

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**REP18/MAS**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

***41<sup>st</sup> Session***

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**REPORT OF THE 39<sup>th</sup> SESSION OF  
THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**

***Budapest, Hungary***

***7 - 11 May 2018***

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## SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text / Topic	Code / Reference	Step	Para(s)
Members CCEXEC75 CAC41	Adoption / revocation	Methods of analysis / performance criteria for provisions in Codex standards	CXS 234-1999	-	22, Appendix II
CCNFSDU	Clarification/ harmonisation	Provision for Vitamin D	CXS 72-1981	-	12 and 22
CCCF	Action / Information	Sampling plan for methylmercury in fish and related questions	-	-	18,20,22
	Information	STC	-	-	21
CCCPL	Information	Saponins	-	-	17, 22
EWG (USA)/ CCMAS40	Discussion	Guidance for endorsement	-	-	34(i)
EWG (USA / NZ) PWG on endorsement CCMAS40	Review / update	Dairy workable package	CXS 234-1999	-	34(ii)
AACCI / AOCS	Review / update	Cereals, pulses and legumes and fats and oils workable packages	CXS 234-1999	-	47
Secretariat CAC41	Adoption	Editorial corrections	CXS 234-1999	-	34(iii)
EWG (Brazil / Uruguay) PWG (Brazil/Uruguay) CCMAS40	Revision	Preamble and structure of CXS 234-1999	CXS 234-1999	2/3	47, Appendix III
Codex and Hungarian Secretariat CAC40	Information	Information document of provisions updated since CCMAS39 (new format)	CXS 234-1999	-	47
CCMAS39	Discontinued	Criteria for endorsement of biological methods to detect chemicals of concern	-	-	54
CCEXEC75 CAC41 EWG (Germany) CCMAS40	New work	Revision of the <i>Guidelines on measurement uncertainty</i>	CXG 54-2004	-	61, Appendix IV
CCEXEC75 CAC41 EWG (New Zealand) CCMAS40	New work	Revision of the <i>Guidelines on Sampling</i>	CXG 50-2004	-	71, Appendices V and VI
PWG (USA / Australia) CCMAS40	Endorsement	Methods of analysis and sampling for endorsement and other related matters	CXS 234-1999	-	23

### LIST OF ABBREVIATIONS

AACCI	The American Association of Cereal Chemists International
AOAC	AOAC International (formerly known as Association of Official Agricultural Chemists)
AOCS	American Oil Chemists' Society
CAC	Codex Alimentarius Commission
CCCF	Committee on Contaminants in Foods
CCCPL	Committee on Cereals, Pulses and Legumes
CCFH	Committee on Food Hygiene
CCMAS	Committee on Methods of Analysis and Sampling
CCNFSDU	Committee on Nutrition and Foods for Special Dietary Uses
CRD	Conference room document
EU	European Union
EWG	Electronic working group
HPLC	High performance liquid chromatography
IAM	Interagency Meeting
IDF	International Dairy Federation
ISO	International Organization for Standardization
NFCISO	National Food Chain Safety Office (Hungary)
ML	Maximum level
MU	Measurement uncertainty
PWG	Physical working group
SDO	Standards development organisations
USPC	United States Pharmacopeial Convention
UV	Ultra violet
WG	Working group

## INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling (CCMAS) held its 39<sup>th</sup> Session in Budapest, Hungary, from 7 to 11 May 2018, at the kind invitation of the Government of Hungary. The Session was chaired by Dr. Marót Hibbey, Veterinary officer, Ministry of Agriculture. Dr. Attila Nagy, Vice director, National Food Chain Safety Office (NFC SO) and Dr Andrea Zentai, Food Safety Analyst (NFC SO), acted as the Vice-Chairpersons. The Session was attended by 51 Member countries and 1 Member organization and 13 observer organizations. A list of participants is given in Appendix I.

## OPENING OF THE SESSION

2. The Session was opened by Dr. Lajos Bognár, Chief Veterinary Officer of the Ministry of Agriculture who welcomed delegates to Hungary. Dr Márton Oravec, President of the NFC SO and Ms. Mary Kenny, Food Safety and Consumer Protection Officer, Regional Office for Europe and Central Asia (REU) of the Food and Agriculture Organization of the United Nations (FAO) also attended the opening ceremony. Dr. Lajos Bognár, reminded the Committee of the importance of Codex standards considering global food trade and rapid development of food technologies, and wished the Committee successful deliberations.

## Division of Competence<sup>1</sup>

3. CCMAS noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission.

## ADOPTION OF THE AGENDA (Agenda Item 1)<sup>2</sup>

4. CCMAS agreed to the proposal from the chair to have a discussion under Agenda Item 9 on the work output of the Committee and adopted the agenda as amended.
5. CCMAS agreed to establish in-session working group (WG) on the *Revision of the Recommended Methods* (CXS 234-1999) chaired by Brazil, to consider comments submitted on the preamble and structure of CXS 234 and to prepare a revised preamble and structure.

## MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (Agenda Item 2)<sup>3</sup>

6. CCMAS noted (i) the matters of interest arising from the Codex Alimentarius Commission (CAC) and its subsidiary bodies; and (ii) several matters for action had been considered by the physical Working Group (PWG) on endorsement and would be considered under Agenda Item 3.

## Matters of interest arising from other international organizations (Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture)

7. The Representative of the Joint FAO/IAEA Division provided a summary of their technical cooperation activities in the Latin America and Caribbean region, Africa and lately in the Asian region. The Representative also provided information on their coordinated research activities and work in support to Codex and relevant committees in the areas of analytical methods; pesticide residues, veterinary drugs, contaminants in food and feed, and on food integrity/authenticity.
8. CCMAS noted the information and thanked IAEA for their contribution.
9. CCMAS also encouraged other organizations to submit relevant information which could be presented under an item 'Matters of Interest arising from other international organizations' in future.

## ENDORSEMENT OF METHODS OF ANALYSIS AND SAMPLING PLANS FOR PROVISIONS IN CODEX STANDARDS (Agenda Item 3)<sup>4</sup>

10. CCMAS considered the recommendations on methods of analysis and the sampling plan proposed for endorsement and other related matters as presented in CRD2. CCMAS agreed with some of the recommendations of the WG and made the following amendments or recommendations. All decisions are presented in Appendix II.

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<sup>1</sup> CRD1

<sup>2</sup> CX/MAS 18/39/1

<sup>3</sup> CX/MAS 18/39/2; CX/MAS 18/39/2-Add.1; CX/MAS 18/39/2-Add.2; CRD2 (Report of the PWG on Endorsement); CRD8 (Kenya)

<sup>4</sup> CX/MAS 18/39/3; CX/MAS 18/39/3-Add.1; CRD2 (Report of the PWG on Endorsement); CRD3 (AOAC, ISO and IDF); CRD4 (Switzerland and IDF); CRD7 (Philippines); CRD8 (Kenya); CRD10 (Ghana); CRD11 (India); CRD12 (Ecuador)

**Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)**Methods of analysis for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)

11. CCMAS noted the clarification from AOAC that AOAC 995.05 method for the determination of Vitamin D<sub>3</sub> used an internal standard, which was necessary for analytical methods (included hot saponification as part of the sample preparation) and was fit for purpose. In view of this clarification, the Committee agreed to endorse the method as Type III and clarified the principle as HPLC-UV.
12. CCMAS agreed to request CCNFSDU to clarify the provision for Vitamin D in CXS 72 - 1981 noting the disparity between the provision in CXS 72 - 1981 (Vitamin D<sub>3</sub>) and the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children* (CXG 10-1979), which indicated the source of Vitamin D as Vitamin D<sub>2</sub> and Vitamin D<sub>3</sub>.
13. CCMAS also noted that ISO 20636 for determination of Vitamin D and ISO 21422 | IDF 242 for determination of chloride had been finalized and publication would be prior to CAC41, and agreed to endorse the method and recommend adoption by CAC41 pending publication.

