

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling (CCMAS) held its thirty fifth Session in Budapest, Hungary from 3 to 7 March 2014, at the kind invitation of the Government of Hungary.
2. 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.
3. The Session was attended by delegates from 50 Member countries and one Member organization and Observers from 14 international organizations. The list of participants, including the Secretariats, is given in Appendix I to this report.

OPENING OF THE SESSION

4. The session was opened by Dr Márton Oravecz the President of the National Food Chain Safety Office who welcomed delegates to Hungary. He reminded the delegates of the importance of Codex in protecting public health and promoting fairness in trade. He also pointed out that Codex standards were the main benchmark on which the Hungarian food industry was being governed and the work of CCMAS was important in supporting the Hungarian National Food Safety Monitoring programmes. He highlighted some of the important work of the Committee and wished the Committee successful deliberations.
5. Mr Vladimir Rakhmanin, the FAO Regional Representative for Europe and Central Asia and Dr Zsófia Pusztai Representative of WHO also addressed the Committee and expressed their continued support to the work of Codex.

Division of Competence¹

6. 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 2.

¹CRD 2 (Annotated Agenda – Division of competence between the European Union and its Member States).

ADOPTION OF THE AGENDA (Agenda Item 1)²

7. The Committee adopted the Provisional Agenda as its Agenda for the Session and agreed to establish an in-session Working Group, chaired by Germany, to consider written comments received and to prepare a revised Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade: Explanatory notes.

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

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

Committee on Fish and Fishery Products (CCFFP)

9. The Committee recalled that CCFFP had requested the Committee to provide guidance on what is to be expected from CCFFP to include or consider in sampling plans for quality parameters or for the Committee to provide proposed sampling plans for consideration by CCFFP.

10. The Committee agreed to consider the proposed sampling plans in CRD 10 item by item and made the following amendments.

Standard for Live Abalone and For Raw, Fresh Chilled or Frozen Abalone for Direct Consumption or for Further Processing (CODEX STAN 312-2013)

II-8.6 Determination of biotoxins

11. The Committee noted that biotoxins should be considered as a contaminant and not a microbiological criterion and that CAC/GL 21-1997 was not applicable in this case, and therefore agreed to consider the proposed sampling plan for biotoxins at its next session as information was not sufficient at this time.

Standard for Smoked Fish, Smoke-Flavoured Fish and Smoked-Dried Fish (CODEX STAN 311-2013)

8.3 Histamine and 8.6 Determination of *Listeria monocytogenes* and *Clostridium botulinum*

12. The Committee agreed not to propose sampling plans for these provisions as these were not within the scope of CCMAS.

² CX/MAS 14/35/1 – Provisional Agenda

³ CX/MAS 14/35/2; CX/MAS 14/35/2-Add.1; MAS 35 INF 1 (FAO/WHO information paper); CRD 10 (comments of Norway and NMKL) ; CRD 11 (comments of Egypt).

8.7 Determination of Parasites

13. It was clarified that parasites in this section are not related to consumer health issues, but to quality defects. The Committee agreed to propose an attribute sampling plan (CAC/GL 50, Section 4.2, Table 10) using AQL 6.5% and acceptance number $c = 0$. The same proposal was made for the Draft Standard for Fresh and Quick Frozen Raw Scallop Products.

Draft Standard for Fresh and Quick Frozen Raw Scallop Products

14. The Committee noted that while a specific request had not been made for proposals for sampling plans for this draft Standard, proposals in CRD 10 could be of assistance to CCFFP in the development of sampling plans for this draft Standard.

8.6 Determination of the presence of viscera

15. The Committee noted that the sampling plan for determination of the presence of viscera should depend on whether it is a source of biotoxins and could be considered as a health issue or a quality defect and that whether or not viscera would be found depends on the technology used for processing. The Committee agreed not to propose a sampling plan and that CCFFP should consider sampling plans for determination of the presence of viscera taking into account these matters.

Conclusion

16. The Committee agreed to propose sampling plans to CCFFP for the *Standard for Live Abalone and For Raw, Fresh Chilled or Frozen Abalone for Direct Consumption or for Further Processing; Standard for Smoked Fish, Smoke-Flavoured Fish and Smoked-Dried Fish; and Draft Standard for Fresh and Quick Frozen Raw Scallop Products* (Appendix III, Part C).

17. The Committee clarified that a sampling plan in any standard should not be a simple reference to the *General Guidelines on Sampling* (CAC/GL 50-2004), but could be a reference to a specific table in the Guidelines accompanied by an AQL.

