CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP15/MAS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty eighth Session
Geneva, Switzerland, 6 - 11 July 2015

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

Budapest, Hungary
23 – 27 February 2015

This report incorporates CL 2015/6-MAS.

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CL 2015/6-MAS
March 2015

TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
FAO, 00153 Rome, Italy

SUBJECT: **Distribution of the Report of the 36th Session of the Codex Committee on Methods of Analysis and Sampling (REP15/MAS)**

MATTERS FOR ADOPTION BY THE 38th SESSION OF THE COMMISSION:

1. Methods of Analysis and Sampling in Codex Standards (para. 42, Appendix III); and

2. Proposed Draft Explanatory Notes to the *Principles for the Use of Sampling and Testing in International Food Trade* (CAC/GL 83-2013) at Step 5/8 (para. 83, Appendix IV).

Governments and interested international organizations wishing to comment on the above document should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 and Step 5/8 (see Procedural Manual of the Codex Alimentarius Commission) to the above address before **31 May 2015**.

REQUEST FOR INFORMATION:

3. Information on the applicability of ISO 1211|IDF 1:2010 for lipid determination in tempe and information on whether this method had been tested on tempe products (para. 39).

Governments and interested international organizations wishing to provide information should do so to the above address before **30 November 2015**.

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SUMMARY AND CONCLUSIONS

The 36th Session of the Codex Committee on Methods of Analysis and Sampling reached the following conclusions:

Matters for adoption by the 38th Session of the Codex Alimentarius Commission

The Committee forwarded:

- methods of analysis and sampling in Codex Standards at different steps for adoption (para. 42, Appendix III);
- proposed draft explanatory notes to the *Principles for the Use of Sampling and Testing in International Food Trade* (CAC/GL 83-2013) (Para 83, Appendix IV); and
- agreed to maintain its endorsement of the methods for the determination of marine biotoxins (section I-8.6.2 - *Standard for Live and Raw Bivalve Molluscs*) as Type IV (para. 56).

Matters of interest to the Commission

The Committee:

- provided replies concerning the monitoring of the implementation of the Codex Strategic Plan 2014-2019 as to those activities relevant to the work of CCMAS (paras 9 - 10, Appendix II);
- agreed to consider criteria for biological methods as a matter of urgency in light of its decision to maintain the endorsement of the methods for determination of marine biotoxins as Type IV (para. 56);
- agreed to continue preparation of practical examples to assist with the understanding of the implementation of the *Principles for the Use of Sampling and Testing in International Food Trade* (CAC/GL 83-2013) as an information document (para. 76); and
- agreed to continue consideration of the development of procedures/guidelines for determining equivalency to Type I methods (para. 96); criteria approach for methods which use a "sum of components" (paras 100 - 101); update and review of the endorsed methods of analysis and the development of CODEX STAN 234-1999 as a single reference for methods of analysis in Codex (paras 111 - 113); and a paper on sampling to be prepared by the Interagency Meeting (IAM) (para. 117).

Matters referred to other committees

Committee on Processed Fruits and Vegetables (CCPFV)

The Committee:

- agreed to replace the CAC/RM 46-1972 (method for fill of glass containers) with ISO 8106 (Glass containers – determination of capacity by gravimetric methods) and to apply this change to all relevant standards on processed fruits and vegetables (para. 12); and
- did not endorse the sampling plans in the Standard for Ginseng and Ginseng Products (para.16).

Committee on Contaminants in Foods (CCCF)

The Committee:

- did not endorse the sampling plans nor the analytical methods for fumonisins (B1 + B2) in maize grain and maize flour and maize meal (paras 17 – 18).

Committee on Fats and Oils (CCFO)

The Committee:

- did not endorse the methods for determination of arsenic and lead and recommended that criteria be developed once the ML for arsenic and lead were finalised (para. 22); and
- did not endorse the methods for the determination of phospholipids and agreed request CCFO to establish a conversion factor for inclusion in the Standard for Fish Oils or to indicate in the Standard that the provision applied to phospholipids expressed as phosphorous before the methods could be endorsed (para. 26).

Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

The Committee:

- noted that it would be difficult to provide information on the lowest level of TFAs that current analytical methods can accurately determine as well as consistently reproduce as the levels would depend on the matrix of the product (para. 31); and
- noted that if the G12 method for detection of the toxic fraction in gluten harmful for individuals were added, the provision in the Standard would need to be differentiated to allow for both methods (R5 and G12) to be included as Type I methods (paras 35 - 36).

Committee on General Principles (CCGP)

The Committee agreed:

- to request clarification from CCGP on the legal implications, if any, of having referenced information documents in Codex standards and related texts (para. 77); and
- to request CCGP to consider amending the Procedural Manual in order to have CODEX STAN 234 as a single reference for methods of analysis in Codex (para. 112).

All Other Relevant Codex committees

Principles for the use of sampling and testing in international food trade – practical examples

The Committee agreed:

- to invite Codex committees to provide examples within their field of competence for which they would like to receive advice from CCMAS which could be included in the information document on practical examples (for selection of appropriate sampling plans) (para. 79); and
- to inform Codex committees that the practical examples would not interfere with sampling and testing procedures developed by other committees, but show how samples taken according to the procedures developed by those committees could be used for the decision making process (para. 82).

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling held its 36th Session in Budapest, Hungary, from 23 to 27 February 2015, at the kind invitation of the Government of Hungary. The Session was chaired by Professor Dr Árpád Ambrus, Chief Scientific Advisor, National Food Chain Safety Office (NFCSO). Ms Andrea Zentai, Food Safety Coordinator (NFCSO) acted as the Vice-Chairperson. The Session was attended by 52 Member countries, 1 Member Organization and Observers from 11 international organizations. The list of participants is given in Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Dr. Márton Oravecz, President of NFCSO. Mr. Tony Alonzi, the FAO Deputy Regional Representative for Europe and Central Asia and Mr. Tom Heilandt, Secretary, Codex Alimentarius Commission also addressed the Committee.

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 the Rules of Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

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

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

5. In addition, the Committee agreed to:

- establish an in-session Working Group chaired by the United Kingdom to consider the discussion paper on the criteria approach for methods which use a "sum of components" to: evaluate and discuss current options, consider general guidelines, and evaluate criteria for use on a case-by-case basis; and
- consider a request on methods for non-dioxin like PCBs in food under Item 9.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (Agenda Item 2)[3]

6. The Committee noted matters arising from the Codex Alimentarius Commission.

7. The Committee further noted that a number of matters referred by the Commission and other subsidiary bodies would be considered under Items 3 and 4 as more related to the endorsement of methods of analysis in Codex standards and the consideration of practical examples in the Annex to the *Principles for the use of sampling and testing in international food trade* (CAC/GL 83-2013).

Monitoring of the Codex Strategic Plan 2014-2019

8. The Committee noted that the 37th Session of the Commission agreed to establish a monitoring framework for the implementation of the Strategic Plan. Following this decision, the Codex Secretariat prepared a template for systematic data collection to make assessing information from committees easier. The replies to the template would be considered by the 70th Session of the Executive Committee and the 38th Session of the Commission.

9. The Committee agreed that the activities described in Goals 1, 3 and 4 were relevant to the work of CCMAS. In general, the current procedures and practices were sufficient to ensure efficient work output while there was room for improvements in certain activities as presented in Appendix II.

10. As regards Goal 2 on the application of risk analysis principles in the development of Codex standards, the Committee recognized that work on methods of analysis and sampling was based on science, while not directly related to the application of risk analysis. Goal 2 contained activities that were more related to the provision of scientific advice by FAO and WHO through their expert advisory scientific bodies e.g. JECFA, JMPR, etc. or ad hoc expert consultations while CCMAS relied on the technical expertise of Member countries and observer international organizations to carry out its work.

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1 CRD 1.

2 CX/MAS 15/36/1; CRD 4 (Iceland).

3 CX/MAS 15/36/2; CX/MAS 15/36/2-Add.1; comments of Argentina, Belize, Chile, Costa Rica, El Salvador, EU, Kenya, Peru and Uruguay (CRD 5); EU and Kenya (CRD 7); Kenya (CRD 8).

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS (Agenda Item 3)[4]

11. The Committee considered the methods proposed for endorsement and other related matters as presented in CRD 2. The Committee agreed with the recommendations of the working group and made the following amendments or decisions. All decisions taken are presented in Appendix III.

Committee on Processed Fruits and Vegetables

Standard for Certain Canned Fruits

Methods of Analysis

12. The Committee agreed to replace the CAC/RM 46-1972 (method for fill of glass containers) with ISO 8106 (Glass containers – determination of capacity by gravimetric methods). The Committee agreed to apply this change to all relevant standards on processed fruits and vegetables and to inform the Committee on Processed Fruits and Vegetables accordingly.

Sampling Plans

13. The Committee endorsed the attributes sampling plans and agreed to indicate that the sampling plans applied to defects only.

Standard for Ginseng and Ginseng Products

Methods of Analysis

14. The Committee agreed to endorse the AACCI Intl 08-01.01 for the determination of ash as Type I method, as this method was identical to AOAC 923.03.

15. The Committee encouraged the Republic of Korea to publish the validation studies in public literature. The classification of the method for the identification of ginsenosides Rb1 and Rf could be reconsidered upon publication of the studies.

