organisation (EU) and 9 international organizations.

OPENING OF THE SESSION

2. The session was opened by Mr Zoltán Gyaraky, Head of Department, Ministry of Rural Development, on behalf of Dr Sándor Fazekas, Minister of Rural Development. In his opening remarks, Mr Gyaraky welcomed participants to the 32nd Session of the Committee. He highlighted the importance of the agricultural sector in Hungary and the relevance of the work of the Committee and more generally the role of Codex international standards for food safety and quality in a globalised environment, taking into account consumer requirements. He recalled that Hungary had hosted the Committee since 1972, which reflected its commitment to Codex work, and was now in the post of EU Presidency for the first half of 2011.

Division of Competence[1]

3. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of Procedure of the Codex Alimentarius Commission, as presented in CRD 3.

ADOPTION OF THE AGENDA (Agenda Item 1)[2]

4. The Committee adopted the Provisional Agenda as its Agenda for the Session.

5. The Delegation of Brazil proposed that, as the working group on endorsement is an important part of the Committee's work, it should be reflected clearly in the Provisional Agenda. The Committee noted that, while currently the working group is mentioned in the invitation and in the Provisional Agenda, consideration could be given to improving their presentation.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER COMMITTEES (Agenda Item 2)[3]

6. The Committee noted that some matters were for information and that several matters would be considered under other agenda items.

7. The Committee noted the clarification from the Committee on Processed Fruits and Vegetables that the AOAC 968.30 method for drained weight mentioned a No. 8 sieve for canned vegetables and a *7/16"* sieve screen for canned tomatoes, but due to the nature of crushed style preserved tomatoes, a screen size of No. 14 sieve was needed to measure drained weight.

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1 CRD 3 (Division of competence between the European Union and its Member States according to Rule of Procedure II, paragraph 5 of the Procedural Manual of the Codex Alimentarius Commission)

2 CX/MAS 11/32/1

3 CX/MAS 10/31/2

DRAFT REVISED GUIDELINES ON MEASUREMENT UNCERTAINTY (Agenda Item 3)[4]

8. The Committee recalled that the Draft Revised Guidelines had been adopted at Step 5 by the 33rd Session of the Commission and circulated for comments at Step 6. The Chair recalled that the original purpose of the revision of the Guidelines was to include explanatory notes and not detailed technical explanations and noted that several additional issues that had been put forward in the comments and required further consideration, such as sampling uncertainty, should be considered in the framework of the discussion paper on conformity assessment and resolution of disputes The Committee therefore agreed to proceed with the finalisation of the document in its present form and in addition to editorial corrections, made the following amendments and comments.

Section 1

9. It was proposed to replace the estimate of the "true value of the concentration of the measurand" by the "true value of the measurand" for clarification purposes. However the Committee noted that the current wording was a direct quote from the text of the adopted *Guidelines on Measurement Uncertainty* and could not be amended as the main text of the *Guidelines* was not for revision.

Section 2

10. The Committee amended the first sentence to make it consistent with the text of ISO/IEC 17025, agreed that measurement uncertainty "shall be estimated and then made available if requested" and deleted the rest of the sentence concerning uncertainty and compliance as it was not necessary.

Section 3

11. The Committee agreed to insert a new paragraph to reflect that in many cases sampling uncertainty is as large as or larger than analytical measurement uncertainty, and to refer to the General Guidelines on Sampling in relation to sampling uncertainty.

Section 4

12. It was agreed to clarify that the uncertainty was associated with the result, not the method itself and the text was reworded accordingly. Some amendments were proposed to describe the values obtained in validation and/or quality control and after some discussion it was agreed to refer to "estimates of performance characteristics".

Section 5

13. The Committee recalled that there were no "recognised" procedures and amended the text accordingly, deleting also the last sentence as it was superfluous.

14. In the fourth paragraph, the text was amended to reflect that some sources of uncertainty are partly covered by validations studies; a reference to the EURACHEM Guide was inserted; and another source of uncertainty from "imprecision in estimating method or laboratory bias" was added to the list. It was also agreed to refer to "proficiency testing programmes" (instead of "schemes") throughout the text.

Section 8

15. Some delegations expressed the view that, as the notes should only provide explanations and should not address issues related to conformity assessment, the section should be either deleted as a whole or substantially reworded. Other delegations indicated that the notes were useful to clarify the situations occurring in practice

4 CX/MAS 11/32/3 (comments of Argentina, Brazil, Canada, Cuba, European Union, Japan, New Zealand, United States); CRD 9 (comments of Philippines); CRD 10 (comments of Thailand); CRD 12 (comments of Nigeria); CRD 13 (comments of Japan); CRD 18 (comments of Kenya); CRD 26 (comments of EU); CRD 27 (comments of Australia); CRD 28 (comments of Republic of Korea)

and it was agreed to retain the section and to review it in detail to ensure that it was consistent with the purpose of the revision of the Guidelines.

16. In section 8.1, the Committee agreed to insert a new sentence at the end of the second paragraph to clarify that the example illustrates how measurement uncertainty could be taken into account when interpreting analytical results on a tested sample. It was agreed to refer to "expanded measurement uncertainty" throughout the section (Situations I to IV) to ensure consistency.

17. The Committee agreed to clarify that in Situation I, the results indicate that the measured analyte in the test sample is above the specification, as this situation does not refer to the sampled lot.

18. In reply to a question, it was noted that the description of the four situations was intended to clarify the issues but not to address them or to give guidance to regulators and that such issues would be discussed further when considering the document on conformity assessment.

19. In section 8.2 Recovery, it was agreed that measurement uncertainty should include the uncertainty associated with the recovery correction or be quoted in conjunction with the stated recovery and the text was amended accordingly.

Section 9

20. The Committee agreed to amend the introductory sentence to reflect that these references were for information purposes and made editorial corrections to some references.

21. The Committee agreed to delete the fourth reference under *Procedures for the Validation of Analytical Methods and Method Performance* as there was no consensus on the relevance of this publication in the context of the Guidelines.

22. The Committee noted that all issues had been addressed and that the revision of the Guidelines was completed and therefore the document could be forwarded to the Commission for adoption.

Status of the Draft Revised Guidelines on Measurement Uncertainty

23. The Committee agreed to advance the Draft Revised Guidelines to Step 8 for adoption by the 34th Session of the Commission (see Appendix II).

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS (Agenda Item 4)[5]

24. The report of the Working Group was presented by its Chair, Dr Roger Wood (United Kingdom). The Committee considered the methods proposed for endorsement and in addition to editorial changes made the amendments and recommendations presented below (*see* Appendix III).

Part 1. METHODS OF ANALYSIS

Contaminants in Foods

25. The Committee noted that the ISO | IDF guidelines for the quantitative determination of melamine and cyanuric acid were structured according to the criteria approach and agreed to endorse them as Type IV as the method included in the guidelines was not collaboratively tested. In view of the interest of the method, ISO and IDF were encouraged to arrange collaborative testing so that the method could be endorsed as Type II.

5 CX/MAS 11/32/4; CRD 1 (Report of the Working Group); CRD 3 (Comments of the European Union); CRD 6 (Comments of Switzerland); CRD 7 (Comments of the European Union); CRD 8 (Comments of the United Kingdom); CRD 9 (Comments of Philippines); CRD 12 (Comments of Nigeria); CRD 17 (reproduction of CRD 32 of the CCNFSDU); CRD 18 (Comments of Kenya); CRD 20 (Comments of Chile); CRD 21 (Comments of Argentina); CRD 22 (Comments of ISO); CRD 23 (Comments of Malaysia); CRD 29 (Comments of AOCS)

Processed Fruits and Vegetables

26. The Committee corrected the reference to the ISO and AOCS methods for the determination of total acidity of the extracted oil in desiccated coconut, which had been updated in 2009.

27. The Committee agreed to retain the updated ISO method for mineral impurities in certain canned vegetables (canned palmito) as the method was equivalent to the AOAC method which had been endorsed as Type I.

Nutrition and Foods for Special Dietary Uses

28. The Committee recalled that its last session had endorsed the methods for the determination of dietary fibre as Type IV and asked the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to define the scope of the methods more precisely.

29. The Committee noted that the working group had discussed whether several Type I methods should be included in view of the possible overlap between these methods and had amended the type of some methods.

30. In the third group of methods, the two methods for insoluble and soluble dietary fibres were moved to the first group as these methods did not measure the lower molecular weight fraction and were retained as Type I. The Committee noted that the method for fructans (not applicable to highly depolymerised fructans) had a more limited scope and agreed to endorse it as Type III. The Committee also agreed to endorse the remaining methods in this group as Type II as they were rational methods.