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

18. The Committee considered the methods proposed for endorsement and in addition to editorial changes it made the amendments and recommendations presented below. (Appendix III)

Committee on Contaminants in Foods

⁴ CX/MAS 14/35/3; CX/MAS 14/35/3-Add.1; CX/MAS 14/35/3-Add.2; CRD 3 (comments of Kenya); CRD 12 (comments of IDF); CRD 13 (comments of ISO); CRD 14 (comments of CEN and BSI); CRD 18 (comments of AACCI)

Proposed Draft Maximum Level for Deoxynivalenol (DON) in Cereals and Cereal-Based Products and Associated Sampling Plans

Methods of Analysis

19. The Committee noted that the proposal was consistent with criteria of the methods of analysis for aflatoxins currently listed in *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995), which had been endorsed before the *Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance thereof* was finalized by the Committee. The Committee, noting that the criteria of the methods for DON should be in line with the Guidelines, agreed not to endorse the criteria proposed by CCCF and proposed alternative criteria that the Committee can endorse for consideration by CCCF (Appendix III Part A).

Sampling Plans

20. Several delegations proposed that the aggregate sample weight for raw wheat and barley and for maize should be 10 kg instead of 1 kg as if each incremental sample was 100 g and if the number of incremental samples was 100, it would result in 10 kg and it was normal to deal with 10 kg samples in laboratories. Several other delegations were of the view that 1 kg was appropriate for raw wheat and barley and 5 kg for raw maize as this took into account the difference in kernel size between maize, wheat and barley and distribution of DON is generally less heterogeneous. The Committee was also informed that CCCF had carefully considered this matter and that the rationale for their decision was explained in REP13/CF.

21. Questions were also raised on whether 3 increment samples for a lot not more than 0.05 tonnes in Table 2 might not be sufficient; and whether particle size for a test portion could affect the result for compliance.

22. After some discussion, the Committee agreed not to endorse the sampling plan and to request CCCF (1) to provide the rationale why the aggregate sample weight was 1-5 kg; (2) to consider whether 3 increment samples is sufficient for samples not more than 50 kg; and (3) to consider whether particle size should be specified for the test portion.

Committee on Fish and Fishery Products

Performance Criteria for methods for the determination of marine biotoxins in the Standard for Live and Raw Bivalve Molluscs

I-8.6.1 Criteria for determination of Toxin Analogues by chemical methods

23. The Committee endorsed the criteria as proposed by CCFFP. The Committee noted that AOAC 2005.06 does not analyse all the substances in the table but covers major toxic components. It was also noted that it was helpful to provide to analysts information in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) on which methods of analysis meet the criteria.

I-8.6.2 Biological and Functional Methods to Determine Paralytic Shellfish Toxicity

24. The Committee endorsed AOAC 959.08 as well as AOAC 2011.27 (Receptor binding assay) as Type IV.

25. The Committee was informed that AOAC 959.08 is not feasible in some countries where saxitoxin (STX) reference materials are not available, noting that its trade is restricted by the Chemical Weapons Convention.

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

26. The Committee agreed to update the methods as proposed in CX/MAS 14/35/3-Add.1. (Appendix II).

27. The Committee noted that there were some technical differences between the method in the Standard (CODEX STAN 234) (ISO 8968-1/2|IDF 20-1/2:2001) and newly proposed method (ISO 8968-1|IDF 20-1:2014) and that it was not clear whether AOAC 991.20, listed as equivalent to the method in the Standard, is still equivalent to the newly proposed methods, including those 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 is covered by the scope of the AOAC method. The Committee agreed that the AOAC method should be retained for the time being and ask for clarification from AOAC for consideration at its next session.

28. The Committee agreed to delete IDF 165:1993 for antioxidants in milk fat products as the method is no longer available. It was noted that as the provision still exists in the *Standard for Milkfat Products* (CODEX STAN 280-1973), it would be necessary to identify a new method for the provision.

Other proposals

29. The Committee considered the proposals in CRDs 13 and 14. The Committee agreed to consider them at its next session as it was not clear which proposals were editorial and which were of a more substantial nature. The Committee encouraged the Standards Developing Organizations to submit documents regarding the update of the methods of analysis in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) prior to the Committee.

30. With regard to the general methods for dietary fibre that measure both the higher and the lower molecular weight fraction, the Committee noted that in addition to the currently adopted Type I methods (AOAC 2009.01|AACCI 32-45.01), AACCI 32-50.01|AOAC 2011.25 is available. AACCI suggested it should be classified as Type I if included in the Codex system. The Committee recalled that more than one Type I method cannot be endorsed for the same provision unless their scopes are different. The Committee agreed to request CCNFSDU to consider whether the new method should be included in the Standard and if so, how it should be accommodated (Appendix III Part B).

31. The Committee endorsed its previous decision that “date” for the methods of analysis should be removed in the Standard (see also Agenda Item 6).

PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE: EXPLANATORY NOTES (Agenda Item 4)⁵

32. The Committee recalled that its last session returned the explanatory notes for redrafting by an electronic working group led by Germany, circulation for comments and consideration by this session. It further recalled its decision to establish an in-session working group to prepare a further revised draft based on the written comments received (see Agenda Item 1).