**Committee on Milk and Milk Products (CCMMP)**Methods of analysis for dairy permeate powders

14. CCMAS did not endorse the method for lactose, anhydrous (ISO 22662|IDF 198:2007) as the method has been validated in a number of milk based products, but would require a change to the mass of test portion analysed when applied to dairy permeate powder. The Committee agreed that this change should be made to the method prior to endorsement and typing as Type II.

**Committee on Cereals, Pulses and Legumes (CCCPL)**Methods of analysis for quinoa*Moisture content*

15. CCMAS agreed to also endorse the AACCI 44-15.02 for the determination of moisture as Type I, noting that the method was identical to ISO 712.

*Protein content*

16. CCMAS agreed to endorse the general method, ISO 1871 as Type IV for the determination of protein content, noting that under a project undertaken in several Andean countries, the method had been validated for protein determination in quinoa. The Committee agreed that the method could be retyped as Type I, pending submission of the validation data in quinoa to CCMAS40.

*Saponins*

17. CCMAS was not in a position to recommend a suitable method for determination of saponins, and noted the interest of AACCI to undertake collaborative studies using an appropriate method. The Committee agreed to inform CCCPL accordingly.

**Committee on Contaminants in Foods (CCCF)**Sampling plan for MLs for methylmercury in fish (CXS 193-1995)

18. CCMAS did not endorse the sampling plan for MLs for methylmercury in fish for the following reasons:
  - Table 5 (*performance criteria for methods of analysis of mercury and methylmercury*) in the sampling plan would need to be revised according to the requirements of the Procedural Manual (*Guidelines for establishing numeric values for the criteria*) or should be removed from the sampling plan and replaced with a reference to the Procedural Manual.
  - The measurement uncertainty, in the view of some delegations, should not be used in decision rule in Codex Standards for acceptance or rejection of lots (section on Interpretation of Results); and this approach was not consistent with other sampling plans already adopted for contaminants in foods.

Performance criteria for methods of analysis for mercury and methylmercury (Table 7)

19. CCMAS noted that the PWG had amended Table 7 to meet the format or information currently used in the requirements and format in the Procedural Manual, and in CXS 234 - 1999 and endorsed the performance criteria for methods for methylmercury as proposed by the PWG. CCMAS also agreed to include example methods which could meet the criteria, the previously endorsed AOAC 988.11, except for in all tuna, and an EN 16801. The Committee noted that this list was not exhaustive and served only as examples of methods

that meet the criteria for methods for methylmercury and that countries could choose any other methods that meet the criteria.

#### Request for advice

20. CCMAS agreed to inform CCCF that it was not in a position to reply to the questions from CCCF as the questions were outside the remit of CCMAS. The Committee encouraged delegates to CCMAS with the necessary background to respond to the questions through their CCCF delegates.
21. CCMAS encouraged standards development organizations to develop an international validated method for Sterigmatocystin(STC) in cereals.

#### Conclusion

22. CCMAS agreed to:
  - send the methods of analysis and performance criteria, as endorsed, to CAC41 for adoption (Appendix II);
  - request clarification from CCNFSDU on the provision for Vitamin D in CXS 72 and harmonization with GL10 (para.12);
  - return the sampling plan for MLs for methylmercury to CCCF for further consideration and to inform CCCF that CCMAS was unable to respond to the questions raised in relation to the sampling plan (see para. 20); and
  - inform CCCPL that no method for saponins was identified (para. 17).
23. CCMAS agreed to re-establish the PWG on endorsement of methods of analysis and sampling, chaired by USA and co-chaired by Australia, working in English, to meet immediately prior to the next session. CCMAS noted that Hungary, as host of the Committee would consider the possibility for interpretation also to French and Spanish.

#### **Questions raised by IDF/ISO/AOAC<sup>5</sup>**

24. CCMAS noted that there were several questions raised during the review of the dairy group workable package which required clarification in order to allow a consistent approach to endorsement of methods.

#### *Need for precision figures for Type I methods*

25. CCMAS agreed that precision figures for Type I methods are an important aspect of assessing the performance of methods and that for newly developed / proposed Type I methods, precision figures should be presented as part of the data reviewed during the endorsement process. There was also agreement that while such data for longstanding methods would be beneficial, lack of such data would not cause a change in the method type or revocation of a method.

*If a defining method has been subjected to an international collaborative study involving dairy commodities A, B and C, and the method is generally known to work on commodity D, but this commodity was not included in the study, should the method then be listed as Type I or Type IV in CXS 234 for commodity D*

26. CCMAS agreed that a general rule to extend or not extend the typing was not appropriate because the decision would depend on the matrices involved as well as the analytical procedure. The typing determination should therefore, be based on a case-by-case basis.

*Clarify the situation where there are two defining methods (from different organisations) and the degree of validation differs (i.e. one method has been subjected to an international collaborative study, whereas the other method has not), whether one method be Type I and the other method, Type IV, or only one (the best validated) method should be accepted and listed as Type I*

27. CCMAS noted that it was necessary to clarify the terms “technically equivalent” and “technically identical” prior to discussion on this question. (For conclusion see para. 34).

*Clarify those cases where a provision is not specifically listed in the commodity Standard, what decision process is to be followed to determine whether or not to include such provision in CXS 234 - 1999*

28. CCMAS agreed that some indication in the commodity Standard should exist in order for a provision to be listed in CXS 234 - 1999. It was further agreed that the indication did not have to be a specific provision in the standard, but could also be a general text.

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<sup>5</sup> CX/MAS 18/39/4-Add.1

*Apply a consistent approach in listing provisions that require a calculation based on two or more analyses. In some cases, all concerned methods are listed; in other cases only a single method*

29. CCMAS agreed that all concerned methods should be listed and separated by the word “and”. When a provision is determined by calculation, a brief description of the calculation shall be given in the principle column.