31. The Committee briefly discussed the proposal to consider the use of a decision tree to facilitate the selection of adequate methods for the determination of dietary fibre. It was agreed that on the basis of the proposal put forward in CRD 8, an electronic working group, led by the United Kingdom and working in English, would consider the elaboration of a decision tree to facilitate the selection by analysts of available methods for dietary fibre, for consideration at the next session.

32. The Committee considered that at the present time, it was important for analysts to specify what method was used and for what purpose, as this would be especially relevant for enforcement and trade purposes.

Coordinating Committee for Asia

33. The Committee agreed to endorse the methods in the list proposed and to add the NMKL method for pH in chili sauce as Type II as the method had been endorsed for pH in processed fruits and vegetables as Type II.

Natural Mineral Waters

34. It was recalled that the 33rd Session of the Commission had adopted the methods for health related substances as proposed by the CCMAS and noted that additional methods for natural mineral waters could be proposed for consideration by the current session of the Committee. The Committee considered the methods proposed by Malaysia and the Philippines and their performance characteristics.

35. The Committee recalled that several methods and criteria for surface active agents, mineral oils, PCB, pesticides and PAH had been included in the list and adopted by the Commission as provisions for these substances currently appeared in the Standard for Natural Mineral Waters (sections 3.2.17 to 3.2.20). The Committee was informed that the Committee on Contaminants in Foods would discuss further these substances at its next session (March 2011) on the basis of document CX/CF11/5/15. The Committee agreed to insert a sub-heading for the above substances, already presented in a separate table, to read “performance characteristics of suggested methods”. Some delegations noted that there was a need to clarify which substances within some groups (such as PCBs) were covered by the methods.

36. The Committee agreed that it would reconsider the performance criteria and the suggested methods if maximum levels were established for these substances.

37. As it appeared from the information available on the website that the EPA 200.8 method had been collaboratively tested and met the criteria, it was agreed to insert it in the list except for the provision for borate as the method did not apply for borate.

38. Some of the other methods proposed, namely APHA 4500 for cyanide, nitrate and nitrite; APHA 4110B for fluoride; APHA 5540 for surface active agents; EPA 8015 for mineral oil; EPA 1668 for PCB; EPA 508.1 for pesticide; and EPA 550.1 for PAH had been validated in a single laboratory or the information provided as to the performance characteristics was incomplete, and it was therefore agreed not to include them in the table and to ask for further information on their performance characteristics and the status of validation for consideration at the next session.

39. The Committee agreed to delete the ISO 8288:1986, a flame-AAS method for lead because the LOD of the method did not meet the criteria. The Committee also agreed to delete the ISO 6468:1996 for PCB and pesticide because the result of the collaborative study was not sufficient to meet the criteria.

Milk and Milk Products

40. The Committee agreed to insert all editorial corrections and updates proposed by IDF and ISO to the methods for milk and milk products.

Sugars and Honey

41. It was recalled that some methods applicable to honey had been left pending as the Committee on Sugars (CCS) had been adjourned *sine die* and could not provide further clarification. The Committee agreed to amend the note for these methods accordingly.

42. The Committee agreed that more information was required from participants and especially international organisations working on methods of analysis for honey in order to take an informed decision on the status of the current methods or the possible inclusion of other methods. It was therefore agreed that the Committee reconsider the methods for honey at its next session. The Committee noted that it would be helpful for the Secretariat of CCS to contact the relevant international organisations to collect relevant information.

43. The Committee discussed the typing of the Phadebas method for diastase activity and agreed that is should be proposed as Type I as the value was dependent on the method. It was proposed to include a starch iodine test as the reference method (Type II) for the determination of diastase activity. However, as the type of the Phadebas method was not entirely clear and required further discussion, the Committee agreed not to add any additional method at this stage and to reconsider this question when further information became available. The status of all methods was retained as “temporarily endorsed” pending further discussion.

Fats and Oils

44. The Committee agreed to insert the editorial corrections proposed by ISO in CRD 22 and by AOCS in CRD 29. The Committee also agreed that methods of analysis for relative density should be Type I as in general methods of analysis relevant to physical property would be empirical.

45. One observer pointed out that IUPAC methods were no longer available and that they were used for the analysis of relative density in named animal fats and named vegetable oils. The Committee agreed to request the Committee on Fats and Oils (CCFO) whether relative density would still be necessary or it would be possible to use apparent density only instead, or whether CCFO could propose alternative methods of analysis for these provisions in case that CCFO felt that the provisions were needed.

46. The Committee also noted that the IUPAC method for erythrodiol+uvaol content in olive oils was no longer available and asked the CCFO to consider how to proceed as regards the determination of erythrodiol+uvaol, noting that the International Olive Council was currently conducting studies on methods for these substances.

47. In reply to the question whether the methods for heavy metals should be presented according to the criteria, as in the case of natural mineral waters, the Committee agreed to encourage committees to use the criteria approach.

Part 2. SAMPLING PLANS

General Comment

48. The Delegation of Brazil proposed that not only tables for the number of samples to be analysed but also operating characteristic curves should be included to provide useful information for the application of the sampling plans. The Committee however noted that the operating characteristic curve should be taken into account when developing the sampling plan in the commodity committees, but it was not necessary to include it in the sampling plan itself once it had been developed.

Contaminants in Foods

49. The Committee agreed with the provisions of the Sampling Plans for Aflatoxin Contamination in Ready-to-eat Tree Nuts and Tree Nuts Destined for Further Processing: almonds, hazelnuts, pistachios and Brazil nuts (section on Brazil nuts).

Processed Fruits and Vegetables

50. The Committee noted the clarification from the Committee on Processed Fruits and Vegetables to the effect that the sampling plans in the Standard for Jams, Jellies and Marmalades and the Standard for Certain Canned Vegetables applied to quality criteria and minimum fill provisions, and therefore endorsed the sampling plans.

Coordinating Committee for Asia

51. The Committee endorsed the sampling plans for chili sauce, noting that they applied to quality provisions.

Other Matters

52. The Committee noted the proposal from the Delegation of Canada to review the typing of the method for the determination of gluten (ELISA - R5) and agreed to consider it further at its next session, taking into account any additional information that would become available in the meantime.

53. The Committee expressed its appreciation to Dr Roger Wood and to the working group for their excellent work and agreed that the working group on endorsement would be convened prior to the next session.

GUIDANCE ON PROCEDURES FOR CONFORMITY ASSESSMENT AND RESOLUTION OF DISPUTES (Agenda Item 5)[6]

54. The Committee recalled that its last session had discontinued consideration of uncertainty of sampling as a separate item and had agreed to develop a discussion paper on procedures for conformity assessment, resolution of disputes and related issues through an electronic working group led by Brazil with the assistance of New Zealand.

55. The Delegation of Brazil introduced the discussion paper and highlighted the excellent cooperative process followed in the electronic working group, which was facilitated by the use of a website managed by New Zealand. The Delegation stressed the importance of this work for exporting countries in the perspective of ensuring food security, including in a crisis context, and indicated that Brazil had concentrated on the development of part B of the document on dispute resolution.

56. The Delegation of New Zealand indicated that they had developed mainly part A on conformity assessment and highlighted the conclusions and recommendations of the paper concerning future work, especially the need for clarification and expansion of the General Guidelines on Sampling, including

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6 CX/MAS 11/32/5, CRD 9 (comments of Philippines), CRD 11 (comments of Thailand), CRD 14 (project document prepared by the electronic working group), CRD 15 (comments of Switzerland), CRD 16 (comments of EURACHEM), CRD 18 (comments of Kenya), CRD 26 (comments of European Union), CRD 30 (project document as revised during the session)

clarification of its application to sampling in bulk, the whole of food chain approach, the development of principles and guidelines for conformity assessment and resolution of disputes, and noted that in view of the wide range of issues identified, the Committee would need to prioritise its work.

57. The Committee expressed its appreciation to the Delegations of Brazil and New Zealand and to the working group for their comprehensive work in clarifying and addressing many complex issues to facilitate the discussion in the Committee.

58. Several delegations stressed the need to avoid duplication of work with other committees, especially the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) and generally to ensure consistency between Codex texts addressing questions related to conformity assessment and resolution of disputes. The Committee agreed that new work should concentrate on the issues that were clearly the mandate of CCMAS and that items of work should be clearly prioritised, in order to address the various issues in a timely manner. It was also agreed that relevant texts developed by CCFICS would be taken into account as required.

59. Several delegations expressed the view that conformity assessment was outside the mandate of the committee and was not defined in Codex and therefore the use of this term would create confusion. It was agreed that this term should be replaced with appropriate wording in the project document.

60. The Committee discussed whether the new work would entail a revision of the General Guidelines on Sampling or whether it was preferable to retain the current Guidelines and to develop an additional document to facilitate their interpretation and practical use, in order to facilitate their application for inspection purposes.