33. Before proceeding with a section by section consideration of the revised proposed draft explanatory notes contained in CRD 19, the Committee first considered the most appropriate place for the explanatory notes as this could have an impact on any changes made. Two possibilities for the placement of the explanatory notes were explored, either as an annex, similar to the approach taken in the *Guidelines on Measurement Uncertainty* (CAC/GL 54-2004) or to integrate the notes into the main document, *Principles for the Use of Sampling and Testing in International Food Trade* (CAC/GL 83-2013).

⁵ CX/MAS 14/35/4, CX/MAS 14/35/4 Add.1 (comments of Brazil, Ghana, Japan, Kenya and New Zealand), CRD 5 (comments of Argentina), CRD 6 (comments of Mali), CRD 7 (comments of India), CRD 8 (comments of Mexico), CRD 11 (comments of Egypt), CRD 19 (revised proposed draft Explanatory Notes prepared by the in-session working group), CRD 20 (proposal for explanatory notes for Principle 6 prepared by New Zealand).

34. The Committee agreed that the notes would be best integrated within the main document, CAC/GL 83-2013, with the understanding that the Principles defined within CAC/GL 83-2013 were not for further consideration and would remain unchanged, but that the introduction and scope may require some consequential amendment in order to explain the introduction and scope of the explanatory notes.

35. The Committee proceeded with consideration of the proposal in CRD 19 in order to agree on the text that would be integrated into the main document (CAC/GL 83-2013), and that an eWG would be tasked with this integration taking into account the decisions and discussions below. The Committee noted that several editorial corrections were necessary and in addition made the following decisions or recommendations.

Principle 3

36. The Committee agreed to present the notes for this principle in the form of a statement rather than a question as follows: “*Probabilities of wrongly accepting or wrongly rejecting a lot or consignment can never be entirely eliminated because both samples taken and the measurement errors associated with the analysis are subject to random variation.*” This approach would also be taken throughout the document, where applicable.

37. The Committee agreed to use “acceptable quality level” in the text in line with the terminology from the *General Guidelines on Sampling* (CAC/GL 50-2004) and to insert a footnote to clarify that according to ISO 3534 on Standards and Vocabulary, the terminology used is “acceptance quality level”.

38. The Committee agreed to: (i) amend the 2nd sentence of the 5th paragraph to provide a more balanced statement with respect to both consumers and producers, to read: “*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*”; and (ii) delete the last sentence, referring to the probabilities at which sampling plans are set to wrongly reject, as this could be better explained through the practical examples to be developed (see Agenda Item 7).

39. The second last sentence of paragraph 7 was amended to read, “*Further details can be found in the General Guidelines for Food Import Control Systems (CAC/GL 47-2003).*” The reference to the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* was deleted in paragraph 8 as it would appear that the notes were giving an interpretation of the guidelines, which was not the intention.

40. The Committee agreed to retain the last paragraph as it was factually correct and showed the link with the other guidelines developed by CCFICS.

Principle 4

41. The Committee agreed to replace the first paragraph so as not to refer to risk, recalling its earlier discussions on this matter in the Committee and the agreement to delete a definition of risk as it was difficult to determine whether the risk being referred to was a risk to consumer health or an economic risk. The following statement was introduced: *“When sampling and testing procedures are not appropriate, there may be an unduly high probability of wrongfully accept or reject a consignment/lot which can lead to disputes between the countries involved.”*

42. The Committee also agreed to introduce an additional note to the paragraph, to indicate that producers might not apply the same sampling plan as receivers of commodities, as follows: *“note that it might not be appropriate for producers to apply the same sampling plan as those used by receivers of commodities.”*

43. The Committee agreed to delete the words *“as far as possible”* from the 2nd paragraph.

44. The Committee agreed to split the 5th bullet point in the third paragraph in order to provide more clarity to the two concepts being addressed: *“whether sampling plans will be on inspection by attributes basis or inspection by variables basis”* and *“parameters such as the AQL or LQ.”*

45. The Committee made amendments to the first bullet point in the fourth paragraph for better readability and clarity and agreed to replace “parameter” with “characteristics” and to apply this change throughout the document as appropriate. The text would read: *“For inspected characteristics that are qualitative”*

46. The Committee agreed to delete *“by agreement between parties”* in paragraph 5 as it was redundant.

47. The Committee considered whether the term “non-homogenous” should be retained in paragraph 5 noting the term was consistent with CAC/GL 50. However, views were presented that in the context of this section, non-homogenous lots referred to the probability of selecting items with a given level of a characteristic rather than to the level of the characteristic itself and that a footnote could be inserted to explain this aspect. The Committee did not take a decision on this rather technical matter and agreed that further consideration should be given to this aspect by the eWG.

Principle 5

48. In line with its earlier decision to present the notes in the form of a statement, the Committee amended this section by deletion of the question, as the text was self-explanatory. The second paragraph was moved to the top of the section for better flow and readability.