Other questions related to the review of the dairy group workable package

30. CCMAS noted that the PWG had begun the review of the dairy group workable package and in this review several questions had been raised about the applicability of some methods and about previous endorsement and typing decisions, amongst others, but that no agreements were reached. Noting that further consideration should be given to these questions as well as the need to clarify terminology (para .34), CCMAS agreed that a paper should be developed to provide proposals on the way forward.
31. CCMAS further noted that the dairy group workable package required further review in order to provide proposals for consideration by the PWG on endorsement of methods and CCMAS40. CCMAS also noted that a significant proportion of the methods identified in this package required no further correction or clarification and, that editorial corrections to some other methods could be addressed by the Codex Secretariat.
32. It was also noted that several agreements had been made at this session and in the past, and that it was necessary to record the agreements in a single place to guide the work on endorsement.
33. The Secretariat proposed that CCMAS consider developing a guidance document on a procedure to ensure a consistent approach to endorsement of methods of analysis and that such a procedure could be published as an information document. Consideration could also be given to formalising some decisions by inclusion in the Procedural Manual.

**Conclusion**

34. CCMAS agreed:
- (i) to establish an EWG chaired by USA working in English to develop a discussion paper for presentation to CCMAS40 which would address and recommend guidance for the endorsement and designation of empirical methods as Type I and/or Type IV and issues around two Type II methods for the same provision and commodity. The discussion paper will address among others the following questions:
    - When there are two empirical (i.e. defining) methods (from different organizations) and the degree of validation differs (i.e. one method has been subjected to an international collaborative study, whereas the other method has not), should one method be Type I and the other method Type IV, or should only one (the best validated) method be endorsed and be listed as Type I?
    - Can 2 different empirical methods be endorsed as Type IV for the same commodity and provision?
    - Clarify when two different reference methods endorsed as Type II for the same commodity and provision are identical.
  - (ii) to establish an EWG chaired by USA and co-chaired by New Zealand working in English to continue with the review of the dairy group workable package.
  - (iii) that the Codex Secretariat would do the editorial corrections to some of the methods identified in the dairy workable package.

**REVIEW / REVISION (UPDATE) OF THE STANDARD FOR METHODS OF ANALYSIS AND SAMPLING (CXS 234-1999) (Agenda Item 4)<sup>6</sup>**

35. Brazil, as Chair of the EWG and the in-session WG on the revision of CXS 234, introduced the item and highlighted the key points of the discussion, conclusions and recommendations put forward by the in-session WG for consideration by CCMAS.
36. CCMAS considered the document as revised by the in-session WG and made comments and decisions as follows:

**PART I – PREAMBLE**

*Structure*

<sup>6</sup> CL 2018/18/OCS-MAS; CX/MAS 18/39/4; CX/MAS 18/39/4-Add.1; CX/MAS 18/39/4-Add.2 (Ecuador, Egypt, Canada, Guatemala, Kazakhstan, Mexico, Norway, Switzerland, USA, AOCS, IUFOST and NMKL); CRD2 (Report of the PWG on Endorsement); CRD5 (Sudan and EU); CRD8 (Kenya); CRD10 (Ghana); CRD11 (India); CRD17 (Report of the in-Session WG on the revision of CXS 234)



37. CCMAS agreed that the Annexes were useful but should be simplified and retained as an internal document to guide the work of the Committee when revising and updating CXS 234. In particular for the commodity categorization, they should be aligned with the commodities as currently described in CXS 234 which reflect the structure of CAC and its subsidiary bodies (e.g. commodity committees) and would therefore facilitate the inclusion of commodities and corresponding methods of analysis in CXS 234.
38. CCMAS also agreed that the structure of CXS 234 should reflect the current policy of CCMAS to encourage Codex committees to develop method performance criteria as opposed to the identification of methods of analysis and as such identified four sections that would constitute the structure of CXS 234.
39. It was clarified that section I did not list any method performance criteria nor analytical methods but provided an indication of the method performance criteria and/or analytical method available for a given commodity/provision combination. The links to the available method performance criteria / analytical method would lead to sections II (method performance criteria); III (list of methods developed by international organizations e.g. AOAC, IDF, ISO, etc.); and IV (description of methods developed by Codex i.e. CAC/RMs).
40. It was further noted that one of the goals of the revision of CXS 234 was to have a user-friendly document to easily identify methods available for compliance with the provisions in Codex standards. Thus the inclusion of section I may introduce unnecessary complexity to CXS 234 and give rise to inconsistencies between the information given in this section and the subsequent sections, and make maintenance of the Standard difficult. The Codex Secretariat noted that this matter could be further considered by the EWG on the revision of CXS 234 as part of its next exercise.

#### *Definitions*

41. CCMAS agreed that the description provided under Part II (Methods of Analysis) was sufficient to address the definition / interpretation of "identical methods" and thus there was no need to define "technically equivalent methods" in the Standard.
42. CCMAS further agreed that when a method is endorsed as Type I for a specific commodity/provision combination, only one method should be listed in CXS 234. For some commodity/provision combinations CXS 234 may list more than one method and these methods have been determined to be identical. Identical methods, published in a single document by different SDOs, are in the same row separated by a vertical bar "|". Identical methods, published in separate documents by different standard development organizations, that differ only in formatting and written differently but that contain identical technical procedures are in the same row and separated by a forward slash "/".
43. CCMAS agreed to add a definition for method performance criteria in line with the definition in the Procedural Manual and the definition of provision was clarified to cover both quality and safety provisions by referring to criterion only.

#### PART II – METHODS OF ANALYSIS

44. CCMAS agreed that explanatory text under this provision would require further consideration especially as to the description of provisions determined by calculation where two or more methods and a calculation are required to get the result of the relevant provision.

#### OTHER MATTERS

45. CCMAS recalled that the dairy group workable package was considered under Agenda Item 3 and that for those provisions which had been updated or, for which no further work were required, they would, in addition to being listed in CXS 234, also be included in an excel spreadsheet in the revised format agreed by CCMAS to populate the future database on methods of analysis and sampling. In addition, all provisions endorsed by CCMAS from now onwards would be kept in an excel spreadsheet in the revised format and made available to CCMAS at every session as an information document to facilitate work on endorsement of provisions from Codex committees (see Agenda Item 3).
46. CCMAS noted that workable package on the inconsistencies was still pending revision except the dairy package.

#### Conclusion

47. CCMAS agreed:
- to return the revision of CXS 234 to Step 2/3 for further consideration by an EWG chaired by Brazil and co-chaired by Uruguay, to further develop CXS 234 (Introduction, Part I, Part II and sections I – IV). The Annexes (I: structure; II: provisions; and III: principles) would also be revised and simplified (for internal use by CCMAS). The EWG would work in English only. The revised CXS 234 (preamble and sections I – IV) are attached in Appendix III.

- to proceed with the update on workable packages for (i) cereals, pulses and legumes; and (ii) fats and oils. The revision will be led by AACCI (cereals, pulses and legumes) and AOCS (fats and oils). All interested members and SDOs are invited to assist in this work as appropriate. The same protocol followed by IDF, ISO and AOAC in the revision of the dairy group workable package will be followed and enhanced.
- the Codex and Hungarian Secretariats would create and maintain an excel spreadsheet in the revised format with provisions which had been updated and for which no further work were required.
- The Codex Secretariat will issue a circular letter requesting comments on the workable package on inconsistencies and all comments submitted will be addressed by the EWG chaired by Brazil and co-chaired by Uruguay.