Sampling Plans

16. The Committee did not endorse the sampling plans since the values in the table did not correspond to those recommended in the *General Guidelines on Sampling* (CAC/GL 50-2004). It was unclear whether the attributes sampling plan actually applied to attributes and not to characteristics that might be described as variable and requested CCPFV to reconsider the values in line with CAC/GL 50-2004.

Committee on Contaminants in Foods

Sampling plans for fumonisins (B1+B2) in maize grain and maize flour and maize meal

17. The Committee did not endorse the sampling plans noting that there were several inconsistencies between the tables and text in the sampling plans. The Committee agreed to request CCCF to consider removing the inconsistencies as presented in CRD 25 and to present a revised version to the next session of CCMAS.

Analytical method for fumonisins (B1 + B2) in maize grain and maize flour and maize meal

18. The Committee, while supporting the criteria approach, did not endorse the performance criteria for the analytical method, as these were not consistent with those given in the Procedural Manual "*Guidelines for establishing numerical values for criteria"*. The Committee agreed to request CCCF to consider all the characteristics, including LOQ and to align the values with those in the Procedural Manual.

19. Questions were raised on whether the criteria approach was appropriate for sum of components and whether it would not be more appropriate to establish performance criteria for each of the components (FB1 and FB2).

20. The Committee noted that the ML for fumonisins relates to total fumonisin (B1+ B2) and that analysts are required to apply the analytical characteristics on individual basis which would be sufficient for their purposes.

[4] CX/MAS 15/36/3; CX/MAS 15/36/3 Add.1; CRD2 (report of the Physical Working Group on Endorsement); comments of EU, Kenya, Republic of Korea (CRD 6); Thailand (CRD 13); Chile (CRD 24); Inconsistencies in the sampling plans on fumonisins (CRD 25).

Committee on Fats and Oils

Standard for Fish Oils

Determination of fatty acid composition

21. The Committee endorsed the methods and noted that ISO 5508 would be superseded by ISO 12966-2, but that this method was maintained because it was still effective and could be used until it was withdrawn.

Determination of arsenic and lead

22. The Committee recommended that criteria be developed once the ML for arsenic and lead were finalised. The Committee noted that a similar approach taken for the performance criteria for natural mineral waters provisions could be taken, i.e. provide performance criteria and examples of methods that meet the criteria for inclusion in CODEX STAN 234.

Determination of acid value

23. In addition to the proposal of the working group, the Committee also agreed to endorse the NMKL 38 and the European Pharmacopoeia 2.5.1 as Type I methods, as these methods were identical to the AOCS methods.

Determination of Peroxide Value

24. The Committee noted that European Pharmacopoeia 2.5.5 had two parts, which required the use of different reagents and endorsed the European Pharmacopoeia 2.5.5 (Part B iso-octane as solvent), while maintaining the recommendation of the working group not to endorse the EP method that used chloroform as a reagent. The Committee also endorsed the NMKL 158 as it was applicable and identical to the other methods endorsed.

Determination of Vitamin D

25. The Committee considered whether to endorse the European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01/2005:1192, with LC end-point 2.2.29, which only determined Vitamin D3, while other methods determined D2 and D3. The committee was informed that for fish oils Vitamin D3 was the analyte of concern. It was noted that either Vitamin D3 or Vitamin D2 were determined, but could not be carried out together, and therefore all three methods submitted were fit for purpose and were endorsed.

Determination of Phospholipids

26. The Committee noted that the provision in the Standard referred to phospholipids and that there were currently no methods for the determination of phospholipids, but for phosphorous. The Committee therefore did not endorse the method, as a conversion factor was needed to convert the phosphorous to phospholipids. The Committee agreed to request CCFO to establish a conversion factor for inclusion in the Standard or to indicate in the Standard that the provision applied to phospholipids expressed as phosphorous before the methods could be endorsed.

Committee on Nutrition and Foods for Special Dietary Uses

Methods of analysis for dietary fibre: guidelines for the use of nutrition and health claims: Table of conditions for claims

27. The Committee endorsed the methods of analysis for dietary fibre as proposed by the working group.

28. It was noted that there were several methods for dietary fibre classified as Type I and that it was not always clear which method to use.

29. It was recalled that there had been discussion on this matter in the Committee previously and that it was agreed that no additional guidance would be provided, but that the publication Garrett Zielinski, Jon W. DeVries, Stuart A. Craig, Anne R. Bridges, *Dietary Fiber Methods in Codex Alimentarius: Current Status and Ongoing Discussions* Cereal Foods World 2013, 58(3), 148-152. was available to provide guidance. A delegation questioned whether there was a need to amend this document to accommodate the newly endorsed methods.

Other related matters[5]

Committee on Nutrition and Foods for Special Dietary Uses

Trans fatty acids

30. The Committee considered the request from CCNFSDU on the lowest level of TFAs that current analytical methods can accurately determine as well as consistently reproduce.

31. The Committee noted that it would be difficult to provide such information to CCNFSDU, as the levels obtained would depend on the matrix of the product. It would be more appropriate for CCNFSDU to provide CCMAS with the levels for total TFA and the matrix to which the level applies. The Committee also pointed out that it would not be possible to establish a single level for TFA for all foods, but that CCNFSDU would have to develop separate levels for different commodities.

32. The Committee noted that in-depth analysis in some matrices had been carried out by ISO, IDF and AOAC, and gave some results as summarized in CRD 16. The method would be published by end of 2015.

33. The Observer from AOCS reiterated its concern previously expressed at CCNFSDU, that low levels of *trans* fatty acids cannot be routinely determined by the average laboratory with any high degree of reproducibility. This situation might lead to confusion in the marketplace and in general trade where products might be deemed to be *"trans-free"* by one laboratory and above the threshold for this claim in another.

Method for detection of the toxic fraction in gluten harmful for individuals

34. The Committee noted the request from CCNFSDU to examine ELISA G12 method as an additional method. The Committee noted that any potential endorsement of G12 would be as a Type I procedure and that it would not be possible to have two Type I methods in the Standard for the same matrices and determination.

35. If the G12 method were to be added, the provision in the Standard would need to be differentiated to allow for both methods to be included as Type I methods. The Committee noted that G12 had been validated for gluten-free foods, rice matrices, whereas R5 had been validated for gluten-free foods, maize matrices. Both methods had recently been fully validated by collaborative trial and are published by AACCI as:

- R5 method: AACC Intl 38-50.01 (immunoassay procedure (validated using maize materials)); and
- G12 method: AACC Intl 38-52.01(immunoassay procedure (validated using rice matrices)).

36. The Committee recommended that decision in this regard should be taken by CCNFSDU.

Committee on Fats and Oils (CCFO)

Standard for Olive Oils and Olive Pomace Oils (CODEX STAN 33-1981)

Determination of sterols

37. The Committee noted the concerns whether the COI/T.20 doc. No. 30-2013 was equivalent to ISO 12228-2:2014 since data indicated that there was a high level of discrepancy observed in the application–of the methods for determination of sterols. The Committee agreed to request ISO to provide information on the equivalence of their method with the COI/T.20 doc. No. 30-2013 to allow the Committee to take a decision at its next session.

Relative Density

38. The Committee noted that CCFO had been informed that the methods for relative density, ISO 6883:2007 and AOCS Cc 10c-95, were equivalent and that these methods were harmonized by the relevant committees of both organizations.

FAO/WHO Coordinating Committee for Asia (CCASIA)

Regional Standard for Tempe (*determination of lipid content*)

39. The Committee noted that CCASIA had agreed to replace the method of analysis for lipid content with ISO 1211|IDF 1:2010 as proposed by CCMAS in order to replace AOAC 983.23 which used chloroform as a reagent. It was pointed out that the scope of the ISO 1211|IDF 1:2010 did not include solid foods, such as tempe and that IDF and ISO did not intend to carry out work to extend the scope at this stage. The Committee agreed to retain the current method AOAC 983.23 for lipid determination

[5] CX/MAS 15/36/2, CX/MAS 15/36/2 Add.1.

in tempe and to request information from, in particular countries in the Asia region as to the applicability of the methods to tempe and whether this method had been tested on tempe products.

Proposals from Standards Developing Organizations to update the Methods in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999)

Methods of analysis for milk and milk products and for nutrition and foods for special dietary uses[6]

40. The Committee recalled that at its last session it had agreed to retain AOAC 991.20 as equivalent to ISO 8968-1|IDF 20-1:2014 until clarification could be provided on its equivalence to the aforementioned ISO|IDF method for blend of skimmed milk and vegetable fat in powdered form; and reduced fat blend of sweetened condensed skimmed milk and vegetable fat and whether infant formula was covered by the scope of the method.

41. The Observer of AOAC confirmed that the method had not been updated and was not equivalent to the ISO|IDF method. The Committee agreed to update CODEX STAN 234 with respect to AOAC 991.20.

Conclusion

42. The Committee agreed to send the methods as endorsed to the 38th Session of the Commission for adoption (Appendix III).

43. The Committee agreed in principle to re-establish the physical Working Group to meet immediately prior to the next session of the Committee, led by the Delegation of the USA with assistance of the Observer of ICUMSA, and working in English only. The Committee noted that convening the working group would depend on the number of methods of analysis and sampling and other related matters submitted by the Commission and/or other Codex Committees and that confirmation would be provided in advance of the session.