61. As regards the consideration of disputes, some delegations pointed out that it was preferable not to reopen the Guidelines for Settling Disputes on Analytical (Test) Methods as they were the result of extensive discussions and the new document should rather concentrate on the prevention of disputes. Other delegations noted that it might be necessary to review the Guidelines as a result of new work on resolution of disputes. It was also proposed to group all requirements for conformity assessment and resolution of disputes in a single document.

62. Following the general discussion, the Committee established an in-session working group chaired by the delegations of Brazil and New Zealand, working in English, to prepare a project document in the light of the discussion.

63. The Delegation of New Zealand introduced the revised proposal in CRD 30, recalling the importance of following a scientific process: new work should concentrate on principles rather than guidelines; items of work were prioritised; the term “conformity assessment” was replaced with “procedures for the use of sampling and testing of foods in trade” in view of the concerns expressed; and it was also proposed to consider preventive measures to avoid dispute situations.

64. The Committee agreed that the title of the document to be developed should read “Principles for the Use of Sampling and Testing in International Food Trade” and that these principles should be developed on a scientific basis.

65. As regards the reference to dispute resolution, the Delegation of Brazil expressed the view that the *Guidelines for Settling Disputes on Analytical (Test) Methods* did not address all dispute situations and therefore the new document should also consider the resolution of disputes, and take into account issues that had not been previously discussed such as sampling of perishable products and its consequences at the import stage. The Committee however agreed that dispute resolution was covered by the *Guidelines for Settling Disputes,* that the new document should concentrate on dispute prevention and this was reflected in all sections referring to disputes.

66. The Committee agreed that the proposed principles would not provide detailed guidance to governments but would provide a framework for the development of guidance on the choice of an appropriate sampling and testing procedure taking into account sampling variability; considerations on measurement uncertainty; consideration of preventive measures in exporting countries to ensure exported foods meet requirements, and the possible implications of those measures for the design of sampling and testing procedures at the point of import; and reducing the probability of a subsequent dispute occurring through pre-market procedures.

67. The Committee discussed the need to control producer's and consumer's risks which were initially mentioned in the project document. Although it was clarified that these were statistical terms in the context of sampling, related to the risk of wrong decisions, several delegations expressed the view that they were not consistent with the mandate of Codex to ensure consumer's health protection and could also create confusion with the definition of risk in the framework of risk analysis. These terms were deleted throughout the text, with the understanding that these concepts would be addressed while considering sampling issues.

68. The Committee agreed that the new work should not result in a reconsideration of current approaches and procedures for establishing food safety provisions and in particular maximum limits or levels, and that no changes should be made to existing documents.

69. The Committee agreed that in Section 5, Goal 2, reference should be made to the *Working Risk Analysis Principles for Food Safety for Application by Governments* as the new principles were intended for governments.

70. As regards the timeframe, the Committee agreed that the objective was to complete the work in 2013, and that in any case the timeline should not exceed five years.

71. The Committee agreed that all questions had been clarified on the development of this new document and agreed to propose to the Commission to initiate new work according to the project document presented in Appendix IV.

72. The Committee agreed that, subject to the approval of the Commission, an electronic working group chaired by New Zealand, with the assistance of the Netherlands and the United States, working in English only, would develop Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade for circulation at Step 3 and consideration by the next session.

USE OF PROPRIETARY METHODS IN CODEX STANDARDS (Agenda Item 6)[7]

73. The Committee recalled that its last session had noted that the Inter-Agency Meeting (IAM) would proceed with its consideration of proprietary methods, invited wider contribution than only IAM members and would provide an update to the current session.

74. The Delegation of the United Kingdom introduced the discussion paper and pointed out that the problems of endorsing a proprietary method were mostly limited to Type I as for the "alternative" proprietary methods of analysis, which would be endorsed as Type III, there appeared to be little advantage in specifying such methods in national legislation or in Codex Standards. The discussion paper proposed to consider including in the Codex Procedural Manual a definition of proprietary methods and criteria for the selection of such methods, whether it would be necessary to define additional characteristics that a proprietary method should meet. The situation in which no alternative methods existed was also discussed, including a possibility to define the proprietary chemical used in the method or other alternatives.

75. Some delegations, noting that a proprietary method was easy to use for industry and competent authorities, were of the opinion that several potential problems resulted from the endorsement of proprietary methods in Codex: availability to end-users; potential risk to stop developing new methods of analysis; a "black box method" in which key information would not be disclosed; significant financial advantages for some manufacturers, which would distort competition; and difficulties for governments when using such methods for enforcement purposes.

76. Some delegations pointed out that if CCMAS would endorse a proprietary method as Type I, CCMAS should define a procedure, criteria to assess the need for the method, information requirements about the method such as performance characteristics, validation status, cross reaction, and they should be clearly stated in the Procedural Manual. The Committee noted that a proprietary method without such information would be endorsed as Type IV only.

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7 CX/MAS 11/32/6; CRD 4 (Comments of AOECS and ISO); CRD 5 REV (Comments of Japan); CRD 12 (Comments of Nigeria); CRD 18 (Comments of Kenya); CRD 19 (Comments of IAM); CRD 21 (Comments of Argentina); CRD 24 (Comments of IAM); CRD 26 (Comments of the European Union)

77. Some delegations and observers drew the attention of the Committee to the fact that the term “proprietary method” should be clearly defined as there was no internationally recognized definition, and that confusion should be avoided with intellectual property rights related to method development in general.

78. After some discussion, the Committee agreed to initiate new work on the development of provisions for proprietary methods in the Procedural Manual and agreed that an electronic working group, led by the United Kingdom and Germany and working in English, would define the term “proprietary method” and prepare a draft version of the criteria to be included in the Procedural Manual. The Committee further agreed that the definition and the draft should be circulated to invite comments from Members and Observers and it would be discussed at the next session.

Other matters

79. The Observer from EURACHEM introduced the discussion paper that had been presented in the IAM concerning the extension of the criteria approach in Codex to Type I methods (CRD 19 and CRD 24), and proposed to discuss how to apply the criteria approach, at least partially, for Type I methods.

80. The discussion paper considered the criteria that could be applied and concluded that, while trueness was not relevant, it may be useful to set additional performance criteria, particularly for precision for establishing Type I methods when the intended use is for calibration. It was proposed to note in Codex guidance that Type I methods define a measurand that could in principle be estimated using alternative methods of measurement, subject to demonstration of adequate performance as defined by the Criteria Approach.

81. Some delegations pointed out that calibration was carried out internally in laboratories but in the framework of Codex and for enforcement purposes there was no need to consider alternative methods to Type I methods, and they did not support further consideration of this approach.

82. The Committee noted that discussion on this question would proceed in the IAM and that the next session would be informed of any further development in the organisations concerned.

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 7)[8]

83. The Secretary of the Inter-Agency Meeting, Dr Richard Cantrill (AOCS), introduced the report of the 23rd meeting of international organizations working in the field of methods of analysis and sampling (IAM) held on 4th March 2011. In addition to the matters on the agenda of the Committee, the meeting had considered the activities of the organizations concerned, some of which are highlighted below.

84. The IAM had considered the criteria approach and the members had had different levels of reliance on HorRat values when determining method acceptability.

85. The Committee noted that the IAM/MoniQA workshop on Codex methods of analysis organized prior to the meeting had been very successful and attended by more than 70 delegates, and participants were invited to make proposals for a future workshop which might be held in 2012.

86. With regard to harmonisation of analytical terminology in accordance with international standards, the Committee noted that IUPAC was revising the definitions in the “Orange Book” and EURACHEM were preparing a Guide to the VIM which explained further the definition and provided “how to” information.

87. The Committee noted that when considering recovery, laboratory bias and whether data were corrected or uncorrected should be taken into account and the process for determining recovery should be documented when comparing two sets of data since recovery also contributed to laboratory bias.

88. The Committee was informed that ISO 5725, redeveloped as ISO 15725, was in a preparatory phase and that a first draft would be available within 12 months. It was further informed that the ISO standard would include concepts and definitions, trueness and the basic methodology, and examples in part 1, part 2 and part 4, respectively.