49. The Committee agreed to amend paragraph 3 by referring to “various guidelines” rather than “different guidelines” as it was more correct; to use the term “analytical measurement uncertainty” for consistency with para 2; to amend the last paragraph by deletion of the second last sentence, “*The procedures for estimating measurement uncertainty and interpreting results should be agreed by the parties*”, as it was already covered by the preceding paragraph.

Principle 6

50. The Committee considered the proposal as in CRD19 and an alternate proposal by New Zealand in CRD 20. The Committee noted that the notes on “fitness for purpose” as presented in CRD 19 placed emphasis on the laboratory component of the assessment procedure, while the proposal in CRD 20 tried to capture all three elements from Principle 2. It was therefore agreed that further work was required on providing a more balanced text for this section.

Other information

51. The Committee also considered a proposal to introduce a text that would introduce the practical examples to be provided in the annex and provide a link between the main document and the annex. The Committee agreed that that such text was necessary and that it should be developed further.

Bibliography

52. The Committee agreed that the bibliography should be limited to only those references essential to the text.

Conclusion

53. The Committee agreed to establish an electronic working group led by Germany, with assistance of New Zealand and the Netherlands open to all members and observers, and working in English only, with the following terms of reference: to (i) integrate the explanatory notes as agreed and amended; (ii) further develop text for Principles 4 and 6, and introductory text to link the Principles to the annex on practical examples, taking into account the discussion. The Committee further noted that CAC/GL 83-2013 was not open for discussion nor should be revised, but that the integration of the explanatory notes may only result in consequential changes in order to explain the introduction of the explanatory notes and the annex on practical examples (see Agenda item 7).

Status of the Proposed Draft Principles for the Use of Sampling and Testing In International Food Trade: Explanatory Notes

54. The Committee agreed to return the explanatory notes to Step 2/3 for integration into the Principles for the Use of Sampling and Testing in International Food Trade and attach to it practical examples for sampling plans as an annex, for comment and consideration by the next session.

DISCUSSION PAPER ON CONSIDERING PROCEDURES FOR ESTABLISHING CRITERIA (Agenda Item 5)⁶

55. The Committee recalled that the last session of the committee had agreed that an electronic working group led by the United States of America would create a discussion paper considering procedures for establishing criteria for (i) multi-analyte methods that are used for specifications that require a combination of components, or use toxic equivalency factors (TEF) and (ii) Type I methods.

56. The Delegation of United States of America introduced the report of the EWG as presented in CX/MAS 14/35/5 and noted that there was general interest in the concept of developing criteria for Type I methods and/or multi-analyte methods, but that this was a starting point and no attempt was made to reach consensus on this. The Delegation highlighted the recommendations made and pointed out that the Committee would need to consider a number of factors when deciding on development of criteria for either Type I methods or for multi-analyte methods, such as: (i) when considering criteria for Type I methods, it may be possible to establish procedures for assessing equivalency between methods and not Criteria. However, since not all Type I methods were created equal there may be instances where equivalency could not be established, (ii) in the case of multi-analyte methods, how to deal with TEFs, whether these should be left out of the standard as in the approach taken by CCFFP (see Agenda Item 3); (iii) whether a general approach was appropriate or whether different approaches would be necessary for multi-analyte methods (there might be differences between different toxins).

57. The Committee considered each of the recommendations.

Recommendation 1 – The establishment of Criteria for the different circumstances (Type 1 and multi-analyte method) should be addressed separately both during the development of the criteria and within the Procedural Manual.

58. There was general agreement with this recommendation.

⁶ CX/MAS 14/35/5, CRD 9 (comments of Thailand)

Recommendation 2 – whether criteria for Type 1 methods should be established; or if a procedure for determining when methods have comparable performance should be developed; or if the current system should remain unchanged

59. There was general agreement that numeric criteria for Type I methods should not be developed, however procedures for establishing the equivalency to Type I methods should be considered.

Recommendation 3 and 4 – establish a criteria approach for multi-analyte methods

60. There was general agreement that work should continue in this regard, that TEFs should not be contained within a specific analytical method and could be referenced either in the standard or elsewhere where they can be regularly updated and evaluated by internationally recognized procedures.

Conclusion

61. In view of the general discussion on the recommendations, the committee agreed to pursue the work further through the establishment of two electronic working groups open to all members and observers and working in English only as follows:

- (1) development of procedures / guidelines for determining equivalency to Type 1 methods, led by USA, to prepare a discussion paper which would consider different approaches for different classes of Type 1 methods; and
- (2) development of a criteria approach for methods which use a “ sum of components”, led by United Kingdom. The working group would prepare a discussion paper that evaluates and discusses current options; and considers general guidelines and evaluates criteria for use on a case by case basis.