Methods for determination of marine biotoxins

44. The Committee considered the request of the Commission to review the typing of the methods for determination of marine biotoxins (Section I-8.6.2: Biological and Functional Methods to Determine Paralytic Shellfish Toxicity) in the *Standard for Live and Raw Bivalve Molluscs*. The concerns expressed at the 37th Session of the Commission were mainly regarding the classification of the mouse bioassay (MBA) as Type IV.

45. The Committee recalled the history of the discussion on the methods of determination for marine biotoxins and its decision at the previous session to endorse the methods AOAC 959.08 (mouse bioassay) and AOAC 2011.27 (receptor binding assay) as Type IV.

46. To facilitate discussion, the Chair of the Committee proposed that discussion should focus on identifying the characteristics of the MBA that doesn't allow it to be classified as Type III and to see how information could be provided. The Chairperson proposed that an electronic Working Group could be established to undertake work to define in general, the criteria for characterising bioassay methods. If this approach were followed, the decision to endorse as Type IV could be retained until required information is made available, whereupon, the classification could be reassessed.

47. Those members in favour of maintaining the classification as Type IV indicated that the decision of the 35th Session of CCMAS had been based on the procedures and principles in the Procedural Manual and that there was no other option in its classification, and if the decision was not upheld, there was a risk of not having any method for bioassays in the Standard. Some of these delegations supported the proposal of the chair to consider the development of criteria for biological methods.

48. It was explained that at the time the method had been developed (in the 1950s), it was the only tool for determination of paralytical shellfish toxicity and had been validated by AOAC, but since then there had been developments and there were now alternatives for both chemical and biological methods, such as the receptor binding assay (RBA).

49. It was expressed by a delegation that the current criteria in the Procedural Manual would not allow the MBA to be classified as Type I, and the lack of validation data, further prevented the classification of the method as Type II or III. The only option was classification as Type IV. The problem seemed to be with the interpretation of Type IV and whether it could be used for control and inspection purposes.

6 REP14/MAS, para.27

50. Those members in favour of reclassification of the method to Type I or III indicated that in their countries the method was widely used and efficient, that their data indicated that the MBA was more reliable than chemical methods and provided adequate protection of human health. Data had also shown that in terms of precision, trueness and recovery better results were obtained from biological methods, than with chemical methods (CRD 5). It was possible to establish toxic equivalence, and the MBA could determine toxicity directly while chemical methods used the toxic equivalence determined through the MBA.

51. Some delegations stated that the MBA is used for control, inspection and regulatory purposes, and that in their interpretation, the classification as Type IV, would not allow its use for control, inspection and regulatory purposes and could negatively impact trade.

52. But in a spirit of compromise these delegations could agree to accept the classification of the MBA as Type IV with a footnote to clearly indicate that the method could be used for national regulation, control, inspection and trade dispute purposes and that work should be undertaken to develop criteria for biological methods.

53. The chairperson clarified that once methods were adopted and included in CODEX STAN 234, all the methods could be used for any purpose in line with the Principles in the Procedural Manual.

54. It was also pointed out that in cases of disputes, the *Guidelines for Settling Disputes on Analytical (Test) Results* (CAC/GL 70-2009) would apply.

55. The Secretariat offered to prepare a preamble for the updated CODEX STAN 234 in which the various fields of the potential use of Codex Methods could be included (also see Agenda Item 7). The proposal would be made available for consideration prior to the next session of the Committee.

Conclusion

56. Noting the willingness for compromise, the Committee agreed to maintain its endorsement of the methods in section I-8.6.2 as Type IV and agreed that the development of criteria for biological methods should be considered as a matter of urgency as also encouraged by the Commission, and to inform the 38th Session of the Commission, accordingly. All Codex methods, including Type IV methods, could be used for control, inspection and regulation (Principles for the establishment of methods of analysis) and when parties so agreed, for resolution of disputes (*Guidelines for Settling Disputes on Analytical (Test) Results* (CAC/GL 70-2009. These aspects would be considered in the proposed preamble for CODEX STAN 234.

57. The Committee agreed to establish an electronic Working Group on criteria for endorsement of biological methods to detect chemicals of concern, led by Chile, and co-chaired by France, and working in English only.

58. For the purpose of this working group biological methods are considered to be those methods of analysis which use whole or parts of organisms as analytical indicators, for example bacterial growth to determine vitamins, animal bioassays to determine toxins, excluding PCR, enzymatic and ELISA methods as these are covered in the *Guidelines on performance criteria and validation of methods for detection, identification and quantification of specific DNA sequences and specific proteins in foods (*CAC/GL 74-2010). This work will exclude the methods for the assessment of microbiological quality and safety in food, which fall within the remit of CCFH.

59. The eWG will:

i) classify biological methods according to their nature, principles, characteristics, etc.;

ii) Identify to which classes of the method the criteria approach applies; and

iii) Recommend criteria to endorse each class of biological methods identified in step (ii).

PROPOSED DRAFT *PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE* (CAC/GL 83-2013): EXPLANATORY NOTES AND PRACTICAL EXAMPLES (Agenda Item 4)[7]

60. The Committee considered a revised version of the explanatory notes and practical examples based on the written comments submitted to this Session (see CRD 17).

EXPLANATORY NOTES

[7] CX/MAS 15/36/4; Comments of Australia, Canada, Costa Rica, Hungary, India, Japan, Norway, Peru, Switzerland and IDF (CX/MAS 15/36/4-Add.1); Brazil, India and ICUMSA (CX/MAS 15/36/4-Add.2); India (CRD 11); EU (CRD 14); Revised proposed draft Principles for the use of sampling and testing in international trade: Explanatory notes and practical examples (CRD 17); and Ghana (CRD 20).

61. The Delegation of Germany indicated that the changes made were mainly of editorial nature to provide more clarity in the explanatory notes.

62. In addition to editorial changes, the Committee agreed on the following:

Section 1 - Introduction

63. In the footnote, the definition for consignment was deleted as already covered by Section 3 – Definitions. The provision for sampling when the consignment is to be accepted or rejected in its entirety was transferred to the explanatory notes under Principle 4 as more appropriate.

64. The reference to the terms of reference of Codex committees was removed as the Principles are intended for application by Member countries.

65. References to practical examples were removed throughout the Principles in accordance with the decision on practical examples (see paragraph 76).

Section 4 - Principles

Principle I and Principle 3

66. The specification of the principles concerning acceptance or rejection of a lot of consignment was kept flexible by referencing the *General Guidelines on Sampling* (CAC/GL 50-2004) as an example, as the GL50 did not cover all situations for sampling. This approach would apply consistently throughout the notes.

67. The term “inhomogeneity”, as opposed to “homogeneity”, was retained as the standard deviation reflected the lot inhomogeneity.

68. The proposed text in the explanatory notes in Principle 3 relating to measurement error and uncertainty; and measurement error and sampling error respectively, were deleted, as they were too detailed information and were already available elsewhere.

69. In view of this decision, a proposal was made to include these concepts in Principle 1, but this proposal was not accepted, as there were currently no internationally agreed guidelines on measurement of uncertainty due to sampling procedures and measurement error due to sampling procedures. The inclusion of this example could be considered in future when such guidelines became available.

Principle 5

70. References to specific situations, e.g. pesticide residues, were removed as it was preferable to keep the explanatory notes focused on the two key general guidelines on measurement uncertainty (CAC/GL 54-2004) and on estimation of uncertainty of results (CAC/GL 59-2006) which constitute the source of the explanatory notes.

Principle 6

71. The quality criteria for laboratories involved in the import and export control of foods were aligned with the *Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Foods* (CAC/GL 27-1997) for consistency. References to the year of adoption of ISO 1725 referred to in the quality criteria were deleted to make sure the most updated version was always used.

Bibliography

72. The literature references were deleted as fully referenced in the Principles.

Practical Examples

73. The Delegation of Germany provided a summary of the key changes made, namely:

i) Introduction: Clarification on why the particular sampling plans had been chosen; clarification on why the condensed text was suitable for experts who were familiar with the standards; reference to EURACHEM guide for uncertainty instead of detailed development of procedure for measurement uncertainty.

ii) Table 1: Two additional examples for determination of residues of veterinary drugs in milk and meat.

iii) Table 2: Reference to CAC/GL 50-2004 where applicable; update of ISO 3951 covering the situation with measurement uncertainty greater than 10% of sampling uncertainty or process uncertainty respectively; and the inclusion of two additional examples.

74. The Committee noted the changes made to the annex on examples.

75. The Committee noted that practical examples did not interfere with sampling and testing procedures developed by other Codex committees, e.g. Committee on Pesticide Residues, Committee on Residues of Veterinary Drugs in Foods, etc., but would show how samples taken according to the procedures developed by these committees could be used for the decision making process, and agreed to inform relevant Committees accordingly.

76. The Committee agreed that the Annex on practical examples would be more appropriate as an information document and posted on the Codex website following the guidance on information documents recommended by the Committee on General Principles (CCGP). The Committee agreed that this would be indicated in a footnote to the Principles as presented in Appendix IV.

77. The Committee further agreed to request clarification from CCGP on the legal implications, if any, of having referenced information documents in Codex standards and related texts.

Conclusion

Explanatory Notes

78. The Committee noted that all comments on the explanatory notes had been addressed and that no outstanding issues remained. The Committee therefore agreed that the explanatory notes were ready for adoption by the Codex Alimentarius Commission.