8 CRD 2 (Draft report of the 23rd Inter-Agency Meeting)

89. The Committee expressed its appreciation to the international organisations participating in the inter-agency meeting for their contribution to its work and the organisation of the IAM/MoniQA workshop, and to the Hungarian Food Safety Office for hosting the IAM. It was noted that the next IAM meeting would be held prior to the 33rd Session of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 8)

90. Other business and future work were discussed under the relevant Agenda Items.

DATE AND PLACE OF NEXT SESSION (Agenda Item 9)

91. The Committee was informed that the 33rd Session of the Committee was scheduled to be held in Hungary from 5 to 9 March 2012 and that the exact date and venue would be determined by the host country and Codex Secretariat.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP11/MAS)
Draft revised guidelines on measurement uncertainty	8	Governments 34th CAC	para. 23 Appendix II
Endorsement of methods of analysis in Codex Standards, including methods of analysis for natural mineral waters		Governments 34th CAC	paras. 25-51 Appendix III
Principles for the use of sampling and testing in international food trade	1/2/3	34th CAC eWG led by New Zealand, USA and Netherlands Governments 33rd CCMAS	para. 71 Appendix IV
Provisions for proprietary methods	(PM)	34th CAC eWG led by UK and Germany Governments 33rd CCMAS	para. 78

REP 11/MAS
APPENDIX I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

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DRAFT REVISED GUIDELINES ON MEASUREMENT UNCERTAINTY

EXPLANATORY NOTES TO THE CODEX GUIDELINES ON MEASUREMENT UNCERTAINTY

(To be included as an Annex to the Guidelines on Measurement Uncertainty (CAC/GL 54-2004))

(At Step 8 of the Procedure)

1 What is Measurement Uncertainty?

It is not always appreciated that analytical results are variable, and just how large that variability may be, particularly when low concentrations of a measurand (i.e. ppb levels) are being determined. As stated in the Guidelines, "most quantitative analytical results take the form of "a ± 2u" or "a ± U" where "a" is the best estimate of the true value of the concentration of the measurand (the analytical result) and "u" is the standard uncertainty to 68% level of confidence and "U" (equal to 2u) is the expanded uncertainty to 95% level of confidence.. The range "a ± 2u" represents a 95% level of confidence in which the true value would be found. The value of "U" or "2u" is the value which is normally used and reported by analysts, normally referred to as "measurement uncertainty" and may be estimated in a number of different ways. "

In food analysis it is the (approximately) 95% probability (i.e. 2u) which is used to calculate the expanded uncertainty. Other sectors may specify a different probability.

Thus measurement uncertainty can be regarded as the variability around the reported results which is quantified as the value "U" when considering the expanded uncertainty and within which the "true" result may be expected to lie.

2 Does the Measurement Uncertainty have to be Estimated in Codex?

Yes, one of the requirements of the ISO/IEC 17025:2005 Standard that Codex has adopted by reference is that the measurement uncertainty of a result shall be estimated and then made available if requested. The Codex Alimentarius Commission has developed Guidelines CAC/GL 27-1997 that require laboratories involved in the import/export of foods to comply with general criteria in ISO/IEC 17025. As Codex is concerned with goods moving in international trade it would be anticipated that the request for measurement uncertainty estimates will be made.

3 Does Measurement Uncertainty Arise From both Sampling and Analysis?

Measurement uncertainty applies to the whole measurement process. However, this guidance only considers analytical measurement uncertainty.

In many cases uncertainty of sampling is as large as or larger than analytical measurement uncertainty. Uncertainty of sampling is often the overriding factor in conformity assessment procedures. Sampling procedures in the *General Guidelines on Sampling* are designed to take account of uncertainty of sampling.

4 What is the Relationship between Measurement Uncertainty, the Analytical Result and the Method Used to Obtain the Result?

The uncertainty of test results is not associated with the method of analysis. However, the estimates of analytical performance characteristics that are obtained in the validation and/or in quality control of a method may be used to estimate the uncertainty of a result in some situations. The differentiation between measurement uncertainty associated with the result and precision obtained during the validation of the method is frequently not appreciated. As a consequence precision demonstrated for a validated method (the repeatability or reproducibility standard deviation) cannot be used as the sole estimate of the measurement uncertainty without qualification. In particular additional factors such as uncertainty associated with bias, matrix effect, and competence of laboratory must be considered.

5 Procedures for Estimating Measurement Uncertainty

There are many procedures available for estimating the measurement uncertainty of a result. The Codex guidelines do not recommend any particular approach, but it is important that whatever approach is used, the procedure is scientifically credible. No one approach may be said to be better than any other provided the procedure used is appropriate and credible - i.e. there is no "hierarchy" of the procedures.

In general, procedures are based on a component-by-component ("bottom-up") approach or on a "top-down" approach using data from collaborative trials, proficiency studies, validation studies or intra-laboratory quality control samples, or a combination of such data.

In the *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods* (CAC/GL 27-1997) there is a requirement to use validated methods and so it is usually more cost-efficient to use data from the method validation studies rather than using another approach (i.e. the component-by-component approach).

Users of validation data should note that sources of uncertainty that are not or only partly covered by validation studies include[1]:

- Sampling
- Pre-treatment
- Method bias
- Variation in conditions
- Changes in sample matrix
- Imprecision in estimating method or laboratory bias

For methods operating within their defined scopes, when the reconciliation stage shows that all the identified sources have been included in the validation study or when the contributions from any remaining sources have been shown to be negligible, then the reproducibility standard deviation s_R, adjusted for concentration if necessary, may be used as the combined standard uncertainty.

It is recognised that further procedures for the estimation of measurement uncertainty are being developed, and that, in this evolving situation, further recommendations will be made as to acceptable procedures. It is anticipated that procedures based on results obtained from participation in proficiency testing programmes, as an example, will be developed.

6 Considerations when Estimating Measurement Uncertainty within the Context of Codex

It is important that the requirement to estimate measurement uncertainty does not impose any unnecessary additional workloads on laboratories.

When deciding on which procedure is to be used when estimating measurement uncertainty within the Codex context it is important to recognise that Codex has adopted a number of formal quality assurance measures that have to be implemented by control laboratories. In particular, such laboratories should:

- be in compliance with an internationally recognised standard (now with ISO/IEC 17025:2005 Standard); such compliance is aided by the use of internal quality control procedures,
- participate in proficiency testing programmes, and
- use validated methods.

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[1] EURACHEM/CITAC Guide on the Use of uncertainty information in compliance assessment EURACHEM Secretariat, BAM, Berlin, 2007. This is available as a free download from http://www.eurachem.org/

It is essential that the information provided as a result of these requirements being implemented is used by laboratories when estimating their measurement uncertainties in order to avoid unnecessary work being carried out by laboratories. In Codex, where there is a high emphasis being placed on the use of "validated" methods of analysis, i.e. methods which have been validated through collaborative trials, information obtained from such trials can be used in many situations.

In addition, information derived from internal quality control procedures may also be used to estimate uncertainties in some situations.

This section re-emphasises that for the analyst it is important that no unnecessary duplication of existing work is undertaken.

7 Values of Measurement Uncertainty Estimates ~~Estimations~~

Stipulating information on the anticipated values of measurement uncertainty estimates is frequently not supported by analysts. The users of analytical data and the customers of the laboratories producing such data frequently ask for such information regarding the level of uncertainty that may be expected for test results. They have concerns that some laboratories underestimate the size of their uncertainties and so report unrealistically small uncertainties to their customers.

For chemical analyses, using the values of s_R from collaborative trials, it would be reasonable to anticipate that the (expanded) uncertainties reported by laboratories would be approximately the following:

Nominal Concentration	**Typical Expanded Uncertainty**	**Expected Range of Results***
100g/100g	4%	96 to 104g/100g
10g/100g	5%	9.5 to 10.5g/100g
1g/100g	8%	0.92 to 1.08g/100g
1g/kg	11%	0.89 to 1.11g/kg
100mg/kg	16%	84 to 116mg/kg
10mg/kg	22%	7.8 to 12.2mg/kg
1mg/kg	32%	0.68 to 1.32mg/kg
< 100µg/kg	44%	0.56 x concentration to 1.44 x concentration µg/kg

* this effectively means that values falling within these ranges may be regarded as being of the same analytical population.

It would be expected that the reported measurement uncertainties by any laboratory would not significantly exceed the value estimated from the s_R at the concentration of interest if the laboratory is in "analytical control". Very experienced laboratories carrying out any particular analysis on a regular basis would be expected to obtain uncertainty values less than the values given above.