DISCUSSION PAPER ON ELABORATION OF PROCEDURES FOR REGULAR UPDATING OF METHODS (Agenda Item 6)⁷

62. The Committee recalled that at its last session, it had agreed to establish an electronic working group (eWG), chaired by Brazil, to prepare a discussion paper with proposals: on establishing a format for a single source document (database) to capture all methods in the scope of CCMAS; the process for updating references to methods of analysis; and a plan to prioritize the

⁷ CX/MAS 14/35/6, CRD 1 (report of Inter-Agency Meeting); CRD 3 (comments of Kenya), CRD 4 (comments of Ghana), CRD 6 (comments of Mali), CRD 9 (comments of Thailand), CRD 13 (comments of ISO), CRD 16 (comments of AOCS, AOAC and AACCI), CRD 22 (information on Table 1 prepared by Brazil)

(re)endorsement of current methods in the Recommended Methods of Analysis and Sampling (CODEX STAN 234) and commodity standards.

63. The delegation of Brazil as chair of the eWG, introduced the report of the working group (CX/MAS 14/35/6) and pointed out that the eWG had generally agreed that CODEX STAN 234 and commodity standards contained a number of inconsistencies that included: making reference to outdated methods, errors and omissions, and use of the references that were not traceable. The Committee was informed that a proposal was made for development of a single reference for methods of analysis and that the eWG had proposed a 5 step procedure for up-dating the standards which included: i) establishing a single workable list for all methods in CODEX STAN 234 and commodity standards; ii) establishing criteria for prioritisation of the methods of analysis; iii) dividing the priority list into work packages; iv) verifying the validity of each of the methods with the author; and v) consideration of the recommendations by CCMAS.

64. The Committee considered the proposals made and reached the following conclusions:

Establishing a single source (document/database) for methods of analysis

65. Several delegations supported establishing a workable list as a starting point for undertaking the review and proposed that such a list should allow sorting of the methods/standards and should also provide for assigning the methods' ownership.

66. Some observers noted that every stakeholder should work towards ensuring that methods are updated and that Standards Developing Organisations (SDOs) should always monitor Codex Standards relevant to their scope of work and check whether references within such standards falling within their scope of work require updating, and that proposals for reviews should be brought to the attention of CCMAS.

67. Several delegations pointed out that the proposed list should be for internal use only and for purposes of updating CODEX STAN 234 and other Codex standards; and that the Committee could consider if the list should be officially made publically available at a later stage. An observer also pointed out that methods of analysis should not be removed from commodity standards as lots of methods in some of these standards, such as the General Standard for Fruit Juices and Nectars were not aimed at a specific provision.

Process to update methods of analysis

68. There was general agreement to develop a process for the update of methods of analysis but that such a process should be used on trial basis before new procedures were considered for inclusion in the Procedural Manual. The period for review of 5 years as proposed by the eWG was

also questioned and a proposal was made to extend this to a period of 8 or 10 years.

Conclusion

69. *The Committee agreed that the list to be compiled would be utilised for internal use of the Committee i.e. for updating the methods and that the mechanism for this process would first be tried before examining the necessity of having it recommended for inclusion in the Procedural Manual.*

Criteria for prioritisation of the methods of analysis;

70. The Committee recalled that during the 34th Session, it had agreed to remove dates from standards as this would make their updating easier and that ISO 17025 required analysts to use the most recent versions of analytical methods and older version of methods are generally not available.

71. Several delegations supported the inclusion of dates in the single list for internal use and proposed that such dates would include: year of endorsement of the method by the Committee, date of publication of the standard, year of the latest version, because this information would enable efficient management of methods and their review. Some observers clarified that during revision of standards, their reference numbers are changed only when there were significant technical changes made. They further pointed out that for revisions associated with minor changes such as editorial amendments or inclusion of information on collaborative studies, the standards normally retain their original reference numbers. Some delegations were of the view that assessment of analytical methods by the Committee was therefore necessary since it was not clear what SDOs called “minor” changes within the standards.

Conclusion

72. *The Committee agreed to include in the list three types of dates i.e. date of publication of the standard, year of endorsement; year of the latest version.*

Terminology in CODEX STAN 234

73. The Committee considered the proposal to replace “provision” with “analyte” or “measurand”, as this created confusion for Spanish-speaking members, but did not conclude and agreed that this issue would require further discussion.

74. With regard to the term “all food”, the Committee agreed further consideration should be given to whether the terminology was appropriate, taking into account that the methods for all food are not validated for “all” foods.

Information Content for Table in the single source document

75. On the use of POD instead of LOD as proposed by the WG, it was clarified that this concept was still under discussion and should not be considered at the moment.

76. Some delegations noted that information on performance criteria of analytical methods as proposed in the Table was important for laboratories and that users of analytical methods should be aware of such information, while other delegations questioned the relevance of the performance criteria to the updating of methods, noting that such information was more relevant during the endorsement process. Observers did not support the inclusion of the performance criteria of analytical methods in the form as such data was considered proprietary information that can only be shared in a restricted manner.