Practical Examples

79. The Committee agreed to re-establish the EWG chaired by Germany and co-chaired by New Zealand, working in English only, to continue work in line with the terms of reference established at the 35th Session of CCMAS: (i) to develop practical examples on the selection of appropriate sampling plans and to invite Codex committees to provide examples within their field of competence for which they would like to receive advice from CCMAS which would be included in the information document (REP14/MAS, paragraph 85) and (ii) to develop procedures for determining uncertainty of measurement results including subsampling, sample processing and analysis (REP14/MAS, paragraph 86).

80. The Committee noted that other Codex committees would be informed of this work and the request for practical examples through the normal procedures for communication between committees (e.g. matters referred). Members were also encouraged to consult with their national counterparts to other Codex committees on this request.

81. As regards work on sampling (measurement) uncertainty, the Committee noted this work would not overlap with the discussion paper on sampling plans in Codex standards (see Item 8).

82. The Committee agreed to inform other Codex committees that the practical examples would not interfere with sampling and testing procedures developed by other committees, but show how samples taken according to the procedures developed by those committees could be used for the decision making process.

STATUS OF THE PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE: EXPLANATORY NOTES AND PRACTICAL EXAMPLES

83. The Committee agreed to forward the proposed draft Principles (explanatory notes) to the Commission for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix IV).

DISCUSSION PAPER ON DEVELOPMENT OF PROCEDURES / GUIDELINES FOR DETERMINING EQUIVALENCY TO TYPE I METHODS (Agenda Item 5)[8]

84. The Delegation of the United States of America introduced the discussion paper and recalled the decision of the 35th session of CCMAS that numerical criteria for Type I methods should not be established, but that it might be more useful to consider procedures for establishing equivalency to Type I methods.

85. The Delegation reported that the eWG had been established, but that the paper had not been completed in time to allow for discussion in the eWG. The discussion paper was therefore presented as a first draft for discussion and comment.

[8] CX/MAS 15/36/5; comments of Kenya (CRD 8); India (CRD 11); Thailand (CRD 13).

86. The Delegation indicated that evaluating method equivalence requires the comparison of the means of results obtained with the two methods using a relevant set of samples that define the full scope of the intended use of the methods. For this reason, a prerequisite is that both methods must produce results with the same measurand and units of measure.

87. From a review of the scientific literature, three options were identified for the purpose of determining method equivalency:

    i) the two-sample *t*-test;

    ii) the limit of agreement method; and

    iii) the Two one-sided *t*-test or TOST method.

88. The Delegation pointed out advantages and disadvantages for each of the options, noting that option (iii) was probably the most rigorous statistical method and might be challenging since it might be difficult to create a generalized guideline for the specification of a parameter called the acceptance criterion, which represents the range of mean values within which the two methods would be deemed equivalent.

89. The Delegation also pointed out that the paper went beyond comparing one Type I method with another Type I method, but compared another Type with a Type I method (e.g. Type II with Type I).

90. The Delegation proposed that feedback be provided on the possible approaches and that the Committee considers whether there was a continued need for equivalence procedures, and if so, whether it was practical to establish one set of equivalence procedures for all Codex methods; and if such procedures were developed, where they would belong in the Codex system.

91. There was general agreement in the Committee that work should continue, but with caution, since such criteria could have many unintended implications.

92. It was noted that it would be important to clearly define the concept of equivalent methods and whether equivalency would apply between Type I methods, or other methods with Type I methods and that the development of criteria should not disrupt the current concept of Type I methods. Problems could arise in international trade if a dispute were to arise, especially if methods were found to be equivalent to Type I methods, which would require a decision to be made as to which method was the defining method.

93. Opinions were also expressed that currently once a method had been classified Type I, it was difficult to be replaced. By showing equivalence or superiority, this would allow a Type I method to be replaced. This was especially important in the light of technological advances.

94. The Committee noted that there were several other statistical approaches that could be considered and that the statistical approaches presented were a starting point.

95. The Committee noted that there were other protocols available to assess methods against reference methods, such as the NMKL NordVal Protocol No.2, as well as other national protocols.

96. Noting the support for further work and recalling the decision of the 35th Session of the Committee that criteria should not be established for Type I, and that there was a need to establish criteria for equivalency to Type I methods (i.e. Type I to Type I or any other method to Type I), the Committee agreed to re-establish the eWG, led by the United States of America, working in English only. The eWG would further develop the paper taking into account the points raised in the discussion and the written comments submitted, and to make proposals for consideration by the next session of the Committee.

DISCUSSION PAPER ON CRITERIA APPROACH FOR METHODS WHICH USE A 'SUM OF COMPONENTS' (Agenda Item 6)[9]

97. The Delegation of the United Kingdom introduced the report of the in-session Working Group on criteria approach for methods, which use a "sum of components" and the recommendations as presented in CRD 22. The Delegation indicated that the in-session WG had not discussed the discussion paper, CX/MAS 15/36/6, in detail, but had focused its discussion on proposals for a way forward.

[9] CX/MAS 15/36/7; comments of India (CRD 11); Republic of Korea (CRD 12), Thailand (CRD 13), Report of the In-session Working Group (CRD 22).

98. The Committee generally supported further work on the criteria approach for methods which use a sum of components, and noted that such work should focus on chemical methods only, and should also not overlap with the work on equivalency to Type I methods.

99. The Committee also noted that clarification was needed on the purpose of the work and who it was aimed at. Delegations expressed the view that while criteria might be useful for use within Codex, in particular by the Committee, that there might also be value in providing guidance to member countries.

Conclusion

100. The Committee therefore agreed that work should continue and re-established the eWG, led by the United Kingdom, and working in English.

101. The Working Group would:

i) Concentrate on chemical methods of analysis only.

ii) Undertake an analysis of CODEX STAN 234-1999 and individual methods in relevant commodity standards, to determine the extent to which methods of analysis that use a sum of components approach are cited and used; and try to identify potential methods that could be considered by the Committee for future conversion to method performance criteria.

iii) Develop potential options for establishing criteria approaches for methods that are sum of components using CX/MAS 14/35/5 and CX/MAS 15/36/6 as a starting point.

iv) Evaluate the options identified within recommendation 3 to ascertain fitness for purpose.

v) Based on the outcome of recommendations 1 – 4, consider the need to either amend the General Criteria for the Selection of Methods of Analysis section of the Procedural Manual and/or for development of a Guideline Document for governments.

REVIEW AND UPDATE OF METHODS IN CODEX STAN 234-1999 (Agenda Item 7)[10]

102. The Delegation of Brazil presented the report of the eWG and recalled the background to the work. The Delegation highlighted the approach taken by the WG and indicated that nine packages were identified according the criteria established by the Committee. The work excluded 215 methods from the Committee on Nutrition and Foods for Special Dietary Uses, as there was a need to undertake extensive work to examine reports to find the location of the methods. The methods listed in the first package were presented in the Annex to CX/MAS 15/36/7, which highlighted all the methods with inaccurate information endorsed for over ten years, and it was proposed by the Delegation that comments be requested on this Annex.

103. The Delegation noted that the work undertaken reaffirmed the inconsistencies between methods in commodity standards and CODEX STAN 234 and the lack of a harmonized presentation of methods, amongst others. The delegation also highlighted the difficulty to trace decisions, especially on whether methods had been revoked or not endorsed, and that there would be a benefit for the Secretariat to present the appendix on methods endorsement to Reports of the Committee in such a way to provide information on revocation and non-endorsement and the reasons for this.

104. Furthermore, it had been noticed that there were several provisions for which no methods of analysis had been identified in commodity standards and that the Committee would have to consider the identification of methods for these provisions in future.

105. The Delegation noted that several recommendations were made in CRD 21 that could be considered by the Committee.

Discussion

106. There was general support for continuation of the work.

107. The Committee noted that to avoid discrepancies between CODEX STAN 234 and commodity standards, consideration should be given to a single reference for methods of analysis. It was noted that this approach would have procedural consequences and that the CCGP could be requested to amend the Procedural Manual to allow such an approach. There would also be a need to remove discrepancies in CODEX STAN 234.

[10] CX/MAS 15/36/7; comments of European Union and Kenya (CRD 9); Thailand (CRD 13); proposal by observers from standards development organisations (CRD 21); IFU (CRD 23); Chile (CRD 24).

108. It was noted that a single reference would be useful for analysts, but that information needed to be provided as to what kinds of products the methods apply to, as well as the numerical levels to be measured, either directly in the CODEX STAN 234 or by a hyperlink to the actual commodity standards.

109. Views were expressed that while a single reference would have advantages, there might still be a need to retain methods in commodity standards, especially in cases where full descriptions were provided in the commodity standards. The methods of analysis for determination of authenticity of fruits juices, was cited as an example where it might be essential to maintain the methods of analysis in the commodity standard.

110. The Secretariat, noting the support for CODEX STAN 234 as a single reference for methods of analysis, proposed that CODEX STAN 234 be amended to the normal format for a standard, i.e. to include a preamble and other relevant information as to the scope and use of the Standard. The *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) or the *General Standard for Food Additives* (CODEX STAN 192-1995) could be used as examples for the amendment. The Secretariat offered to prepare a proposal for the preamble and other introductory text for consideration by the next session of the Committee.