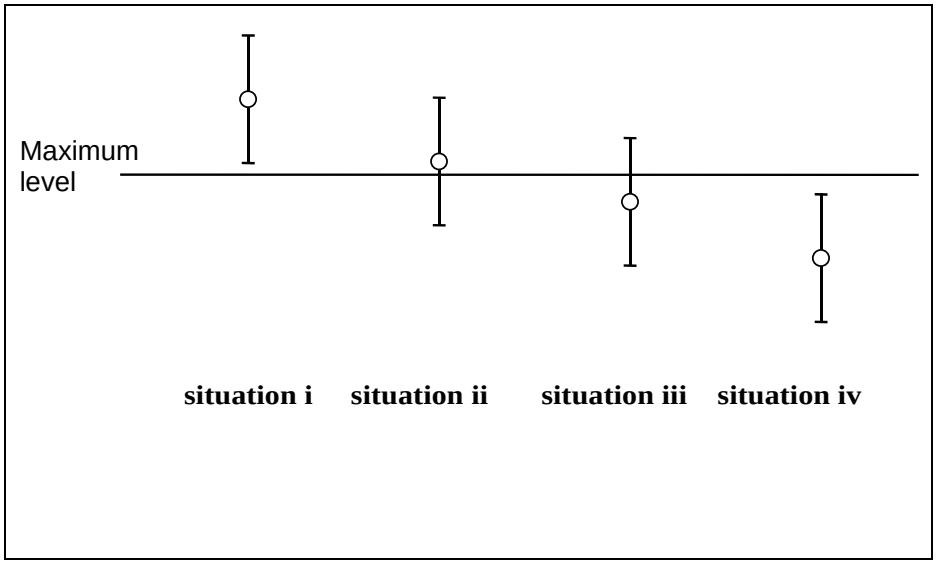
8. Relationship between analytical results, measurement uncertainty and recovery factors

This section attempts to explain the significance of analytical results and their associated measurement uncertainties and recoveries.

8.1 Measurement Uncertainty

It is important that measurement uncertainty is considered when deciding whether or not a sample meets the specification. This consideration may not apply when a direct health hazard is concerned. The significance of this can be illustrated by an example shown in the diagram below, which shows the simplest case when decisions are made based on a single test sample.

The example shown here is one where the test result is compared against the specification consisting of a maximum level. It illustrates how the concept of measurement uncertainty could be taken into account when interpreting analytical results on a tested sample.



This diagram demonstrates the importance of defining clear guidelines to allow unambiguous interpretation of analytical results with respect to their measurement uncertainties.

Situation i

The analytical result minus the measurement expanded uncertainty exceeds the maximum level. The result indicates that the measured analyte in the test sample is above the specification.

Situation ii

The analytical result exceeds the maximum level by less than the expanded measurement uncertainty.

Situation iii

The analytical result is less than the maximum level by less than the expanded measurement uncertainty.

Situation iv

The analytical result is less than the maximum level by more than the expanded measurement uncertainty.

82 Recovery

The Codex Alimentarius Commission has adopted the IUPAC Guidelines on the use of recovery information by reference (see CAC/GL 37-2001).

Analytical results should be expressed on a recovery-corrected basis where appropriate and relevant, and when corrected they have to be stated as such.

If a result has been corrected for recovery, the method by which the recovery was taken into account should also be stated. The recovery rate is to be quoted wherever possible. The uncertainty of measurement should include the uncertainty associated with the recovery correction or be quoted in conjunction with the stated recovery.

When laying down provisions for standards, it will be necessary to state whether the result obtained by a method used for analysis within conformity checks is expressed on a recovery-corrected basis or not.

9 Useful References

These references are provided for information purposes only.

Guides for the Estimation of Measurement Uncertainty

Guide 98, Guide to the Expression of Uncertainty in Measurement (GUM) ISO, Geneva (1995)

EURACHEM/CITAC Guide Quantifying Uncertainty in Analytical Measurement (Second Edition), EURACHEM 2000. This is available as a free download from http://www.eurachem.org/

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Compliance

EURACHEM/CITAC Guide on the Use of uncertainty information in compliance assessment EURACHEM, 2007. This is available as a free download from http://www.eurachem.org/

Terminology

ISO (2nd ed., 1993) VIM "International Vocabulary of Basic and General Terms in Metrology". Geneva

ISO Guide 99, International Vocabulary of Basic and General Terms in Metrology, 3rd Ed., VIM3, ISO, Geneva (2008)

REP11/MAS

APPENDIX III

STATUS OF ENDORSEMENT OF METHODS OF ANALYSIS AND SAMPLING

A. Contaminants in Foods
B. Processed Fruits and Vegetables
C. Nutrition and Foods for Special Dietary Uses
D. Coordinating Committee for Asia
E. Natural Mineral Waters
F. Milk and Milk Products
G. Sugars and Honey
H. Fats and Oils

A. COMMITTEE ON CONTAMINANTS IN FOODS

1. Methods of analysis

Maximum Levels for Melamine in Food and Feed

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Milk, milk products and infant formulae	melamine	ISO/TS 15495 | IDF/RM 230:2010	LC-MS/MS	Type IV

2. Sampling

Sampling plans for aflatoxin contamination in ready-to-eat tree nuts and tree nuts destined for further processing: almonds, hazel nuts, pistachios and shelled Brazil nuts

COMMODITY	SAMPLING PLAN	STATUS
Brazil nuts	Described in the Standards	Endorsed

B. COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

1. Methods of analysis

Proposed Draft Standard for Desiccated Coconut

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Desiccated Coconut	Ash	AOAC 950.49	Gravimetry	Type I
Desiccated Coconut	Extraneous vegetable material	See below	Counting extraneous material with the naked eye	Type IV
Desiccated Coconut	Moisture	AOAC 925.40	Gravimetry (loss on drying)	Type I
Desiccated Coconut	Oil content	AOAC 948.22	Gravimetry	Type I
Desiccated Coconut	Total acidity of the extracted oil	ISO 660:2009 or AOCS Cd 3d-63 (09)	Titrimetry	Type I

Determination of extraneous vegetable material
The determination is carried out by spreading 100 g of the sample in a thin layer against a white background and counting the extraneous material with the naked eye.

Standard for Certain Canned Vegetables (palmito)

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type proposed
Certain canned vegetables	mineral impurities (sand)	AOAC 971.33 ISO 762:2003	Gravimetry	Type I

2. Sampling

Standards for processed fruits and vegetables

COMMODITY	SAMPLING PLAN	STATUS
Certain canned vegetables, jams and jellies	Described in the Standards	Endorsed

C. COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Method of Analysis of Dietary Fibre

Standard	Provisions	Method	Principle	Type
General methods that do not measure the lower molecular weight fraction (i.e. monomeric units<=9)[(2)]				
All foods (1)	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction. (4)	AOAC 985.29 AACC Intl 32-05.01 (1991,1999)	Enzymatic gravimetry	Type I
All foods (1)	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction and also includes determination for soluble and insoluble dietary fibres (4)	AOAC 991.43 AACC Intl 32-07.01 (1999, 1991) NMKL 129, 2003	Enzymatic gravimetry	Type I
All foods (1)	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction, in foods and food products containing more than 10% dietary fibres and less than 2% starch (e.g. fruits) (4)	AOAC 993.21	gravimetry	Type I
All foods (1)	Method applicable for determining dietary fibres that do not include the lower molecular weight fraction. Provides sugar residue composition of dietary fibre polysaccharides, as well as content of Klason lignin (4).	AOAC 994.13 AACC Intl 32- 25.01 (1999, 1994) NMKL 162, 1998	Enzymatic GC/ colorimetry gravimetry	Type I
All foods (1)	Insoluble dietary fibres in food and food products (4)	AOAC 991.42 (Specific for insoluble fibre) AACC Intl 32-20.01 (1999, 1982)	Enzymatic gravimetry	Type I
All foods (1)	Soluble dietary fibres in food and food products (4)	AOAC 993.19 (Specific for soluble fibre)	Enzymatic gravimetry	Type I

General methods that measure both the higher (monomeric units > 9) and the lower molecular weight fraction (monomeric units <=9) [(2)]				
All foods (1)	Method applicable for determining the content of dietary fibres of higher and lower molecular weight, in food where resistant starches are not present	AOAC 2001.03 AACC Intl 32-41.01 (2002)	Enzymatic gravimetry and Liquid chromatography	Type I
All foods (1)	Method applicable for determining the content of dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches.	AOAC 2009.01 AACC Intl 32-45.01 (2009)	Enzymatic-Gravimetry High Pressure Liquid Chromatography	Type I
Methods that measure individual specific components (monomeric units: the whole range for each type of components is covered)[(2)]				
All foods (1)	(1→3)(1→4) *Beta*-D-Glucans	AOAC 995.16 AACC Intl 32-23.01 (1999, 1995)	Enzymatic	Type II
All foods (1)	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (applicable to added fructans)	AOAC 997.08 AACC Intl 32-31.01 (2001)	Enzymatic & HPAEC-PAD	Type II
All foods (1)	Fructans (oligofructoses, inulin, hydrolyzed inulin, polyfructoses, fructooligosaccharides) (not applicable highly depolymerised fructans)	AOAC 999.03 AACC Intl 32-32.01 (2001)	Enzymatic & colorimetric	Type III
All foods (1)	Polydextrose	AOAC 2000.11 AACC Intl 32-28.01 (2001)	HPAEC-PAD	Type II
All foods (1)	Trans-galacto-oligo saccharides	AOAC 2001.02 AACC Intl 32-33.01 (2001)	HPAEC-PAD	Type II
All foods (1)	Resistant starch (Recommended for RS3)	AOAC 2002.02 AACC Intl 32-40.01 (2002)	Enzymatic	Type II