48. CCMAS further agreed that a PWG chaired by Brazil, and co-chaired by Uruguay, could be held prior to the next session of the Committee as required and subject to confirmation by the Host Country Secretariat. The possibility to provide for simultaneous interpretation in English, French and Spanish to facilitate discussion and work progress would also be considered.

#### **CRITERIA FOR ENDORSEMENT OF BIOLOGICAL METHODS USED TO DETECT CHEMICALS OF CONCERN (Agenda Item 5)<sup>7</sup>**

49. Chile, as Chair of the EWG also on behalf of Mexico, co-Chair of the EWG, presented the report of the EWG. She explained that they had evaluated two example biological methods, i.e. AOAC 959.08 and AOAC 992.07 first against the *General criteria for the selection of methods of analysis*; and then the *Guidelines for the establishment of numerical criteria* in the Procedural Manual in order to look for practical evidence of the application of both sets of criteria recognized by Codex; and also against other criteria gathered from other international references. She explained that while the performance criteria established in the Procedural Manual were established for approving chemical methods, some of these criteria could be applied for the adoption and classification of biological methods and in addition, other criteria from other relevant international organisations could be used for evaluation of biological methods.
50. The EWG recommended that the current criteria could be used on a case-by-case basis and that there was no further need for additional criteria.

#### **Discussion**

51. There was general support to evaluate biological methods on a case-by-case basis using the *General Criteria for Selection of Methods of Analysis* in the Procedural Manual.
52. Proposals were made to also consider the use of other criteria from other recognized international organizations, for example, the AOAC International Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures.
53. Noting the general agreement for the use of the criteria from the Procedural Manual on a case-by-case basis, and the proposal to consider also other criteria (see paras 51 - 52), a proposal was made to clarify this by adding a note (Note 3) to the *Working Instructions for the Implementation for the Criteria Approach in Codex*. However, there was no support for this proposal.

#### **Conclusion**

54. CCMAS agreed that no further work was necessary and to use the *General Criteria for the Selection of Methods of Analysis* in the Procedural Manual, but may consider other criteria referenced in other internationally recognized organizations' documents on a case-by-case basis for evaluation of biological methods.

#### **PROPOSAL TO AMEND THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54-2004) (Agenda Item 6)<sup>8</sup>**

55. Germany, Chair of the EWG, recalled the history of discussion in CCMAS and highlighted the key issues discussed in the EWG that needed consideration by CCMAS in order to proceed with the new work, i.e. (i) the influence of measurement uncertainty (MU) on decision-making and its role in conformity assessment of a particular analytical test sample; and (ii) the relationship between MU and sampling plans. She noted that discussion on these aspects would be needed in order to provide a clear scope for the new work.

<sup>7</sup> CX/MAS 18/39/5; CRD6 (EU); CRD8 (Kenya); CRD9 (Morocco); CRD15 (Philippine)

<sup>8</sup> CX/MAS 18/39/6; CRD6 (EU); CRD8 (Kenya); CRD12 (Ecuador); CRD13 (New Zealand); CRD15 (Philippines)

## Discussion

56. There was general agreement that the Guidelines needed revision in order to improve and clarify the content, but that the guidelines should not cover how MU would influence the decision-making process regarding conformity assessment. Views were expressed that conformity assessment and the use of uncertainty of analytical results should rest with national governments or agreements between trading partners. It was also noted that this aspect was not covered by the current GL 54 and that the *Principles for the use of sampling and testing in international food trade* (CXG 83-2013) stated “*The exporting country and the importing country should agree on how the analytical measurement uncertainty is taken into account when assessing the conformity of a measurement against a legal limit.*”
57. CCMAS acknowledged that MU for the purpose of the guidelines comprised only laboratory samples and would solely concern the uncertainty of results for laboratory test samples, including subsampling. Measurement uncertainty relating to sampling would be covered by the work on the revision of GL50 (Agenda Item 7).
58. In order to clarify these issues, CCMAS agreed to establish an in-session working group led by Germany to prepare a revised scope for the new work.
59. The Committee considered the revised scope and project document and agreed that the revised GL54 would illustrate:
- (i) the use of measurement uncertainty in the interpretation of measurement results
  - (ii) the relationship between the measurement uncertainty and (given) sampling plans.
60. It was further noted that an information document containing examples would support the revision of GL54.

## Conclusion

61. CCMAS agreed to:
- start new work on the revision of the *Guidelines on Measurement Uncertainty* (CXG 54-2004) and to submit the revised project document (Appendix IV) for approval by CAC41; and
  - establish an EWG chaired by Germany working in English to develop the proposed draft revised Guidelines for consideration by CCMAS40.

## PROPOSAL TO AMEND THE GENERAL GUIDELINES ON SAMPLING (CXG 50-2004) (Agenda Item 7)<sup>9</sup>

62. New Zealand, chair of the EWG, introduced the paper (CX/MAS 18/39/7) and recalled that some committees and CCMAS had expressed the view that the current guidelines were difficult to understand and that a revision of GL 50 was necessary to simplify and make it more readable and understandable.
63. She explained that the purpose of the revised GL50 was to help those responsible to select statistical sampling plans that are appropriate for inspections under specifications laid down by Codex standards. The guidelines are primarily aimed at Codex committees which select plans recommended, but could also be used, if applicable, by governments in case of international trade disputes.
64. The Delegation noted that the work would be quite extensive and would require experts from member countries to contribute to the revision and proposed to amend the timelines for completion of work.

## Discussion

65. CCMAS discussed the proposal for new work with a focus on the main aspects to be covered.
66. There was general support for the new work and it was proposed, in the spirit of simplification, to reference appropriate sampling plan tools (e.g. apps); that guidance on sampling of inhomogeneous lots should be covered, but should take low priority in the step-wise development of the revision; and that clarification of measurement error in relation to measurement uncertainty was needed.
67. CCMAS noted that work on the revision of GL50 should run concurrently with that of the revision of GL54 (Agenda Item 6) and that it would be preferable to wait for the completion of the two sets of work to address the interrelationship between MU and sampling.
68. Questions were raised on whether it was appropriate to also cover microbiological and histamine parameters in the guidelines. It was clarified that the current GL already has reference or guidance on these aspects and that while hygiene was not within the purview of CCMAS, a single guideline document covering all sampling

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<sup>9</sup> CX/MAS 18/39/7; CRD6 (EU); CRD8 (Kenya); CRD10 (Ghana); CRD12 (Ecuador); CRD14 (United Kingdom); CRD15 (Philippine)

plan aspects would be useful for governments and that CCFH should be informed of this work and that their inputs could be requested.

69. It was further noted that several commodity and other standards contained sampling plans which could be affected by the revision of GL50 and it was clarified that once the revision was completed, all committees would have an opportunity to review their sampling plans and revise as appropriate taking into account the new GL50.
70. CCMAS also noted that the GL would be generic and could be applied to any materials being inspected, including feed.

### **Conclusion**

71. CCMAS agreed:
- to start new work and submit a revised project document (Appendix V) to CAC41 for approval as new work;
  - to the prioritisation areas of work (Appendix VI);
  - to establish an EWG chaired by New Zealand, working in English only, to develop the revised GL 50 based on the draft presented in CX/MAS 18/39/7 Appendix VI.