Conclusion

111. The Committee agreed to continue the work on the update and review of the endorsed methods of analysis through an eWG led by Brazil, co-chaired by Japan, and working in English only with the following terms of reference:

- Continue working on the identification of inconsistencies in CODEX STAN 234 and other Codex Standards.
- Include methods from CCNFSDU in the workable packages.
- Look over the Codex Committees Standards to identify limits and parameters that don't have related method of analysis.
- Discuss where and how to make reference to methods completely described in the Commodity Standards.
- Propose to CCMAS a process to update the endorsement of Codex Methods.
- Incorporate the suggestions made by the CCMAS regarding the inclusion of the numerical provisions and identification of the Commodity Standards to which the methods apply in CODEX STAN 234.

112. The Committee further agreed to request CCGP to consider amending the Procedural Manual in order to have CODEX STAN 234 as a single reference for methods of analysis in Codex.

113. The Committee also agreed to request the Secretariat to prepare a proposal for the preamble and other introductory text for CODEX STAN 234.

REPORT OF INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 8)[11]

114. The Observer of AOCS, as secretariat of IAM, introduced the report of the IAM in CRD 3 and highlighted the various issues that IAM had discussed with respect to the work of CCMAS and other related matters.

115. The Committee noted that several of the issues raised in the report of the IAM had been considered under the relevant items.

116. The Committee also noted the request of the Observer from AOECS for the development of a single method to determine gluten in all types of foods. The Observer from AACCI indicated that it would be desirable to have a single method, but that the method validation presented, did not allow this. The AACCI would continue to validate methods as they became available and would encourage that validation be carried out across a wide range of food matrices, in order to make the claim that the method applied to all foods.

[11] Report of the Inter-Agency Meeting on Method of Analysis (CRD 3)

117. In relation to the outstanding issue of sampling in Codex standards, the Committee noted that the paper prepared by IAM and presented at the last session of the Committee would continue to be developed by members of IAM with inputs from Codex members which could potentially provide guidance on how to interpret the sampling principles. It was requested that this paper should be aimed at non-specialist and that it would be useful for CCMAS to see the paper before its publication. The Committee agreed that IAM would present its paper to the next session of CCMAS. It was further noted that there would be no overlap between this work and the activities of the eWG established under Agenda Item 4.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)[12]

Method for non-dioxin like PCBs in food

118. The Delegation of Iceland introduced CRD 4 and explained that non-dioxin like PCBs in food is a very important contaminant in food and feed. Currently Codex member countries used a variety of methods for the analysis of non-dioxin like PCBs in foods, some of which were outdated, and did not give comparable results to newer methods, thus giving rise to trade problems. The Delegation proposed that CCMAS puts forward a method or methods for the analysis for a range of non-dioxin like PCBs in foods and/or establishes specific performance criteria for methods for these contaminants.

119. The Committee noted that it would be difficult to consider this matter at this time as there was no Codex provision for non-dioxin like PCBs. JECFA would be undertaking a risk assessment in June 2015 upon which the CCCF would consider whether risk management options were needed, e.g. the establishment of an ML.

120. The Committee further noted that CCMAS normally considered such matters on referral from other Codex Committees and it could therefore be expected that if CCCF were to develop an ML, that a method for its determination would be forwarded to CCMAS for consideration and endorsement.

Conclusion

121. The Delegation of Iceland was therefore advised to follow discussions in CCCF and CCMAS.

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

122. The Committee was informed that its 37th Session was tentatively scheduled to be held in Budapest, Hungary from the 22 to 26 February 2016, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

123. The Committee noted that there might be the possibility to convene physical working group(s) immediately prior to the next Session, to facilitate discussion in plenary. Members and Observers will be informed of these physical working groups well in advance of the Session.

[12] Proposal from Iceland (CRD 4).

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP14/MAS)
Methods of Analysis and Sampling in Codex Standards at different steps	-	Governments 38th CAC	Para. 42 Appendix III
Principles for the Use of Sampling and Testing in International Food Trade – Proposed Draft Explanatory notes	5/8	Governments 38th CAC	Para. 83 Appendix IV
Criteria for endorsement of biological methods to detect chemical of concern	-	Electronic Working Group (Chile and France) 37th CCMAS	Paras 57 - 59
Practical Examples (Information Document)	-	Electronic Working Group (Germany and New Zealand) 37th CCMAS	Para. 79
Procedures for determining uncertainty of measurement results			
Development of procedures/guidelines for determining equivalency to Type I methods	-	Electronic Working Group (United States of America) 37th CCMAS	Para. 96
Criteria approach for methods which use a “sum of components”	-	Electronic Working Group (United Kingdom) 37th CCMAS	Paras 100 - 101
Review and update of methods in CODEX STAN 234-1999	-	Electronic Working Group (Brazil and Japan) 37th CCMAS	Para. 111
Follow-up on methods of analysis and sampling plans	-	37th CCMAS	Paras 37 and 39
Sampling in Codex standards	-	Members of the Inter-Agency Meeting	Para. 117

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Appendix II

RESPONSE OF CCMAS36 TO THE 2014-2019 STRATEGIC PLAN IMPLEMENTATION

Responses of CCMAS36 are shown in **bold and underlined** font.

Strategic Goal	Objective	Activity	Expected Outcome	Measurable Indicators/Outputs
1: Establish international food standards that address current and emerging food issues.	1.1: Establish new and review existing Codex standards, based on priorities of the CAC	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.	New or updated standards are developed in a timely manner	- Priority setting criteria are reviewed, revised as required and applied. - # of standards revised and # of new standards developed based on these criteria.
Question to the Committee: Is this activity relevant to the work of the Committee? **Yes.** Does the Committee use any specific criteria for standards development? **No, the Committee applies the relative procedures laid down in Procedural Manual, e.g. Criteria for the establishment of work priorities and the decision-making criteria for the development of standards and guidelines, particularly in the section on procedures for the elaboration of Codex standards and related texts'.** Does the Committee intend to develop such criteria? **No. The Committee will continue to refer to the general ones laid down in the Procedural Manual.** **The Committee should ensure that the provisions included in the relevant parts of the Procedural Manual are strictly applied and that no proposal for new work is submitted to the CAC if this has not been the case.**				
	1.2: Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.	1.2.1: Develop a systematic approach to promote identification of emerging issues related to food safety, nutrition, and fair practices in the food trade.	Timely Codex response to emerging issues and to the needs of Members.	- Committees implement systematic approaches for identification of emerging issues. - Regular reports on systematic approach and emerging issues made to the CCEXEC through the Codex Secretariat.
Question to the Committee: Is this activity relevant to the work of the Committee? **Yes.** How does the Committee identify emerging issues and members needs? Is there a systematic approach? Is it necessary to develop such an approach? **Emerging issues can be reported by the members directly to the CCMAS or to other Committees, which then report specific issues relating to methods of analysis and sampling to the CCMAS. The Inter-Agency Meeting also proposes emerging issues to be dealt within CCMAS. This process then leads to the revision or the development of Standards and Guidelines. Unless there is evidence of some failure in this process, the Committee does not see benefits in the development of a systematic approach for the CCMAS.**				

		1.2.2: Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade.	Improved ability of Codex to develop standards relevant to the needs of its Members.	- Input from committees identifying and prioritizing needs of Members. - Report to CCEXEC from committees on how standards developed address the needs of the Members as part of critical review process.
Included in question to 1.2.				
2: Ensure the application of risk analysis principles in the development of Codex standards.	2.1: Ensure consistent use of risk analysis principles and scientific advice.	2.1.1: Use the scientific advice of the joint FAO/WHO expert bodies to the fullest extent possible in food safety and nutrition standards development based on the "Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius".	Scientific advice consistently taken into account by all relevant committees during the standard setting process.	-. # of times the need for scientific advice is: - identified, - requested and, - utilized in a timely manner.
Question to the Committee: Is this activity relevant to the work of the Committee? **No, not in the sense of requiring scientific advice from the established FAO/WHO expert scientific advice bodies, however, the Committee does take into account all relevant science and technological information, as necessary.** Does the committee request scientific advice in course of its work, how often does it request such advice? Does the committee always use the scientific advice, if not, why not?				
		2.1.2: Encourage engagement of scientific and technical expertise of Members and their representatives in the development of Codex standards.	Increase in scientific and technical experts at the national level contributing to the development of Codex standards.	- # of scientists and technical experts as part of Member delegations. - # of scientists and technical experts providing appropriate input to country positions.
Question to the Committee: Is this activity relevant to the work of the Committee? **Yes. Scientific and technical expertise is often required to justify the positions advanced by the Members.** How do members make sure that the necessary scientific input is given into country positions and that the composition of the national delegation allows to adequately present and discuss this position? I**t is up to each Member to organise and manage the necessary scientific input with a view to make an informed contribution to the decision making process.** What guidance could be given by the Committee or FAO and WHO? **The Committee does not believe that a specific guidance is needed at this point.**				