Other methods[2] that have not been subjected to interlaboratory evaluation under AOAC international guidelines				
All foods	Insoluble glucans and mannans of yeast cell wall (for yeast cell wall only)	Eurasyp (European association for specialty yeast product) – LM Bonanno. Biospringer- 2004 – online version : http://www.eurasyp.org/public.techniq ue.home.screen.	Chemical & HPAEC-PAD	Type IV
All foods	Fructo-oligosaccharides (monomeric units<5)	Ouarné et al. 1999 in *Complex Carbohydrates in Foods*. Edited by S. Sungsoo, L. Prosky & M. Dreher. Marcel Dekker Inc, New York	HPAEC-PAD	Type IV
All foods	Non-starch polysaccharides (NSP) (3)	Englyst H.N, Quigley M.E., Hudson G. (1994) Determination of dietary fibre as non-starch polysaccharides with gas-liquid chromatographic high performance liquid chromatographic or spectrophotometric measurement of constituent sugars – Analyst 119, 1497-1509	Gas-Liquid Chromatography	Type IV

(1) Users should consult the description of each method for the food matrices that were the subject of interlaboratory study in the Official methods of Analysis of AOAC International.

(2) Two issues are left for national authorities: to include monomeric units 3-9 and which isolated or synthetic compounds have physiological benefit. (Refer to the Guidelines for Nutrition Labelling (CAC/GL 2-1985), as revised in 2009.

(3) Quantitation lost for resistant starch. Refer to specific methods.

(4) Quantitation lost for inulin, resistant starch, polydextrose and resistant maltodextrins. Refer to specific methods.

D. FAO/WHO COORDINATING COMMITTEE FOR ASIA

Proposed Draft Regional Standard for Chili Sauce

1 Methods of analysis

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Chili sauce	pH	NMKL 179:2005 (Codex general method)	Potentiometry	Type II
Chili sauce	pH	AOAC 981.12 (Codex general method)	Potentiometry	Type III
Chili sauce	Fill of containers	CAC/RM 46-1972 (Codex general method)	Weighing	Type I

2 Sampling

COMMODITY	SAMPLING PLAN	STATUS
Chili sauce	Described in the Standards	Endorsed

E. NATURAL MINERAL WATERS

Standard for Natural Mineral Waters (CODEX STAN 108-1981)

Provision	ML (mg/L)	Min. applicable range (mg/L)	LOD (mg/L)	LOQ (mg/L)	Precision RSDR (%) No more than	Recovery (%)	Suggested methods meeting the criteria	Principle
Antimony	0.005	0.0028	0.001	0.002	44	80-110	ISO 17294-2:2003 ISO 15586:2003 EPA 200.8	ICP-MS GF-AAS ICP-MS
Arsenic	0.01	0.0056	0.002	0.004	44	90-107	ISO 17294-2:2003 ISO 15586:2003 ISO 11969:1996 EPA 200.8	ICP-MS GF-AAS AAS (Hydride) ICP-MS
Barium	0.7	0.35	0.07	0.14	34	95-105	ISO 11885:2007 ISO 17294-2:2003 EPA 200.8	ICP-OES ICP-MS ICP-MS

Borate	5	3.1	0.5	1	25	97-103	ISO 9390:1990 ISO 11885:2007 ISO 17294-2:2003	Spectrophotometry ICP-MS[1] ICP-MS[1]
Cadmium	0.003	0.0017	0.0006	0.0012	44	80-110	ISO 11885:2007 ISO 17294-2:2003 ISO 15586:2003 ISO 5961:1994 (Section 3) EPA 200.8	ICP-OES ICP-MS GF-AAS AAS ICP-MS
Chromium	0.05	0.028	0.01	0.02	44	90-107	ISO 11885:2007 ISO 17294-2:2003 ISO 15586:2003 ISO 18412:2005 (Cr VI) ISO 23913:2006 (Cr VI) ISO 9174:1998 (Section 4) EPA 200.8	ICP-OES ICP-MS GF-AAS Photometric CIA, spectrophotometry AAS ICP-MS
Copper	1	0.52	0.1	0.2	32	97-103	ISO 11885:2007 ISO 17294-2:2003 ISO 15586:2003 ISO 8288:1986 EPA 200.8	ICP-OES ICP-MS GF-AAS Flame-AAS ICP-MS
Cyanide	0.07	0.039	0.014	0.028	44	90-107	ISO 14403:2002 ISO 6703-1:1998	CFA Photometric, trimetric
Fluoride	1.0	0.52	0.1	0.2	32	97-103	ISO 10304-1:2007 ISO 10359-1:1992 (dissolved fluoride) ISO 10359-2:1994 (inorganic bound)	HPLC Electrochemical probe Digestion, distillation
Lead	0.01	0.0056	0.002	0.004	44	90-107	ISO 17294-2:2003 ISO 15586:2003 EPA 200.8	ICP-MS GF-AAS ICP-MS

[1] Total Boron is determined

Manganese	0.4	0.18	0.04	0.08	37	95-105	ISO 11885:2007 ISO 17294-2:2003 ISO 15586:2003 EPA 200.8	ICP-OES ICP-MS GF-AAS ICP-MS
Mercury	0.001	0.00056	0.0002	0.0004	44	80-110	EN 1483:2007 ISO 17852:2006 ISO 5666:1999 ISO 16590:2000 EPA 200.8	AAS Enrichment by amalgamation (III) AFS AAS after tin(II) chloride reduction Enrichment by amalgamation (III) ICP-MS
Nickel	0.02	0.011	0.004	0.008	44	90-107	ISO 17294-2:2003 ISO 15586:2003 EPA 200.8	ICP-MS GF-AAS ICP-MS
Nitrate	50	37	5	10	18	98-102	ISO 10304-1:2007 ISO 13395:1996 ISO 7890-3:1988	HPLC CFA, FIA, Spectrophotometry Spectrophotometry
Nitrite	0.1	0.03	0.01	0.02	44	95-105	ISO 10304-1:2007 ISO 13395:1996 ISO 6777:1984	HPLC CFA, FIA, Spectrophotometry Spectrophotometry
Selenium	0.01	0.0056	0.002	0.004	44	90-107	ISO 17294-2:2003 ISO 15586:2003 ISO 9965:1993 EPA 200.8	ICP-MS GF-AAS AAS (Hydride) ICP-MS

Performance characteristics of suggested methods

Provision	ML	Applicable range- from:	LOD	RSDR (%)	Recovery (%)	Suggested methods	Principle
Surface active agents	-	0.05 – 5.0 mg/L	0.05 mg/l	< 44	70-100	ISO 16265:2009	CFA
Mineral oil (hydrocarbon index)	-	>0.1 mg/L		< 41	71-102	ISO 9377-2:2000	GC
PCB	-	>15 ng/L		<20	70-130	AOAC 990.06	GC ECD
Pesticide (organochlorine)	-	> 15 ng/ L		<20	70-130	AOAC 990.06	GC ECD
PAH	-	0.005 µg/L 0.04 µg/L 0.005 µg/L		<10 <18 <19	80-110 80-110 80-100	ISO 17993:2004 ISO 7981-1:2005 ISO 7981-2:2005	HPLC FD TLC HPLC

F. MILK AND MILK PRODUCTS

Update to the current list of recommended IDF/ISO methods in the section Milk and Milk Products of CODEX STAN 234

Products	Provisions	Method	Principle	Type
Milk products	Iron	ISO 6732|IDF 103:2010	Photometry (bathophenanthroline)	IV
Blend of evaporated skimmed milk and vegetable fat	Milk solids-not-fat (MSNF)[1]	ISO 6731|IDF 21:2010 and ISO 1737| IDF 13:2008	Calculation from total solids content and fat content Gravimetry (Röse-Gottlieb)	I
Reduced fat blend of evaporated skimmed milk and vegetable fat	MSNF[1]	ISO 6731|IDF 21:2010 and ISO 1737| IDF 13:2008	Calculation from total solids content and fat content Gravimetry (Röse-Gottlieb)	I
Blend of sweetened condensed skimmed milk and vegetable fat	Milk solids-not-fat (MSNF)[1]	ISO 6734|IDF 15:2010	Calculation from total solids content, fat content and sugar content	IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	MSNF[1]	ISO 6734|IDF 15:2010	Calculation from total solids content, fat content and sugar content	IV
Cream	Solids	ISO 6731|IDF 21:2010	Gravimetry (drying at 102 °C)	I
Edible casein products	pH	ISO 5546|IDF 115:2010	Electrometry	IV
Evaporated milks	Solids, total	ISO 6731|IDF 21:2010	Gravimetry (drying at 102 °C)	I