77. On the issue of who would be responsible for the completion of the information in the Table, it was clarified that the Table defines the roles of various stakeholders, including SDO, Commodity Committees and CCMAS and therefore it would be completed by all concerned parties. Several observers, speaking as members of IAM, pointed out that it was in the interest of SDOs to always notify CCMAS whenever methods within the scope of their operations have changed, and that the endorsement of such methods by CCMAS was not their responsibility, and therefore CCMAS should be responsible for filling in the data in the form.

78. The Committee noted that the information on performance criteria of an analytical method would be required during endorsement by CCMAS, and agreed that such information would not be necessary at the time of identifying the analytical method that needed review, but agreed that this requirement would remain in the Table 1 (as presented in CRD 22), but that the concerns raised should be taken into account when developing the single source document.

Procedure for guiding the process for review of the methods

79. The Committee considered the draft procedure for reviewing the standards and agreed to the following 4–step procedure that would guide the process for review of the methods

1. Put all the methods into one single workable list - eWG
2. Select the methods to examine first using prioritization criteria - eWG
 - analytical methods directly linked with food safety
 - Type I and II methods (reference for disputes)
 - methods with inaccurate information
 - number of years since endorsement (the oldest first).
3. Divide the methods into workable packages - eWG

4. The SDOs will check the references of their methods; the Commodity Committees and/or CCMAS will confirm the applicability of these methods.

80. The Committee expressed gratitude to all Standards Developing Organisations (SDOs) that have continued to provide CCMAS with information regarding the status of various methods with respect to revision and update and for the information and support provided in the endorsement process.

Conclusion

81. The Committee agreed to establish, an electronic working group, led by Brazil, open to all members and observers, and working in English only, with the following terms of reference:

- a) compile a single workable list for all methods in CODEX STAN 234 and commodity standards;
- b) divide the list into work packages based on the criteria developed by the Committee for prioritisation of the methods of analysis;
- c) conduct a validation exercise on one pilot work package of which the results would be considered by the Committee at its next session.

DISCUSSION PAPER ON SAMPLING IN CODEX STANDARDS (Agenda Item 7)⁸

82. The Committee recalled that at its last session it had been agreed that the Inter-Agency Meeting (IAM) would develop a paper on sampling for consideration at this session. The Observer of ICUMSA, on behalf of IAM, introduced CX/MAS 14/35/7 and noted that the paper was comprehensive, and that the recommendations contained therein aim at helping the Committee to examine how best principles of sampling such as auto-control, uncertainty of measurement results, pragmatic approach to sampling, amongst others, can be demonstrated practically in standards.

83. The Committee had a general discussion on the recommendations, noted the information provided and made the following points:

⁸ CX/MAS 14/35/7; CRD 9 (comments of Thailand); CRD 21 (objectives for the electronic working group on examples of sampling plans)

- Commodity committees should be discouraged from simply referencing the *Guidelines on Sampling* (CAC/GL 50-2004), but be encouraged to develop their own sampling plans and in doing so should use CAC/GL 50 and the *Principles for the Establishment or Selection of Codex Sampling Procedures* (Procedural Manual). Should commodity committees not be in a position to do so, CCMAS would be able to elaborate such sampling plans provided that the commodity committees provided information on the AQL or LQ. In cases where committees were no longer active, CCMAS could undertake the development of sampling plans where necessary.
- The Committee recognized that sampling was complex and inherently variable and that provision of practical examples would be able to assist Commodity Committees in developing sampling plans. It was noted that the sampling tools for mycotoxins available at FAO Website (<http://www.fstools.org/mycotoxins>) might be useful when developing such examples.
- In the development of practical examples, the following should also be considered: estimated uncertainty from sampling; auto-control procedures; and whether simple “pragmatic” sampling plans whether scientifically correct or not should be used. It was recognized -control procedures to be used by importers and competent authorities are within the remit of CCFICS, but that from a sampling perspective, CCMAS could undertake such work, and that collaboration with CCFICS was important.
- Recognized that the *Principles for the Establishment or Selection of Codex Sampling Procedures* might need to be revised to permit procedures besides acceptance sampling procedures to be used; but that the Committee was not in a position to undertake such work at this time until more information became available. On the issue of whether the scope of the Principles needed to be revised with respect to “net contents”, it was agreed to keep this open for future consideration and that it could be taken into account in the development of practical examples.

Conclusion

(84) The Committee noted that the paper CX/MAS 14/35/7 would serve as a useful reference for future work in the area of sampling.

84. Noting the points raised, the Committee agreed to develop practical examples of sampling plans and that these examples would be best placed as an Annex to the *Principles for the Use of Sampling and Testing in International Food Trade* (CAC/GL 83-2013) (see Agenda Item 4). For this purpose, the Committee agreed that other Codex Committees would be requested to submit practical examples for consideration by CCMAS.