		2.1.3: Ensure that all relevant factors are fully considered in exploring risk management options in the context of Codex standard development.	Enhanced identification, and documentation of all relevant factors considered by committees during the development of Codex standards.	- # of committee documents identifying all relevant factors guiding risk management recommendations. - # of committee documents clearly reflecting how those relevant factors were considered in the context of standards development.
Question to the Committee: Is this activity relevant to the work of the Committee? **Yes. In its capacity of risk manager, the Committee ensures that all relevant factors in exploring risk management options are considered. This is a prerequisite for Codex standard development according to the Procedural Manual.** How does the Committee ensure that all relevant factors have been taken into account when developing a standard and how are these documented? **Methods of analysis and sampling contribute to the management of risks, mostly in supporting the implementation of risk management decisions.** **The Procedural Manual already establishes Working Principles for Risk Analysis which stipulate that risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken. These principles requests a transparent, consistent and fully documented risk management process, and a presentation of the conclusion of the risk assessment before making final proposals or decisions on the available risk management options. The Committee should therefore recall the importance of applying consistently these principles.**				
		2.1.4: Communicate the risk management recommendations to all interested parties.	Risk management recommendations are effectively communicated and disseminated to all interested parties.	- # of web publication/ communications relaying Codex standards. - # of media releases disseminating Codex standards.
Question to the Committee: Is this activity relevant to the work of the Committee? **Yes. However, currently this is mainly done through the publication of standards and related texts on the Codex website. The development of a communication strategy would have a positive impact on this activity.** When taking a risk management decision, does the committee give guidance to members how to communicate this decision? Would more consideration of this be helpful to members? **No. Once the communication strategy is developed, more consideration could be given to this issue.**				
3: Facilitate the effective participation of all Codex Members.	3.1: Increase the effective participation of developing countries in Codex.	3.1.5: To the extent possible, promote the use of the official languages of the Commission in committees and working groups.	Active participation of Members in committees and working groups.	- Report on number of committees and working groups using the languages of the Commission

Question to the Committee: Is this activity relevant to the work of the Committee? **Yes, the promotion of effective participation of developing countries is of interest to CCMAS.** Is the use of official languages in working groups of the committee sufficient? **The Committee recommends using as many official languages of CAC as possible in WGs in order to enhance participation of members.** What are the factors determining the choice of languages? **This mainly depends on the Member chairing and co-chairing the WG.** How could the situation be improved? **A suggestion could be to promote co-hosting arrangements by countries with different languages.**				
	3.2: Promote capacity development programs that assist countries in creating sustainable national Codex structures.	3.2.3: Where practical, the use of Codex meetings as a forum to effectively conduct educational and technical capacity building activities.	Enhancement of the opportunities to conduct concurrent activities to maximize use of the resources of Codex and Members.	- # of activities hosted on the margins of Codex meetings.
Question to the Committee: Is this activity relevant to the work of the Committee? **Yes, the promotion of such capacity development programs is of interest to CCMAS.** Does the Committee organize technical capacity activities or other activities in the margins of Committee sessions? If yes – how many and with which topics have been organized in the past. **The Committee believes that any capacity building activity should be coordinated by the parent organisations in order to avoid inconsistencies and duplication of work.** **A number of MoniQA/IAM workshops have been organised to inform delegates about issues of high topicality, notably estimation of measurement uncertainty, method validation, proficiency testing, etc.** If no – could this be useful and what topics could be addressed? **The Committee is open to any initiatives in this area.**				
4: Implement effective and efficient work management systems and practices.	4.1: Strive for an effective, efficient, transparent, and consensus based standard setting process.	4.1.4: Ensure timely distribution of all Codex working documents in the working languages of the Committee/ Commission.	Codex documents distributed in a more timely manner consistent with timelines in the Procedural Manual.	- Baseline Ratio (%) established for documents distributed at least 2 months prior to versus less than 2 months prior to a scheduled meeting. - Factors that potentially delay the circulation of documents identified and addressed. - An increase in the ratio (%) of documents circulated 2 months or more prior to meetings.

Question to the Committee: Is this activity relevant to the work of the Committee? **Yes, in particular given the technical nature of issues discussed in this Committee.** Does the Committee have a mechanism in place to ensure timely distribution of documents? What could be done to further improve the situation? **Every possible effort should be made to ensure the timely distribution of documents.** **The requirement for timely distribution of documents already exists and is included in the Procedural Manual. However, all members should be more disciplined in ensuring its implementation.**				
		4.1.5: Increase the scheduling of Work Group meetings in conjunction with Committee meetings.	Improved efficiency in use of resources by Codex committees and Members	- # of physical working group meetings in conjunction with committee meetings, where appropriate.
Question to the Committee: Is this activity relevant to the work of the Committee? **No. The CCMAS already schedules Work Group meetings in conjunction with Committee meetings when necessary.** Does the Committee hold physical working groups independent of Committee sessions? If yes – why is this necessary? **The Committee believes that in general the system in place today, eWG combined with physical working groups organised in conjunction with Committee sessions, is sufficient to ensure the efficiency of the work of the Committee. There does not seem to be any added value of working groups independent of Committee sessions, unless it is fully justified by specific needs. The Committee is rather concerned about the additional resources that such organisation would require.**				
	4.2: Enhance capacity to arrive at consensus in standards setting process.	4.2.1: Improve the understanding of Codex Members and delegates of the importance of and approach to consensus building of Codex work.	Members and delegates awareness of the importance of consensus in the Codex standard setting process improved.	- Training material on guidance to achieve consensus developed and made available in the languages of the Commission to delegates. - Regular dissemination of existing material to Members through Codex Contact Points. - Delegate training programs held in association with Codex meetings. - Impediments to consensus being achieved in Codex identified and analyzed and additional guidance developed to address such impediments, if necessary.

Question to the Committee:

Is this activity relevant to the work of the Committee?

Yes.

The Committee strongly believes that it is essential to maintain consensus-based decision making in the framework of Codex Alimentarius. This is necessary to ensure the legitimacy, credibility and worldwide acceptance of Codex standards. The obligation to strive for consensus-based decision making is clearly spelled out in Rule XII of the Rules of Procedure of the CAC.

It is the role of the chair to explore all possible means to reach consensus before taking any final decision on progressing a standard on the basis of a vote.

Are there problems with finding consensus in the Committee? If yes – what are the impediments to consensus? What has been attempted and what more could be done?

Problems may arise in this Committee, as well as in any other Committees. All efforts should be made to ensure that all decisions of the Committee are taken on the basis of consensus, or the work should not be forwarded to the CAC.

Appendix III

ENDORSED METHODS OF ANALYSIS AND SAMPLING

A. Processed Fruits and Vegetables

B. Fats and Oils

C. Nutrition and Foods for Special Dietary Uses

D. Milk and Milk Products

A. PROCESSED FRUITS AND VEGETABLES

STANDARD FOR CANNED FRUITS – METHODS OF ANALYSIS

Commodity	Provisions	Method	Principle	Type
Canned fruits	Drained weight	AOAC 968.30 (Codex general method for processed fruits and vegetables)	Sieving Gravimetry	I
Canned fruits	Fill of containers	~~**CAC/RM 46-1972 (for glass containers)**~~ ~~**(Codex general method for processed fruit and vegetables)**~~	~~**Weighing**~~	**Revoked**
		ISO 8106 (for glass containers)	Weighing	I
		ISO 90.1 (for metal containers) (Codex general method for processed fruit and vegetables)	Weighing	I
Canned fruits	Soluble solids	ISO 2173 (Codex general method for processed fruit and vegetables) AOAC 932.14C	Refractometry	I

STANDARD FOR CANNED FRUITS – SAMPLING PLAN

Commodity	Sampling Plan
Canned fruit	Described in the Standard

STANDARD FOR GINSENG AND GINSENG PRODUCTS – METHODS OF ANALYSIS

Commodity	Provisions	Method	Principle	Type
Ginseng	Moisture	AOAC 925.45 B (Dried ginseng) Quantity of sample: 2 g	Gravimetry	I
Ginseng	Moisture	AOAC 925.45 D (Ginseng extract) Quantity of sample: 1.5 g (mixing with 20 g of sea sand)	Gravimetry	I
Ginseng	Solids	AOAC 925.45 B (Dried ginseng) calculated by subtracting the content of moisture from 100% Quantity of sample: 2 g	Calculation	I
		AOAC 925.45 D (Ginseng extract) calculated by subtracting the content of moisture from 100% Quantity of sample: 1.5 g (mixing with 20 g of sea sand)	Calculation	I
Ginseng	Ash	AOAC 923.03 AACC Intl 08-01.01	Gravimetry	I

Ginseng	Water-insoluble solids	described in the Standard	Gravimetry	I
Ginseng	Water-saturated n-butanol extracts	described in the Standard	Gravimetry	I
Ginseng	Identification of ginsenosides Rb1, and Rf	described in the Standard	TLC or HPLC	IV

B. FATS AND OILS

STANDARD FOR FISH OILS – METHODS OF ANALYSIS

Commodity	Provisions	Method	Principle	Type
Fish oil	Fatty acid composition	ISO 5508	Gas chromatography	III
		ISO 12966-2	Gas chromatography	III
		AOCS Ce 1b-89	GLC	III
		AOCS Ce 1i-07	Capillary GLC	III
		AOCS Ce 2b-11	Alkali hydrolysis	III
		AOCS Ce 1a-13	Capillary GLC	III
		AOCS Ce 2-66	Preparation of methyl esters by fatty acids	III
Fish oils	Acid value	AOCS Ca 5a-40 AOCS CD 3D-63 ISO 660 NMKL 38	Titration	I
Fish Oils	Peroxide value	AOCS Cd 8b-90 ISO 3960 NMKL 158	Titration	I
		European Pharmacopeia 2.5.5 (Part B Iso-octane as solvent)		
Fish oils	P-Anisidine value	AOCS Cd 18-90	Spectrophotometry	I
Fish Oils	Vitamin A	European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01/2005:1192, with LC end-point 2.2.29.	LC	III
		EN 12823-1(Determination of vitamin A by high performance liquid chromatography - Part 1: Measurement of all-E-retinol and 13-Z-retinol)	LC	III