Products	Provisions	Method	Principle	Type
Milk powders and cream powders	Acidity, titratable	ISO 6091|IDF 86:2010	Titrimetry, titration to pH 8.4	I
Sweetened Condensed Milks	Solids	ISO 6734|IDF 15:2010	Gravimetry, drying at 102 °C	I
Whey cheeses by coagulation	Milk fat in dry matter	ISO 1735|IDF 5:2004 and ISO 5534|IDF 4:2004	Calculation from fat content and dry matter content Gravimetry (Schmid-Bondzynski-Ratzlaff) Gravimetry, drying at 102 °C	I

1 Milk total solids and Milk solids-not-fat content include water of crystallization of lactose

G. SUGARS AND HONEY

COMMODITY	PROVISION	METHOD	PRINCIPLE	Note	Type	Status
Honey	Fructose and Glucose (sum of both)	Harmonised method of the EHC, Apidologie, Special Issue 28, 1997, Chapter 1.7.2	HPLC	It is requested to verify that a collaborative study has been performed on this method.	II	TE
Honey	Sucrose content	Harmonised method of the EHC, Apidologie, Special Issue 28, 1997, Chapter 1.7.2	HPLC	It is requested to verify that a collaborative study has been performed on this method.	II	TE
Honey	Electrical conductivity	Harmonised method of the EHC, Apidologie, Special Issue 28, 1997, Chapter 1.2		It is requested to verify that a collaborative study has been performed on this method.	I	TE
Honey	Diastase activity	Phadebas – Harmonised method of the EHC	Enzyme	It is requested to verify that the reagents for the method are available, and a collaborative study has been performed on this method and to provide a method reference.	I	TE
Honey	Hydroxymethylfurfural	Harmonised method of the EHC	HPLC	It is requested to verify that a collaborative study has been performed on this method and to provide a method reference.	III	TE

H. FATS AND OILS

Update to the current list of recommended ISO methods in the section Fats and Oils of CODEX STAN 234

Products	Provisions	Method	Principle	Type
Fats and oils	Butylhydroxyanisol,butylhydroxytoluene, *tert*-butylhydroquinone, & propylgallate	AOAC 983.15 or AOCS Ce-6-86 (09)	Liquid chromatography	II
Fats and Oils (all)	Lead	AOAC 994.02 ISO 12193:2004 (Codex general method) or AOCS Ca 18c-91 (09)	Atomic absorption Spectrophotometry (direct graphite furnace)	II
Fats and Oils (all)	Soap content	BS 684 Section 2.5; or AOCS Cc 17-95 (09)	Gravimetry	I
Fats and oils not covered by individual standards	Acid value	ISO 660:2009; or AOCS Cd 3d-63 (09)	Titrimetry	I
Fats and oils not covered by individual standards	Copper and Iron	AOAC 990.05 ISO 8294:1994 or AOCS Ca 18b-91 (09) (Codex general method)	Atomic absorption Spectrophotometry (direct graphite furnace)	II
Fats and oils not covered by individual standards	Peroxide value	AOCS Cd 8b-90 (09) ISO 3961:2009	Titrimetry using *iso*-octane	I
Named Animal Fats	Acidity	ISO 660:2009; or AOCS Cd 3d-63 (09)	Titrimetry	I
Named Animal Fats	Copper and Iron	AOAC 990.05 ISO 8294:1994 or AOCS Ca 18b-91 (09) (Codex general method)	Atomic absorption Spectrophotometry (direct graphite furnace)	II
Named Animal Fats	GLC ranges of fatty acid composition	ISO 5508 :1990 and ISO 12966-2:2011 or AOCS Ce 2-66 (09) and Ce 1e-91 (09) or Ce 1f-96 (09)	Gas chromatography of methyl esters	II

Products	Provisions	Method	Principle	Type
Named Animal Fats	Iodine value (IV)	ISO 3961: 2009; or AOAC 993.20; or AOCS Cd 1d-92 (09)	Wijs-Titrimetry	I
Named Animal Fats	Peroxide value	AOCS Cd 8b-90 (09) ISO 3961:2009	Titrimetry using *iso*-octane	I
Named Animal Fats	Relative density	ISO/AOCS method for apparent density to be inserted	Pycnometry	I
Named Animal Fats	Refractive index	ISO 6320:2000 and corr 2006; or AOCS Cc 7-25 (09)	Refractometry	II
Named Animal Fats	Saponification value	ISO 3657:2002; or AOCS Cd 3-25 (09)	Titrimetry	I
Named Animal Fats	Titre	ISO 935:1988; or AOCS Cc 12-59 (09)	Thermometry	I
Named Animal Fats	Unsaponifiable matter	ISO 3596:2000 or ISO 18609: 2000; or AOCS Ca 6b-53 (09)	Titrimetry after extraction with diethyl ether	I
Named Vegetable Oils	Apparent density	ISO 6883:2007 with the appropriate conversion factor ; or AOCS Cc 10c-95 (09)	Pycnometry	I
Named Vegetable Oils	Acidity	ISO 660:2009; or AOCS Cd 3d-63 (09)	Titrimetry	I
Named Vegetable Oils	Apparent density	ISO 6883:2007, with the appropriate conversion factor; or AOCS Cc 10c-95 (09)	Pycnometry	I
Named Vegetable Oils	Baudouin test (modified Villavecchia or sesameseed oil test)	AOCS Cb 2-40 (09)	Colour reaction	I
Named Vegetable Oils	Copper and iron	ISO 8294:1994 or AOAC 990.05; or AOCS Ca 18b-91 (09)	AAS	II
Named Vegetable Oils	Crismer value	AOCS Cb 4-35 (97) and AOCS Ca 5a-40 (09)	Turbidity	I
Named Vegetable Oils	GLC ranges of fatty acid composition	ISO 5508:1990 and ISO 12966-2; or AOCS Ce 2-66 (09) and Ce 1e-91 (09) or Ce 1f-96 (09)	Gas chromatography of methyl esters	II

Products	Provisions	Method	Principle	Type
Named Vegetable Oils	Halphen test	AOCS Cb 1-25 (09)	Colorimetry	I
Named Vegetable Oils	Iodine value (IV)	Wijs - ISO 3961: 2009; or AOAC 993.20; or AOCS Cd 1d-92 (09); or NMKL 39 (2003)	Wijs-Titrimetry [2]	I
Named Vegetable Oils	Lead	AOAC 994.02 ; or ISO 12193: 2004; or AOCS Ca 18c-91 (09)	Atomic Absorption	II
Named Vegetable Oils	Moisture & volatile matter at 105°C	ISO 662:1998	Gravimetry	I
Named Vegetable Oils	Peroxide value (PV)	AOCS Cd 8b-90 (09); or ISO 3960: 2001	Titrimetry	I
Named Vegetable Oils	Refractive index	ISO 6320: 2000 and corr 2006; or AOCS Cc 7-25 (09)	Refractometry	II
Named Vegetable Oils	Reichert value and Polenske value	AOCS Cd 5-40 (09)	Titrimetry	I
Named Vegetable Oils	Relative density	IUPAC 2.101 with the appropriate conversion factor See comment above (Named Animal Fats) [3]	Pycnometry	I
Named Vegetable Oils	Saponification value (SV)	ISO 3657: 2002; or AOCS Cd 3-25 (09)	Titrimetry	I
Named Vegetable Oils	Slip point	ISO 6321:2002 for all oils; AOCS Cc 3b-92 (09) for all oils except palm oils; AOCS Cc 3-25 (09) for palm oils only	Open ended capillary tube	I
Named Vegetable Oils	Soap content	BS 684 Section 2.5; or AOCS Cc 17-95 (09)	Gravimetry	I
Named Vegetable Oils	Sterol content	ISO 12228:1999; or AOCS Ch 6-91 (09)	Gas chromatography	II

[2] It is possible to calculate the Iodine Value from fatty acid composition data obtained by gas chromatography e.g. using AOCS Cd 1b-87 (09)

[3] The method is no longer available.