85. The Committee also agreed that the electronic working group established under Agenda Item 4 would take up the development of practical examples taking into consideration the recommendations from the Discussion paper on sampling in Codex Standards (CX/MAS 14/35/7) and the discussion (para 83) in the Committee. The electronic working group would:

- Provide a brief explanation of the use of sampling and analytical measurement uncertainty in product control and testing compliance.
- Develop examples, including case by case advice of consideration of sampling uncertainty (definition), that fulfil the following criteria: matrix combinations vs measurand / provision:
 - Fruits/vegetables, fats/oils, fish/fishery products, milk/milk products, meat/meat products, natural mineral waters, cereals
 - Sensory inspection, food additives, food hygiene, pesticide residues, contaminants, residues of veterinary drugs
 - Packages/bulk material/foodstuff for consumption.
- Develop procedures for determining uncertainty of measurement results including sub-sampling, sample processing and analysis.
- Consideration of importing and exporting countries including control of production and testing compliance.

REPORT OF INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 8)⁹

86. The Observer from AOCS representing IAM, presented CRD 1 to the Committee and highlighted the various issues that IAM had discussed with respect to the work of CCMAS and other related matters. The Committee thanked IAM for the report and their contribution to its work.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)

⁹ CRD 1 (report of the Inter-Agency Meeting)

87. The Committee noted that no other business had been put forward during the adoption of the Provisional Agenda.

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

88. The Committee was informed that its 36th Session was tentatively scheduled to be held in Budapest, Hungary from the 2 to 6 March 2015, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

Appendix II

STATUS OF ENDORSEMENT OF METHODS OF ANALYSIS AND SAMPLING

- A. Milk and Milk Products
- B. Nutrition and Foods for Special Dietary Uses
- C. Fish and Fishery Products

A. Milk and Milk Products

Products	Provisions	Method	Principle	Type
Blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF ¹⁰	ISO 8968-1/2 IDF 20-1/2:20012014 / AOAC 991.20	Titrimetry (Kjeldahl)	IV
Reduced fat blend of Evaporated skimmed milk and vegetable fat	Milk protein in MSNF ¹	ISO 8968-1/2 IDF 20-1/2:20012014 / AOAC 991.20	Titrimetry (Kjeldahl)	IV
Blend of skimmed milk and vegetable fat in powdered form	Milk protein in MSNF ¹	ISO 8968-1/2 IDF 20-1/2:20012014 / 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 8968-1/2 IDF 20-1/2:20012014 / AOAC 991.20	Titrimetry (Kjeldahl)	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF ¹	ISO 8968-1/2 IDF 20-1/2:20012014 / AOAC 991.20	Titrimetry (Kjeldahl)	IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF ¹	ISO 8968-1/2 IDF 20-1/2:20012014 / AOAC 991.20*	Titrimetry (Kjeldahl)	IV
Cheese, unripened including fresh cheese	<u>Milk</u> Protein	ISO 8968-1/2 IDF 20-1/2:20012014 / AOAC 991.20 and 991.23	Titrimetry (Kjeldahl)	I
Cream and prepared creams	Milk protein	ISO 8968-1/2 IDF 20-1/2:20012014 / AOAC 991.20	Titrimetry (Kjeldahl)	I

¹⁰ Milk total solids and MSNF content include water of crystallization of lactose

Products	Provisions	Method	Principle	Type
Edible casein products	<u>Milk</u> protein (total N x 6.38 in dry matter)	ISO 8968-1/2 <u>IDF 20-1/2:2014</u> IDF 92:1979 / <u>ISO 5549:1978</u>	Titrimetry, (Kjeldahl) digestion	IV <u>I</u>
Evaporated milks	<u>Milk</u> protein <u>in</u> <u>MSNF</u> ¹	ISO 8968-1/2/ IDF 20-1/2:2001 <u>2014</u> / AOAC 991.20 /AOAC 945.48H	Titrimetry (Kjeldahl)	I
Fermented milks	<u>Milk</u> Protein	ISO 8968-1/2/ IDF 20-1/2:2001 <u>2014</u> / AOAC 991.20	Titrimetry (Kjeldahl)	I
Milk powders and cream powders	Milk protein	ISO 8968-1/2/ IDF 20-1/2:2001 <u>2014</u> / AOAC 991.20	Titrimetry (Kjeldahl digestion)	I
Milk fat products	Antioxidants (phenolic)	IDF 165:1993	Reversed — phase gradient — liquid chromatography	H
Milk products obtained from fermented milks — heat-treated — after fermentation	Milk Protein	ISO 8968-1/2/IDF 20-1/2:2001 <u>2014</u> / AOAC 991.20	Titrimetry (Kjeldahl)	I
<i>IDF/ISO: The line above could be removed since it is covered by the provision Fermented milk</i>				
Sweetened Condensed Milks	<u>Milk</u> protein <u>in</u> <u>MSNF</u> ¹	ISO 8968-1/2/ IDF 20-1/2:2001 <u>2014</u> / AOAC 991.20 AOAC 945.48H	Titrimetry (Kjeldahl)	I
Whey powders	Milk protein (total N x 6.38)	ISO 8968-1/2/ IDF 20-1/2:2001 <u>2014</u> / AOAC 991.20	Titrimetry (Kjeldahl)	I
Whey powders	Protein (total N x 6.38)	IDF 92:1979 / ISO 5549:1978	Titrimetry, Kjeldahl digestion	IV

* The Committee at its 36th Session will consider whether the AOAC method is equivalent to the IDF/ISO method taking into consideration the information that will be provided by AOAC.