### **REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 8)<sup>10</sup>**

72. The Observer of the United States Pharmacopeial Convention (USPC), as Chair of the Inter Agency Meeting (IAM), introduced the report of IAM and highlighted the various issues discussed in the IAM with respect to the work of CCMAS and other related matters.
73. CCMAS noted that several of the issues raised in CRD 16 had been considered under the relevant agenda items.
74. The IAM again noted the request of the Codex Secretariat to enhance the role of IAM at CCMAS meetings by submitting an annual summary for inclusion in the CCMAS agenda in a section entitled "Matters of Interest Arising from Other International Organizations". The submission of IAEA was considered a suitable model to cover general items that may be of interest to CCMAS participants.
75. A number of IAM member organizations had supplied information used in the report for CAC41 "Cooperation Between the Codex Alimentarius Commission and Other Standard-Setting Organizations". IAM members noted the report and thanked the Codex Secretariat for the opportunity to make comments.
76. IAM members noted the progress made by ISO/AOAC/IDF in the review of their methods in CXS 234, specifically in the dairy sector. AOAC outlined the progress that had been made in forming a committee to determine the process they would use when undertaking the review of their methods in CXS 234. There was general agreement amongst IAM participants that it was important to first develop guidance on specific issues with the presentation of methods in CXS 234 before advancing into package-wise review. Though the revision of CXS 234 is ongoing, SDOs are encouraged to provide method changes to the Codex Secretariat for consideration at pWG on the endorsement of method analysis.
77. It was noted by IAM that there appeared to be gaps in the endorsement of appropriate methods by different Codex committees and therefore this issue should be developed in a discussion paper and brought to the attention of CCMAS.
78. CCMAS thanked the members of IAM for their contribution to the work of the Committee.

### **OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)**

79. The Chairperson requested the views of the Committee on how to improve the work of CCMAS noting there was good progress made at this session.
80. CCMAS noted the following views expressed by delegations:
- Interpretation in English, French and Spanish would facilitate discussion in the PWG on endorsement.
  - Timely document distribution and information (including how to access the information) is important for good preparation of the meeting.
  - Any new relevant information or methods for consideration by the PWG on endorsement, other than those presented in the relevant working documents should be submitted at least 30 days before the PWG meeting.

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<sup>10</sup> CRD16 (Report of IAM30)

- Development of work procedures and principles for the function of the Committee, in particular the endorsement process was suggested and noted that this could possibly be discussed and be an outcome of the EWG chaired by USA to address specific questions related to endorsement (Agenda Item 3).
- The scheduling of the next CCMAS should take into account proper spacing between meetings to allow sufficient time for preparation and consideration should be given to holding an information session on rules and procedures of CCMAS for delegates.

81. The Chair welcomed the ideas and encouraged members to also, think ahead to possible new issues for CCMAS to address in the future.

**DATE AND PLACE OF NEXT SESSION (Agenda Item 10)**

82. CCMAS was informed that the 40<sup>th</sup> Session would take place in Budapest, Hungary, within the next 12 months, the final arrangements being subject to confirmation by the host country and the Codex Secretariat.

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**Appendix II****PART 1. METHODS OF ANALYSIS FOR ADOPTION BY THE 41<sup>ST</sup> CODEX ALIMENTARIUS COMMISSION**

- A. Codex Committee on Nutrition and Foods for Special Dietary Uses
- B. Codex Committee on Milk and Milk Products
- C. Codex Committee on Cereals, Pulses and Legumes
- D. Codex Committee on Contaminants in Foods

**PART 2. METHODS OF ANALYSIS FOR REVOCATION BY THE 41<sup>ST</sup> CODEX ALIMENTARIUS COMMISSION**

**PART 1. METHODS OF ANALYSIS FOR ADOPTION BY THE 41<sup>ST</sup> CODEX ALIMENTARIUS COMMISSION****A. CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES*****Methods of analysis for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)***

<b>Commodity</b>	<b>Provision</b>	<b>Method</b>	<b>Principle</b>	<b>Proposed Type</b>
Infant Formula	Biotin	EN 15607	HPLC- fluorescence	III
		AOAC 2016.02	HPLC-UV	II
	Vitamin D	EN 12821	HPLC-UV	III
		AOAC 995.05	HPLC-UV	III
		AOAC 2016.05 / ISO 20636	LC-MS	II
	Chloride	AOAC 2016.03 / ISO 21422   IDF 242	Potentiometry	II

**B. CODEX COMMITTEE ON MILK AND MILK PRODUCTS**

<b>Commodity</b>	<b>Provisions</b>	<b>Method</b>	<b>Principle</b>	<b>Type</b>
Dairy permeate powders	Milkfat	ISO 1736   IDF 009	Gravimetry (Röse-Gottlieb)	I
Dairy permeate powders	Nitrogen	ISO 8968-1   IDF 020-1	Titrimetry (Kjeldahl)	I
Dairy permeate powders	Moisture*	ISO 5537   IDF 026	Gravimetry (drying at 87°C)	I
Dairy permeate powders	Ash	NMKL 173	Gravimetry (ashing at 550 °C)	IV
Cheese	Propionic acid	ISO/TS 19046-1I IDF/RM 233-1	Gas Chromatography - FID	IV
Cheese	Propionic acid	ISO/TS 19046-2I IDF/RM 233-2	Ion exchange chromatography-UV	IV
Emmental	Propionic acid	ISO/TS 19046-1I IDF/RM 233-1	Gas Chromatography -FID	IV
Emmental	Propionic acid	ISO/TS 19046-2I IDF/RM 233-2	Ion exchange chromatography - UV	IV

(\*) Moisture content excluding the water of crystallization of lactose.

**C. CODEX COMMITTEE ON CEREALS, PULSES AND LEGUMES****Methods of analysis for quinoa**

Provision	Method	Principle	Type
Moisture content	ISO 712 / AACCI 44-15.02	Gravimetry	I
Protein Content (N x 6.25 in dry weight basis)	ISO 1871	Titrimetry (Kjeldahl)	IV

**D. CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

Performance Criteria for methods of analysis of methylmercury\*

Commodity	Provision	ML (mg/kg)	Min Appl. Range (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	Precision (%) Not more than	Recovery (%)	Examples of applicable Methods that meet the criteria	Principle
All Tuna	methylmercury*	1.2	0.64 – 1.8	0.12	0.24	31	80 – 110	EN 16801	GC-ICP/MS
Alfonsino	methylmercury*	1.5	0.82 – 2.2	0.15	0.30	30	80 – 110	AOAC 988.11 EN 16801	GC-electron capture GC-ICP/MS
All Marlin	methylmercury*	1.7	0.95 – 2.5	0.17	0.34	30	80 – 110	AOAC 988.11 EN 16801	GC-electron capture GC-ICP/MS
Shark	methylmercury*	1.6	0.88 – 2.3	0.16	0.32	30	80-110	AOAC 988.11 EN 16801	GC-electron capture GC-ICP/MS

\* Countries or importers may decide to use their own screening when applying the ML for methylmercury in fish by analysing total mercury in fish. If the total mercury concentration is below or equal to the ML for methylmercury, no further testing is required and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML. The ML also applies to fresh or frozen fish intended for further processing.