Products	Provisions	Method	Principle	Type
Named Vegetable Oils	Tocopherol content	ISO 9936:2006 and corrigendum 2008 or AOCS Ce 8-89 (09)	HPLC	II
Named Vegetable Oils	Unsaponifiable matter	ISO 3596:2000; or ISO 18609: 2000; or AOCS Ca 6b-53 (09)	Gravimetry	I
Olive Oils and Olive Pomace Oils	Absorbency in ultraviolet	COI/T.20/Doc. No. 19 or ISO 3656:2011 or AOCS Ch 5-91 (09).	Absorption in ultra violet	II
Olive Oils and Olive Pomace Oils	Acidity, free (acid value)	ISO 660:2009 or AOCS Cd 3d-63 (09)	Titrimetry	I
Olive Oils and Olive Pomace Oils	Difference between the actual and theoretical ECN 42 triglyceride content	COI/T.20/Doc. no. 20 or AOCS Ce 5b-89 (09)	Analysis of triglycerides of HPLC and calculation	I
Olive Oils and Olive Pomace Oils	Fatty acids in the 2-position of the triglycerides	ISO 6800:1997 or AOCS Ch 3-91 (09)	Gas chromatography	I
Olive Oils and Olive Pomace Oils	Iodine value	ISO 3961:2009 or AOAC 993.20 or AOCS Cd 1d-92 (09) or NMKL 39 (2003)	Wijs-Titrimetry	I
Olive Oils and Olive Pomace Oils	Peroxide value	ISO 3960:2007 or AOCS Cd 8b-90 (09).	Titrimetry	I
Olive Oils and Olive Pomace Oils	Refractive index	ISO 6320:2000 and corr 2006 or AOCS Cc 7-25 (09)	Refractometry	II
Olive Oils and Olive Pomace Oils	Erythrodiol + uvaol content	IUPAC 2.431[4]	Gas chromatography	II
Olive Oils and Olive Pomace Oils	Lead	AOAC 994.02 or ISO 12193:2004 or AOCS Ca 18c-91 (09)	AAS	II
Olive Oils and Olive Pomace Oils	Relative density	IUPAC 2.101, with the appropriate conversion factor See comment above[5]	Pycnometry	I

[4] The method is no longer available.

[5] The method is no longer available.

Products	Provisions	Method	Principle	Type
Olive Oils and Olive Pomace Oils	Saponification value	ISO 3657:2002 or AOCS Cd 3-25 (09)	Titrimetry	I
Olive Oils and Olive Pomace Oils	Sterol composition and total sterols	COI/T.20/Doc. no. 10 or ISO 12228:1999 or AOCS Ch 6-91 (09)	Gas chromatography	II
Olive Oils and Olive Pomace Oils	Stigmastadienes	COl/T.20/Doc. no. 11 or ISO 15788-1:1999 or AOCS Cd 26-96 (09)	Gas chromatography	II
Olive Oils and Olive Pomace Oils	*Trans* fatty acids content	COI/T.20/Doc no. 17 or ISO 15304:2002 or AOCS Ce 1f-96 (09)	Gas chromatography of methyl esters	II
Olive Oils and Olive Pomace Oils	Unsaponifiable matter	ISO 3596:2000 or ISO 18609:2000 or AOCS Ca 6b-53 (09)	Gravimetry	I
Olive Oils and Olive Pomace Oils	Wax content	COI/T.20/Doc. no. 18 or AOCS Ch 8-02 (09)	Gas chromatography	II
Infant formula	Fatty acids (including trans fatty acid)	AOCS Ce 1h-05 (09)	Gas chromatography	III

PROJECT DOCUMENT

PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE

1 Purpose and scope of the proposed document

The purpose of the proposed document is to set out the principles on a scientific basis for the use of sampling and testing to determine whether foods in trade meet specifications, and how to avoid potential disputes.

2 Relevance and timeliness

Many food standards include specifications that are verified by sampling and testing. Such specifications need to include procedures for determining whether foods in trade do, in fact, meet the specifications, and the level of protection afforded to consumers and the risks carried by producers are known. Without such procedures, both importing and exporting countries may use *ad hoc* procedures, and disputes are more likely to occur and be difficult to resolve.

The *General Guidelines on Sampling* state that methods "are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard". To ensure the procedures are valid, they need to be based upon sound scientific principles, and ensure that they can be applied fairly.

This new work shall not affect the current way of setting Codex limits.

3 Main aspects to be covered

The proposed document will outline the scientific principles for determining whether foods in trade meet specifications, based on sampling and testing of those foods, and implications for prevention of disputes. It would acknowledge that there are risks of making incorrect decisions whenever food is sampled and tested. While these risks can never be entirely eliminated, there are means by which they can be evaluated and controlled using sound scientific methods.

The proposed principles would provide a framework for the development of guidance on:

- Choice of an appropriate sampling and testing procedure taking into account sampling variability
- Considerations on measurement uncertainty
- Consideration of preventive measures in exporting countries that ensure exported foods meet requirements, and the possible implications of those measures for the design of sampling and testing procedures at the point of import
- Reducing the probability of a subsequent dispute occuring through pre-market procedures.

4 Assessment against the criteria for the establishment of work priorities

General criterion

The work will ensure that procedures for determining whether foods in trade meet specifications and provide appropriate and clear levels of protection for consumers. It will treat both importing and exporting countries fairly, pointing out also the importance of the inherent risks in these activities.

The principles will assist developing and developed countries in establishing appropriate procedures for determining if both imported and exported food meet specifications, and in prevention of disputes. On a global scale the work will contribute to reduction of adverse human health effects through appropriate control of food-borne risks, will advance fair practices in food trade, and will help to avoid costly, disruptive and wasteful disputes.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade. This new work will assist all member countries in establishing appropriate procedures for sampling and testing of both imported and exported food, resulting in less likelihood of disputes.

(b) Scope of work and establishment of priorities between the various sections of the work. The work will provide Codex with a new document that demonstrates the implications of procedures for sampling and testing of foods in preventing disputes and guaranteeing fair trade practices and appropriate protection of consumers´ health.. The work should be relatively simple since a great amount has already been done by the eWG.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

This work does not duplicate any work already undertaken by other international organizations. The document would take into account relevant work by other international organizations.

5 Relevance to the Codex strategic objectives

The proposed work contributes to all five goals of the Codex Strategic Plan 2008-2013.

Goal 1: Promoting sound regulatory frameworks

This work emphasizes a horizontal approach to principles of sampling and testing of foods in trade and preventing disputes, and is not overly prescriptive nor more trade restrictive than necessary, while respecting the basic objectives of the Codex. It takes into consideration the technical and economic implications for all members as well as the special needs of developing countries including infrastructure, resources and technical and legal capabilities.

Goal 2: Promoting widest and consistent application of scientific principles and risk analysis

This work applies scientific principles to sampling and testing of foods in trade and preventing disputes. The principles would assist management of associated risks, and would be consistent with the Working Principles for Risk Analysis for food safety for application by governments.

Goal 3: Strengthening Codex work-management capabilities

The principles would streamline Codex work by providing guidance for all Codex committees that develop specifications for food that are verified by testing.

Goal 4: Promoting cooperation between Codex and relevant international organizations

The principles would support the work of other international bodies by clarifying what is needed for decisions based on the sampling and testing of food.

Goal 5: Promoting maximum and effective participation of Members

The new work affects all members of Codex and may trigger further participation of both developing and developed countries with interests in trade of foods and food ingredients. (It is noted that 22 member countries from the five continents and three international organizations with the status of observers, participated in the eWG that developed the discussion paper that will form the basis for this proposed new work.)

6 Information on the relation between the proposal and other existing Codex documents

Already existing in Codex are principles and guidelines on systems for the inspection and certification of food in trade, and other relevant documents issued by CCFICS. The proposed principles document would be developed within the context of those documents but its scope would be limited to matters within the mandate of CCMAS.

Also existing are guidelines on measurement uncertainty, sampling, and settling disputes over analytical (test) results. The proposed document would provide a framework for existing and possible future guidance on the use of sampling and testing to determine whether foods in trade meet specifications, and how to prevent disputes.

The preparation of the proposed principles document will be consistent with the *Procedural Manual*, and recognise the existence of related material prepared by other committees.

The proposed principles document would go beyond these existing Codex documents by providing overall horizontal principles, while referring to existing documents where appropriate.

No changes to existing documents would be made or recommended.

7 Identification of any requirement for and availability of expert scientific advice

The proposed principles document can be prepared without a major effort related to scientific advice, since most of the advice has already been presented in the eWG discussion paper. Additional scientific advice could be provided by international organizations occupying themselves with standardization.

8 Identification of any need for technical input to the standard from external bodies so that this can be planned for

None identified.

9 Proposed time-line for completion of the new work

The following timeline is proposed for the completion of the work, preferably for final adoption in 2013. The timeline should not exceed five years (2016).

Timetable	Meeting	Progress
July 2011	34th CAC	Approval of new work
		Preparation of Proposed Draft Principles. Circulation for comments at step 3.
March 2012	33rd session of CCMAS	Consideration of the Proposed Draft Principles and advance to 35th CAC for adoption at step 5
July 2012	35th CAC	Adoption at step 5
		Circulation for comments at step 6
March 2013	34th session of CCMAS	Consideration of the Draft Principles at step 7 and advance for adoption at step 8
July 2013	36th CAC	Final adoption.