Commodity	Provisions	Method	Principle	Type
Fish oils	Vitamin D	European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01	LC	III
		EN 12821 (Determination of vitamin D by high performance liquid chromatography - Measurement of cholecalciferol (D3) or ergocalciferol (D2))	LC	III
		NMKL 167 (Cholecalciferol (vitamin D3) and Ergocalciferol (vitamin D2). Determination by HPLC in foodstuffs).	LC	III

STANDARD FOR FISH OILS – SAMPLING PLAN

Commodity	Sampling Plan
Fish oils	ISO 5555

C. NUTRITION AND FOODS FOR SPECIAL DIETARY USES

STANDARD FOR DIETARY FIBRE - METHODS OF ANALYSIS

Commodity	Provisions	Method	Principle	Type
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	AACC Intl 32-45.01 AOAC 2009.01	Enzymatic-Gravimetry High Pressure Liquid Chromatography	I
All foods (1)	Method applicable for determining the content of insoluble and soluble dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches	AACC Intl 32-50.01 AOAC 2011.25	Enzymatic-Gravimetry High Pressure Liquid Chromatography	I

STANDARD FOR INFANT FORMULA – METHODS OF ANALYSIS

Commodity	Provisions	Method	Principle	Type
Infant formula	Crude protein*	ISO 8968-1|IDF 20-1~~/ AOAC 991.20**~~	Titrimetry (Kjeldahl)	I

The calculation of the protein content of infant formulas prepared ready for consumption may be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products

D. MILK AND MILK PRODUCTS

Commodity	Provisions	Method	Principle	Type
Blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1 ~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	IV
Blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF[1]	AOAC 991.20	Titrimetry (Kjeldahl)	IV
Reduced fat blend of Evaporated skimmed milk and vegetable fat	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1 ~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	IV
Reduced fat blend of Evaporated skimmed milk and vegetable fat	Milk protein in MSNF[1]	AOAC 991.20	Titrimetry (Kjeldahl)	IV
Blend of skimmed milk and vegetable fat in powdered form	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1 ~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	IV
Blend of skimmed milk and vegetable fat in powdered form	Milk protein in MSNF[1]	AOAC 991.20	Titrimetry (Kjeldahl)	IV
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1 ~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	IV
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Milk protein in MSNF[1]	AOAC 991.20	Titrimetry (Kjeldahl)	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1 ~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF[1]	AOAC 991.20	Titrimetry (Kjeldahl)	IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1 ~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	IV

Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF[1]	AOAC 991.20	Titrimetry (Kjeldahl)	IV
Cheese, unripened including fresh cheese	Milk Protein	ISO 8968-1|IDF 20-1~~/ AOAC 991.20 and 991.23~~	Titrimetry (Kjeldahl)	I
Cream and prepared creams	Milk protein	ISO 8968-1|IDF 20-1~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	I
Evaporated milks	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1~~/ AOAC 991.20 /AOAC 945.48H~~	Titrimetry (Kjeldahl)	I
Fermented milks	Milk Protein	ISO 8968-1|IDF 20-1~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	I
Milk powders and cream powders	Milk protein	ISO 8968-1|IDF 20-1~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	I
Sweetened Condensed Milks	Milk protein in MSNF[1]	ISO 8968-1|IDF 20-1~~/ AOAC 991.20 AOAC 945.48H~~	Titrimetry (Kjeldahl)	I
Whey powders	Milk protein (total N x 6.38)	ISO 8968-1|IDF 20-1~~/ AOAC 991.20~~	Titrimetry (Kjeldahl)	I

[1]Milk total solids and MSNF content include water of crystallization of lactose

Appendix IV

Principles for the Use of Sampling and Testing in International Food Trade (integration of the Proposed Draft explanatory notes into the Principles)

(at Step 5/8)

SECTION 1 - INTRODUCTION

Sampling and testing are, among others, procedures utilized to assess whether foods in trade are compliant with particular specifications. These procedures may affect the probabilities of wrongly accepting or wrongly rejecting a lot or consignment[1]. Therefore these probabilities should be evaluated so that they can be controlled to acceptable levels for affected parties. The absence of defined, scientifically valid procedures could lead to *ad hoc* practices being used, resulting in inconsistent decisions and an increased occurrence of disputes.

To ensure the sampling and testing procedures are valid, they should be based upon scientific, internationally accepted principles, and it is necessary to ensure that they can be applied fairly. With regard to sampling, the *General Guidelines on Sampling* states that "Codex Methods of Sampling 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." With regard to testing, the methods of analysis endorsed by Codex should be considered first.

Sampling and testing procedures are often used in international food trade for the purpose of risk management related to safety. For this purpose, sampling and testing procedures should be established as an integral part of a national food control system to the extent possible.

Risk management decisions should be commensurate to the assessed risk, and should take into account risk assessment and other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in the food trade and, if needed, selecting appropriate prevention and control options.

It should be recognised that end-product sampling and testing is only one of the methods by which an exporter can validly claim that a product meets specifications. Other means of establishing whether foods in trade meet specifications exist in Codex.

This document does not affect existing Codex provisions or the current way of setting those provisions. This document should be read in conjunction with the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) and the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).

This document provides assistance in assessing impacts of sampling and testing procedures on affected parties. [2]

SECTION 2 - SCOPE

These principles are intended to assist governments in the establishment and use of sampling and testing procedures for determining, on a scientific basis, whether foods in international trade are in compliance with particular specifications. Compliance with these principles will also assist in avoiding potential disputes.

The explanatory notes are intended:

- to explain the principles and their use in sampling and testing procedures; and

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[1] In the field of acceptance sampling, the probability of wrongly accepting a lot and the probability of wrongly rejecting a lot are referred to as "Consumers' Risk" and "Producers' Risk", respectively (see for example CAC/GL 50-2004).

[2] Practical examples are under development and will be available at www.codexalimentarius.org

- to help governments and other interested parties to understand the principles and to establish and use sampling and testing procedures to assess whether foods in international trade comply with specifications.

SECTION 3 - DEFINITIONS

Testing

Process to examine the specified characteristics of a sample.

Testing procedure

Operational requirements and/or instructions relating to the testing; i.e. preparation of sample and method of analysis to yield knowledge of the characteristic(s) of the sample.[1]

Sampling procedure

Operational requirements and/or instructions relating to the use of a particular sampling plan; i.e. the planned method of selection, withdrawal and transport to the laboratory of sample(s) from a lot or consignment to yield knowledge of its characteristic(s).

Other definitions relevant to these principles include:

Consignment[a]

Lot[a]

Sample[a]

Sampling[a]

Sampling plan[a]

Result[b]

Measurement uncertainty[c]

[a] *General Guidelines on Sampling* (CAC/GL 50-2004)

[b] *Guidelines on Analytical Terminology* (CAC/GL 72-2009)

[c] *Guidelines on Measurement Uncertainty* (CAC/GL 54-2004)

SECTION 4 – PRINCIPLES

Principle 1: Transparency and agreements before initiating trade

Before starting trading activities, or when introducing or modifying an import testing program, the parties concerned should reach agreement related to the sampling and testing procedures that will be applied to assess whether the food in trade meets the specifications of Codex or the importing country. This agreement should also specify the sampling and testing procedures to be followed in the case of a dispute.

When a lot or consignment is to be assessed, the sampling and testing procedures to be used and the criteria for acceptance of a product should be documented and communicated by all parties. In the event of a rejection of a lot or consignment, all relevant information should be shared between governments using mutually agreed upon format and language(s).

Explanatory Notes

Transparent sampling, testing and assessment procedures allow all parties to operate in an open way so that each is fully aware of the actions performed by the other parties. Having full knowledge and understanding of the procedures and the inherent probabilities of wrongly accepting or wrongly rejecting a lot leads to informed decision-making by both parties which in turn can reduce the potential for disputes based on sampling and testing results. When discrepancies do occur, transparency allows for effective communications between parties to address differences.

Agreement is desirable:

- *to maintain the probability of wrongly accepting or wrongly rejecting a lot at reasonable levels fair to both parties;*
- *to avoid future disputes concerning the appropriateness of the methods of sampling and analysis or the criteria used to judge the results.*

The agreements should contain, for example:

- *The language of communication;*
- *The specification of the principles concerning acceptance or rejection of a lot or consignment* e.g. *General Guidelines on Sampling (CAC/GL 50-2004);*
- *The specification of the manner in which production lots or consignments may be linked to inspection samples;*
- *The specification of the sampling procedure;*
- *If the assessment procedure requires an estimate of lot inhomogeneity (e.g. a standard deviation), the method used to estimate the inhomogeneity should be specified. If the standard deviation is treated as "known", the assumed value should be scientifically based and accepted by both parties;*
- *The specification of analytical methods including criteria of appropriateness in order to ensure equivalent measurements (e.g. applicability, limit of detection, limit of quantification, precision, recovery and trueness);*
- *Whether recovery correction is applied to analytical results or not;*
- *The specification of criteria for compliance assessment;*
- *The process for resolving disputes over analytical (test) results* (for example *CAC/GL 70-2009);*
- *The procedures in case of any variations of the above-mentioned terms.*

In line with the principles, the agreed specifications should not restrict the flexibility of the control program in the importing country.