**PART 2. METHODS OF ANALYSIS FOR REVOCATION BY THE 41<sup>ST</sup> CODEX ALIMENTARIUS COMMISSION**

<b>Commodity</b>	<b>Provisions</b>	<b>Method</b>
Fish	Methyl mercury	AOAC 988.11
Infant formula	Vitamin D	AOAC 992.26

**Appendix III****Proposed Draft Preamble and Document Structure for the General Standard on Methods of Analysis and Sampling (CXS 234-1999)****(for consideration by the EWG on the revision of CXS 234)****INTRODUCTION**

This Standard contains definitions, lists of methods of analysis, methods performance criteria, descriptions of some methods and a list of methods of sampling to verify the provisions in Codex standards to be applied to commodities moving in international trade.

The methods are primarily intended to allow competent national and/or regional authorities to select appropriate methods of analysis and sampling for the verification of provisions' commodities found in Codex standards.

It is recommended that this Standard should be read in conjunction with the related Codex standards, guidelines and other documents<sup>1</sup>.

In case of disputes of analytical results, guidance is given in the *Guidelines for Settling Disputes over Analytical (Test) Results* (CXG 70-2009), including guidance on the use of methods of analysis.

When confirming compliance to a Codex standard the methods of analysis and sampling contained in this General Standard that relates to the provision identified in the commodity standard should be used.

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<sup>1</sup> Harmonized IUPAC Guidelines for the Use of Recovery Information in Analytical Measurement (CXG 37-2001), Harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis (CXG 49-2003), Guidelines on Sampling (CXG 50-2004), Guidelines on Measurement Uncertainty (CXG 54-2004), Protocol for the Design, Conduct and Interpretation of Method Performance Studies (CXG 64-1995), Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (CXG 65-1997)

Standard consists of three main parts:

PART I. PREAMBLE

PART II. METHODS OF ANALYSIS

SECTION I - TABLE FOR METHODS OF ANALYSIS AND METHOD PERFORMANCE CRITERIA BY COMMODITY CATEGORIES

SECTION II - PROVISIONS FOR WHICH THERE ARE METHOD PERFORMANCE CRITERIA

SECTION III- METHODS OF ANALYSIS BY COMMODITY CATEGORIES

SECTION IV- COMPLETE DESCRIPTION OF THE METHODS OF ANALYSIS

PART III. METHODS OF SAMPLING BY COMMODITY CATEGORIES AND NAMES

PART I - PREAMBLE

1. Scope

This Standard is intended to provide a single reference to methods of analysis and sampling for food as adopted by the Codex Alimentarius Commission.

2. Definition of Terms

2.1 Codex Method of Analysis: methods for the verification of provisions in Codex standards. The methods are classified as Defining Methods (Type I), Reference Methods (Type II), Alternative Approved Methods (Type III), & Tentative Methods (Type IV) (see Codex Procedural Manual, Section II: Elaboration of Codex texts, Definition of types of methods of analysis).

2.2 Method of Analysis Principle: The science-based analytical principle of the method of analysis, described concisely, focusing on the technique.

2.3 Provision: A criterion of a commodity that needs to be confirmed by analysis to ensure that it conforms to that standard.

2.4 Method criteria: Set of performance characteristics to which a method used for the determination of a criterion or characteristic must comply.

PART II - METHODS OF ANALYSIS

This part contains 4 sections, the first one list all the commodities and provisions including a link to the other sections, depending on how the methodologies are proposed, endorsed and approved by CAC:

*SECTION I – METHODS OF ANALYSIS AND METHOD PERFORMANCE CRITERIA BY COMMODITY CATEGORIES*

This section contains:

- a) The name of the commodity/product;
- b) The provision to which the methods apply;
- c) Codex Standard to which the method is directed;
- d) Link to the performance criteria or method

*SECTION II. PROVISIONS FOR WHICH THERE ARE METHOD PERFORMANCE CRITERIA*

This section contains:

- a) The name of the commodity/product;
- b) The provision to which the methods apply;
- c) Codex Standard to which the method is directed;
- d) Minimum applicable range;
- e) Limit of detection (LOD);
- f) Limit of quantification (LOQ);
- g) RSDR (Relative Standard Deviation of Reproducibility);
- h) % Recovery;
- i) Examples of Methods that meet the criteria and their principles also can be mentioned. However, any method that complies with the established performance criteria can be used.



**SECTION III. COMPLETE DESCRIPTION OF THE METHODS OF ANALYSIS**

This section contains:

- a) The name of the commodity;
- b) The provision to which the methods apply;
- c) Description.

**SECTION IV. METHODS OF ANALYSIS BY COMMODITY CATEGORIES**

This section contains:

- a) The name of the commodity/product;
- b) The provision to which the methods apply;
- c) Identification of the method;
- d) Method of Analysis Principle;
- e) Type of analytical method;

**PART II - METHODS OF ANALYSIS**

*[The section I presents all the methods by commodities and provisions.*

*The most updated version of the method should be used in application of ISO/IEC 17025 unless it is not appropriate or possible to do so. Each line of the methods list corresponds to one method of analysis or more than one if they are necessary to reach a result, in this case they are called complementary with an "and" between them. When a provision is determined by calculation, a brief description of the calculation shall be given in the principle column.*

When the methods are in the same row separated by a vertical bar "|", they are identical and published in a single document by different standards development organizations. When methods are separated by a forward slash "/", the technical procedures are identical and published in separate documents that may have different formats.

All Codex methods, including Type IV methods, could be used for control, inspection and regulation and when parties so agreed, for resolution of disputes. A Type I method determines a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured. A Type II method is the one designated Reference Method where Type I methods do not apply. A Type III Method is one which meets the criteria required by the Committee on Methods of Analysis and Sampling and a Type IV is a method which has been used traditionally or else has been recently introduced but for which the criteria required for acceptance by the Committee on Methods of Analysis and Sampling have not yet been determined.]

*Observation: The examples below will be deleted in the agreed document.*

**SECTION I – METHODS OF ANALYSIS AND METHOD PERFORMANCE CRITERIA BY COMMODITY CATEGORIES**

Commodity	Provision	CXS	Method
Processed fruits and vegetables	Benzoic acid	CXS 13	See Section IV (link to section IV)
Processed fruits and vegetables	Fill of containers (metals containers)	CXS 13	CAC/RM 46 ( link to complete description on Section III)
Natural Mineral Waters	Mercury	CXS 108	See Section II (link to section II)

**SECTION II - PROVISIONS FOR WHICH THERE ARE METHOD PERFORMANCE CRITERIA**

Commodity	Provision	Applicable CXS	Minimum applicable range	LOD	LOQ	RSDR (%)	Recovery (%)	Examples of methods that meet the criteria	Principle
Natural Mineral Waters	Mercury	108-1981	0.00056 mg/L	0.0002 mg/L	0.0004 mg/L	44	80-110	EN 1483 ISO 17852 ISO 5666 ISO 16590 EPA 200.8	AAS Enrichment by amalgamation (III) AFS AAS after tin(II) chloride reduction Enrichment by amalgamation (III) ICP-MS

**SECTION III. COMPLETE DESCRIPTION OF THE METHODS OF ANALYSIS**

Commodity	Provision
Processed fruits and vegetables	Fill of (metals) container
<p><b>DESCRIPTION OF THE METHOD: DETERMINATION OF WATER CAPACITY OF CONTAINERS (CAC/RM 46)</b></p> <p>1. SCOPE This method applies to glass containers.</p> <p>2. DEFINITION The water capacity of a container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.</p> <p>3. PROCEDURE</p> <p>3.1 Select a container which is undamaged in all respects.</p> <p>3.2 Wash, dry and weigh the empty container.</p> <p>3.3 Fill the container with distilled water at 20°C to the level of the top thereof, and weigh the container thus filled.</p> <p>4. CALCULATION AND EXPRESSION OF RESULTS Subtract the weight found in 3.2 from the weight found in 3.3. The difference shall be considered to be the weight of water required to fill the container. Results are expressed as mL of water.</p>	

## SECTION IV –METHODS OF ANALYSIS BY COMMODITY CATEGORIES

Commodity	Provision	Method	Principle	Type
Processed fruits and vegetables	Benzoic acid	NMKL 124	Liquid Chromatography	II

## PART III- RECOMMENDED METHODS OF SAMPLING BY COMMODITY CATEGORIES AND NAMES

Commodity Categories	Method of Sampling	Notes
Cereals, Pulses and Legumes and Derived Products		
Wheat protein products including wheat gluten	ISO 13690	
Fats and Oils		
Olive Oils and Olive-Pomace Oils	ISO 661 and ISO 5555.	
Fish oils	ISO 5555	
Milk and milk products		
Milk products	ISO 707   IDF 50	General instructions for obtaining a sample from a bulk
Milk products	ISO 5538   IDF 113	Inspection by attributes
Milk products	ISO 3951-1	Inspection by variables
Processed Fruits and Vegetables		
Desiccated coconut	Described in the Standard	
Certain canned vegetables, jams and jellies	Described in the Standard	
Chili sauce	Described in the Standard	
Table Olives	Described in the Standard	

## Appendix IV

**PROJECT DOCUMENT****New Work to revise *the Guidelines on Measurement Uncertainty (CXG 54 - 2004)*****(For approval by CAC)****The purpose and the scope of the standard**

The purpose of the proposed new work is to revise the Guidelines on Measurement Uncertainty (CXG 54 – 2004) in order to improve and clarify the content.

The revised guide CXG 54 – 2004 covers general aspects on measurement uncertainty, without recommendation on lot assessment. It illustrates

- the use of measurement uncertainty in the interpretation of measurement results
- the relationship between the measurement uncertainty and (given) sampling plans

**Relevance and timeliness**

The revision of the Guidelines originates from the requests for more detailed explanations regarding the use of measurement uncertainty in the interpretation of measurement results and the relationship between the measurement uncertainty and sampling plans.

The MU deals with laboratory samples and not with the lot (the guide CXG 54 – 2004 does not concern uncertainty, which is derived by sampling). Measurement uncertainty only concerns the uncertainty of results for laboratory test samples. A large measurement uncertainty might have an effect on the number of samples of a sampling plan as well as on the number of test samples per composite sample of the lot. Since it is essential for the responsible authorities to understand the above mentioned relationship, the corresponding amendment of the guidelines is of great importance. A general illustrated introduction into that field is recommended, because the responsible authorities might not be as familiar with measurement uncertainty as the laboratories.

This should be supported by an information document including practical examples, referring to corresponding international standards. These recommended procedures are necessary for determining uncertainty of measurement results, including sub-sampling, sample processing and analysis. The information about the reported expanded measurement uncertainty should comply with the corresponding ISO standards.

**Main aspects to be covered**

- Introduction to the CXG 54 – 2004, which covers general aspects on measurement uncertainty, including the expanded measurement uncertainty as well as to emphasise its influence on sampling plans.
- A prioritised combination of general and technical improvements of an updated CXG 54 – 2004 that is comprehensive, simple to use and understood .

**Assessment against the criteria for the establishment of work priorities****General:**

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

**Specific:****Criteria applicable to general subjects**

- Diversification of national legislations and apparent resultant or potential impediments to international trade: the criteria of product assessment are to be harmonized between the trade partners.
- Work is already undertaken by other international organizations in the field of measurement uncertainty. However, there is a noticeable lack of advice how these standards on measurement uncertainty are linked to sampling plans.
- Amenability of the subject can be achieved by the appropriate amendments of the existing guidelines CXG 54 – 2004.

**Relevance to the Codex strategic objectives**

This proposal for new work is within the scope of the Codex Strategic Vision Statement 'To be the preeminent international food standards-setting body to protect the health of consumers and ensure fair practices in the food trade'. The proposed new work item goes in accordance with the Codex 2014–2019 Strategic Plan:

- Strategic goal 1: Establish international food standards that address current and emerging food issues
- Objective 1.1: Establish new and review existing Codex standards, based on priorities of the CAC.
- Activities 1.1.1: Consistently apply decision-making and priority setting criteria across Committees to ensure that the standards and work areas of highest priority are progressed in a timely manner.
- Activities 1.1.2: Strengthen the critical review process to improve standards monitoring.

**Information on the relation between the proposal and other existing codex document**

A list of issued Codex documents that relate to this proposal are:

- *Guidelines on Estimation of Uncertainty of Results* (CXG 59-2006). Overlapping of these Guidelines on estimation of uncertainty of results, which has been established by the Codex Committee on Pesticide Residues (CCPR) should be avoided.
- *General Guidelines on Sampling* (CXG 50 – 2004)
- *General Guidelines on Principles for the Use of Sampling and Testing in International Food Trade* (CXG 83 - 2013)

**Identification of any requirements for and availability of expert scientific advice**

Expert scientific advice might be needed in future

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

Technical input from external bodies may also be needed. Up to date drafting and editing according to modern standards are essential to deliver a manageable document.

Overlapping of the Guidelines on estimation of uncertainty of results, which has been established by CCPR should be avoided. Also, there are other important and relevant factors that an updated CXG 54 needs to cover, including the relationship between CXG 54 and other international sources of guidance regarding the subject of measurement uncertainty.

**Timeline**

Work to start in 2018 after approval by CAC41, with adoption at Step 5 in 2020 and final adoption in 2021.

**PROJECT DOCUMENT****New Work to revise *the Guidelines on Sampling (CXG 50–2004)*****(For approval by CAC)****THE PURPOSES AND THE SCOPE OF THE STANDARD**

The purpose of this proposed new work is to produce a revision of the General Guidelines on Sampling (CXG 50-2004) (GL 50) and to improve user friendliness.

**RELEVANCE AND TIMELINESS**

The purpose of GL 50 is to help those responsible for sampling to select sampling plans that are appropriate for statistical inspections under specifications laid down by Codex standards.

The Guidelines are primarily aimed at Codex committees which select from the plans recommended. The Guidelines can also be used, if applicable, by governments in case of international trade disputes. The current Guidelines (69 pages) cover, firstly, general concepts of food sampling, applicable in any situations, and later sections cover certain situations of statistical food control, for which certain sampling plans have been selected. The Guidelines were adopted by the Commission in 2004 and there have been no subsequent amendments.