In the case of a rejection the exchange of information should be done according to the Guidelines for the Exchange of Information between Countries on Rejections of Imported Food (CAC/GL 25-1997).

Principle 2: Components of a product assessment procedure

Sampling and testing of food in trade to assess whether the food meets specifications involves three components, and all three of these should be considered when an assessment procedure is selected:

- Selection of samples from a lot or consignment as per the sampling plan;
- Examination or analysis of these samples to produce test results (sample preparation and test method(s));
- Criteria upon which to base a decision using the results.

Principle 3: Probability of incorrect decisions

Whenever food is sampled and tested, the probabilities of wrongly accepting or wrongly rejecting a lot or consignment affect both exporters and importers and can never be entirely eliminated. These probabilities should be evaluated and controlled, preferably using methodology described in internationally recognized standards.

Explanatory Notes

Probabilities of wrongly accepting or wrongly rejecting a lot or consignment can never be entirely eliminated because of the uncertainty of measurement due to both the sampling and testing procedures. The General Guidelines on Sampling (CAC/GL 50-2004), sections 3, 4 and 5, provide guidance on sampling plans for various situations.

Sampling plans are developed considering probabilities of wrongly accepting or wrongly rejecting a lot or consignment. The appropriate levels of the probabilities are set in conjunction with appropriate choice of Acceptable Quality Level (AQL)[3] and Limiting Quality (LQ) for characteristics in foods to be tested.

Characteristics which may be linked to critical defects, for example relating to the sanitary condition of food, should be associated with a low AQL (i.e. 0.1 % to 0.65 %), whereas compositional characteristics, such as the fat or water content, may be associated with a higher AQL (e.g., 2.5 % or 6.5 %).

The specification of acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment should have regard to principles of fairness towards both the consumers and the producers, as well as importing and exporting countries. This means making sure that consumers are not exposed to an unduly high probability of accepting non-compliant product and that a compliant product is not exposed to an unduly high probability of rejection.

Prior information may be useful in controlling the probabilities of wrongly accepting or wrongly rejecting a lot or consignment. For example, the importer can take into account the rate of non-compliance of certain exporter/importer combinations, using procedures with relatively lower sampling rates in cases where past records show that there is a low probability of non-compliance, and higher sampling rates for other situations.

It may also be useful to take into account testing that has already been carried out by the exporter. Export control procedures generally include a combination of end-product testing with a range of other controls, and effective management of these is vital. These management measures should involve Hazard Analysis and Critical Control Point (HACCP), Good Agricultural Practice (GAP), Good Manufacturing/Production Practice (GMP) and traceability aspects, where appropriate. Further details can be found in the General Guidelines for Food Import Control Systems (CAC/GL 47-2003). However, non-stable or perishable foods may need special consideration.

Prior experience, knowledge and confidence in *the exporter's control system can lead to choosing a less strict sampling plan compared to the situation without prior knowledge. If the historical data suggest that the manufacturing process is in statistical control, a good estimate of the process standard deviation may be available, permitting reduced testing whilst maintaining the original stringency.*

Principle 4: Selecting appropriate sampling and testing procedures

The sampling and testing procedures selected should be:

- Scientifically based, taking into account the existing Codex standards;
- Appropriate to the commodity and lot or consignment to be sampled and tested;
- Fit for intended purposes and applied consistently.

The selection of sampling and testing procedures should take into account:

- Practical matters such as cost and timeliness of the assessment and access to lots or consignments, provided that the probability of accepting a non-compliant lot or consignment is not too high;
- Variation within a lot or consignment.

Explanatory Notes

If sampling and testing procedures are not appropriate, there may be an unduly high probability of wrongly accepting or wrongly rejecting a lot or consignment which may lead to disputes between the interested parties[4].

The General Guidelines on Sampling (CAC/GL 50-2004) or considerable information available from elsewhere, e.g. international standards, such as ISO 2859 (Inspection by attributes), ISO 3951 (Inspection by variables) and ISO 10725 (Inspection of bulk materials), and published papers and textbooks, should

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[3] In ISO 3534, *Statistics – Vocabulary and Symbols*, the term used is “acceptance quality level”.

[4] Note that it might not be appropriate for producers to apply the same sampling plans as those used by receivers of commodities.

be consulted when developing appropriate sampling plans. The Guidelines are applicable for control at reception, but may not be applicable for quality control of end-products by manufacturers.

The Guidelines cover the following sampling situations:

- *Control of percentage of defective items, by attributes or by variables, for a continuous series of lots or in individual items;*
- *Control of mean content.*

Information that is needed in order to define an appropriate sampling plan and method of analysis includes:

- *Whether the procedure is to apply to single lots considered in isolation, or to lots forming part of a continuing series;*
- *Whether the methods available to assess the characteristics of samples are qualitative or quantitative;*
- *Whether sampling plans will be on inspection by attributes basis or inspection by variables basis;*
- *Parameters such as the AQL or LQ.*

Each lot or consignment that is to be examined must be clearly defined. If a consignment is to be accepted or rejected in its entirety, the sampling should be carried out over the entire consignment. *In order to avoid any dispute over the representativeness of the sample, a random sampling procedure (CAC/GL 50-2004, 2.3.3) should be chosen whenever possible, alone, or in combination with other sampling techniques.*

If it is required to control the percentage of non-conforming items in a lot, then:

- *For inspected characteristics that are qualitative (including quantitative data classified as attributes, for example "conforming" or "not conforming" with respect to a limit) or distributed in an unknown manner, attributes plans should be used for sampling;*
- *In case of measurable characteristics with normally distributed variability, variables plans should be chosen.*

If it is required to control the average of a characteristic in a lot, then:

- *Single Sampling Plans for Average Control (CAC/GL 50-2004, 4.4) are recommended as tests which aim at ensuring that, on average, the content of the controlled characteristic does not fall outside a specified range.*

Note that CAC/GL 50-2004 does not cover the control of non-homogeneous lots. In case of non-homogeneous lots or consignments (e.g. chemical or microbiological contaminants in food), an appropriate sampling procedure should be selected.

In addition, the physical obtaining of samples for the purpose of laboratory analysis should be performed in accordance with appropriate standards related to the commodity of concern (for example ISO 707|IDF 50 Milk and milk products – Guidance on sampling or the Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs for pesticide residues (CAC/GL 33-1999).

Principle 5: Analytical measurement uncertainty

The selection of the product assessment procedure should take into account analytical measurement uncertainty and its implications.

Explanatory Notes

The analytical measurement uncertainty includes the contribution of all steps of the determination of the measurand in the sample delivered to the laboratory for testing compliance with the relevant specification. The steps of the determination procedure depend on the nature of the sample material and the mass of the sample. They may include sample size reduction, selection of a portion of the commodity to which the corresponding specification refers, homogenization of the sample material, extraction, removal of interfering materials, qualitative and quantitative determination, etc.

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. This agreement should cover all situations where a limit or specification level is to be met, including limits for potential health hazards if such characteristics are to be assessed under the agreement.

Section 8.1 of the Explanatory Notes of Guidelines on Measurement Uncertainty (CAC/GL 54-2004) shows an example of several situations when decisions are made based on a single test sample where an analytical result with analytical measurement uncertainty is compared against a specification level (e.g. a maximum level).

Various guidelines (e.g. Guidelines on Estimation of Uncertainty of Results (CAC/GL 59-2006) and Guidelines on Measurement Uncertainty (CAC/GL 54-2004) describe procedures for estimating analytical measurement uncertainty based on different combinations of in-house validation data, in-house precision data and inter-laboratory data, and illustrate how analytical measurement uncertainty might be taken into account in the most simple case, i.e. when decisions are made based on a single test sample. In all cases the key consideration during uncertainty estimation is the evaluation of all significant sources of uncertainty.

Principle 6: Fitness for purpose

Sampling and testing procedures are fit for purpose in a given product assessment, if, when used in conjunction with appropriate decision criteria, they have acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment.

Explanatory Notes

*In terms of developing a sampling plan, the number of samples and decision criterion are determined by probabilities of wrongly accepting or wrongly rejecting a lot or consignment. In this context**, fitness for purpose** means that the sampling plan is 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.*

For example:

a. *Use of an AQL of 0.1% may be inappropriate for a compositional characteristic such as fat in whole milk powder because this is costly and difficult to achieve for the producer; and*

b. *Use of an AQL of 6.5% may be inappropriate for a hazardous characteristic intended for a consumer because this does not adequately protect the consumer´s health.*

In terms of using a testing procedure, testing laboratories should adhere to the Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food (CAC/GL 27-1997) and to Food Control Laboratory Management: Recommendations (CAC/GL 28-1995).

The following quality assurance criteria should be adopted by laboratories involved in the import and export control of foods:

- *Compliance with the general criteria for testing laboratories laid down in ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories";*
- *Participation in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in "The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories", Pure & Appl. Chem. 78 (2006) 145-196;*
- *Whenever available, use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission;*
- *Use of internal quality control procedures, such as those described in the Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories Pure & Appl. Chem. 67 (1995) 649-666.*

Principle 7: Review procedures

Sampling and testing procedures should be reviewed periodically to ensure they take into account new science and information.