Some commodity committees and some members of CCMAS have expressed the view that the current Guidelines were difficult to understand and apply. The aim of the revision is to provide a simpler more understandable guidance.

**MAIN ASPECTS TO BE COVERED IN THE PROPOSED REVISION**

The proposed approach will result in a shorter document containing understandable and educational guidance, along with links to sampling plan apps. The proposed sections will cover:

- Introduction
- Concepts of sampling
- Guidance on specification of sampling plans for foods
- Sampling plan tools (containing links to apps of sampling plans tools, rather than the larger document full of tables, plots and formulae)
- Other identified technical information e.g. measurement error<sup>1</sup>, sampling of bulk materials, sampling of non-homogeneous lots
- Links to other sources of scientifically valid sampling plans.

The revised GL 50 will align with established Codex principles for sampling plans as set out in the *Codex Procedural Manual*, and in *Principles for the Use of Sampling and Testing in International Food Trade (CXG 83-2013)* (GL 83).

**AN ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES***General criterion*

*Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.*

The revision of the Guidelines is intended to give effect to the principles of sampling expressed in GL 83, in particular:

- fairness towards both the consumers and the producers, as well as importing and exporting countries;
- scientifically based, taking into account the existing Codex standards, appropriate to the commodity and lot or consignment to be sampled, and fit for intended purposes and applied consistently;

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<sup>1</sup> Measurement error is not the same as measurement uncertainty referred to in CXG 54-2004

- commensurate with the potential loss posed to consumers from inappropriate acceptance of poor quality product and the potential loss posed to producers from inappropriate rejection of good quality product.

Clearer guidance, along with access to sampling plan apps and educational resources, will make the Guidelines more usable by all countries.

*Criteria applicable to general subjects*

- (a) *Diversification of national legislations and apparent resultant or potential impediments to international trade.*

Countries take various approaches to sampling according to national circumstances. The improved Guidelines will enable development of more suitable sampling plans for Codex commodity standards, and assist national authorities to select appropriate sampling plans.

- (b) *Scope of work and establishment of priorities between the various sections of the work.*

This project envisages a comprehensive revision of a major document. Accordingly the work will be conducted in stages with priorities as described below.

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

Substantial work on sampling has been undertaken by other international organizations over many years. The revised Guidelines will make full use of this work, and will provide references and links to it.

- (d) *Amenability of the subject of the proposal to standardization.*

The situations in which food must be sampled are very diverse. Nevertheless general guidance is needed to assist those responsible for selecting sampling plans to make an informed decision.

- (e) *Consideration of the global magnitude of the problem or issue.*

Sampling plans are needed for any inspections that may be conducted against specifications laid down by Codex standards. Similarly national authorities need sampling plans for inspection of foods against national specifications.

## **RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES**

This proposal for new work is within the scope of the Codex Strategic Vision Statement 'To be the pre-eminent international food standards-setting body to protect the health of consumers and ensure fair practices in the food trade'.

The specific nature of this proposed new work aligns with the Codex 2014–2019 Strategic Plan:

Strategic goal 1:	Establish international food standards that address current and emerging food issues
Objective 1.1:	Establish new and review existing Codex standards, based on priorities of the CAC.
Activities 1.1.1:	Consistently apply decision-making and priority setting criteria across Committees to ensure that the standards and work areas of highest priority are progressed in a timely manner.

Activities 1.1.2: Strengthen the critical review process to improve standards monitoring.

## **INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS AS WELL AS OTHER ONGOING WORK**

A list of issued Codex documents that relate to this proposal are:

1. *Principles for the Use of Sampling and Testing in International Food Trade* (CXG 83-2013)
2. *Guidelines for Food Import Control Systems* (CXG 47-2003)
3. *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CXG 62-2007).
4. *Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs* (CXG 33-1999)
5. *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals* (CXG 71-2009)

6. *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF, CXS 193-1995)
7. *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21 – 1997)
8. *Guidelines for Food Import Control Systems* (CXG 47-2003)
9. *Guidelines for Settling Disputes over Analytical (test) Results* (CXG 70-2009)
10. Information Document on Practical Examples on the selection of appropriate sampling plans.
11. *Guidelines on Measurement Uncertainty* (CXG 54-2004).

There is no other ongoing work in this area in Codex.

#### **IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE**

Expert scientific advice will be needed to review the new sections (e.g. plans for inspection of bulk consignments) and the sampling plan apps that will be developed. CCMAS representatives may be asked to seek such advice from consultation with statistical experts in their own country.

In addition, the work developing apps consists of two parts, translating published material into apps and doing the research to develop and publish theory to fill identified gaps.

Some statistical expertise is needed for the first activity and a lot for the second. Work on these sections will be undertaken by the eWG. There will still however, be a need for involvement of experts who may be external to CCMAS, for some of these work items.

New Zealand is actively working on some of these items, including the introduction, the general guidance, sampling plan tools etc.

#### **IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR**

It is not envisaged that technical input will be sought from external bodies.

#### **THE PROPOSED TIMEFRAME**

<b>Time</b>	<b>Action</b>
CCMAS39 (2018)	Agree to start new work
CAC 2018	Approval of the new work
CAC 2020	Adoption at Step 5
CAC 2021	Adoption at Step 8



**PRIORITISATION****Work on the revision of *the Guidelines on Sampling (CXG 50–2004)***

This list covers the areas for prioritisation.

<b>PRIORITY AREA AND POTENTIAL OUTCOME</b>
1. An introduction to the revised document
2. Concepts of sampling <ul style="list-style-type: none"> <li>○ Apps to demonstrate concepts of sampling, measurement error etc.</li> </ul>
3. Step-by-step guidance on how to choose a sampling plan for foods
4. Attributes and variables sampling plans <ul style="list-style-type: none"> <li>○ Tools to design and evaluate these plans</li> </ul>
5. Explanation of ISO, GL50 sampling plans <ul style="list-style-type: none"> <li>○ Lot size versus sample size</li> <li>○ Explanation of ISO, GL50 sampling plans</li> <li>○ Sampling schemes vs sampling plans</li> <li>○ Equivalent sampling plans (equivalent to sampling schemes)</li> <li>○ Re-inspection plans</li> <li>○ Tools</li> </ul>
6. Bulk materials <ul style="list-style-type: none"> <li>○ Introduction; what are they?</li> <li>○ Sampling plans, including plans based on the beta distribution</li> <li>○ Tools</li> </ul>
7. Introduction to measurement error <ul style="list-style-type: none"> <li>○ Nature of measurement error</li> <li>○ Design of sampling plans allowing for measurement error</li> <li>○ Tools</li> </ul>
8. Other types of sampling plans and sampling plan tools <ul style="list-style-type: none"> <li>○ For example, for microbiology (product quality, process hygiene, food safety) and histamine among other food safety parameters</li> </ul>
9. Compliance of the average level <ul style="list-style-type: none"> <li>○ Tools</li> </ul>
10. Inhomogeneous lots