B. Nutrition and Foods for Special Dietary Uses

Products	Provisions	Method	Principle	Type
Infant formula	Crude protein*	ISO 8968-1/ 2 / IDF 20-1/ 2 : 2001 <u>2014</u> / AOAC 991.20**	Titrimetry (Kjeldahl)	I

* Determination of Crude Protein

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

** The Committee at its 36th Session will consider whether the AOAC method is equivalent to the IDF/ISO method taking into consideration the information that will be provided by AOAC.

C. Fish and Fishery Products

I-8.6 Determination of Biotoxins

The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use.

I-8.6.1 Criteria for determination of Toxin Analogues by chemical methods

Methods shall meet the numerical criteria listed in Table 1 and may either meet the minimum applicable range, or LOD and LOQ criteria listed.

Table 1. Criteria for determination of Toxin Analogues by Chemical Methods

Toxin Group	Toxin	Minimum applicable range (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	Precision (RSD _R) (%) No more than	Recovery percent	Applicable methods that meet the criteria
STX Group	Saxitoxin (STX)	0.05 – 0.2	0.01	0.02	44%	50 – 130	AOAC 2005.06 NMKL 182:2005 EN 14526:2004 AOAC 2011.02 NMKL 197:2013
	NEO	0.05 – 0.2	0.01	0.02	44%	50 – 130	
	dcSTX	0.05 – 0.2	0.01	0.02	44%	50 – 130	
	GTX1	0.05 – 0.2	0.01	0.02	44%	50 – 130	
	GTX2	0.1 – 0.5	0.03	0.06	38%	50– 130	
	GTX3	0.1 – 0.5	0.03	0.06	38%	50– 130	
	GTX4	0.05 – 0.2	0.01	0.02	44%	50 – 130	
	GTX5	0.1 – 0.5	0.03	0.06	38%	50– 130	
	GTX6	0.1 – 0.5	0.03	0.06	38%	50– 130	
	dcGTX2	0.1 – 0.5	0.03	0.06	38%	50– 130	
	dcGTX3	0.1 – 0.5	0.03	0.06	38%	50– 130	
	C1	0.1 – 0.5	0.03	0.06	38%	50– 130	
	C2	0.1 – 0.5	0.03	0.06	38%	50– 130	
	C3	0.5 – 1.5	0.1	0.2	32%	50– 130	
C4	0.5 – 1.5	0.1	0.2	32%	50– 130		
OA Group	OA	0.03 – 0.2	0.01	0.02	44%	60-115	See reference below
	DTX1	0.03 – 0.2	0.01	0.02	44%	60-115	
	DTX2	0.1 – 0.5	0.03	0.06	38%	60-115	
Domoic Acid	DA	14 - 26	2	4	20%	80-110	
AZA	AZA1	0.03 – 0.2	0.01	0.02	44%	40 - 120	See reference

Toxin Group	Toxin	Minimum applicable range (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	Precision (RSD _R) (%) No more than	Recovery percent	Applicable methods that meet the criteria
Group	AZA2	0.03 – 0.2	0.01	0.02	44%	40 - 120	below
	AZA3	0.03 – 0.2	0.01	0.02	44%	40 - 120	

Reference:

http://aesan.msssi.gob.es/en/CRLMB/web/procedimientos_crlmb/crlmb_standard_operating_procedures.shtml Harmonised-SOP-LCMS-OA-Version4.pdf

Total toxicity is estimated as the sum of the molar concentrations of detected analogs multiplied by the relevant specific toxicity equivalency factors (TEFs). Internationally scientifically validated TEFs must be used. The science behind TEFs is developing. Current internationally validated TEF's will be found on the FAO website. Information on TEFs could be incorporated in this standard at a future date.

Methods should be validated and used for the relevant toxin analogues that may contribute to total toxicity. Currently known toxin analogues to consider are listed in Table 1.

Where toxin analogues that are not listed in Table 1 are determined the competent authority must assess the contribution of these analogs to total toxicity whilst conducting further investigations.

I-8.6.2 Biological and Functional Methods to Determine Paralytic Shellfish Toxicity

Commodity	Provision	Method	Principle	Type
Live and raw bivalve molluscs	Paralytic shellfish toxicity	AOAC 959.08	Mouse bioassay	Type IV
Live and raw bivalve molluscs	Paralytic shellfish toxicity	AOAC 2011.27	Receptor binding assay	Type IV

Appendix III

PROPOSED METHOD CRITERIA, METHODS OF ANALYSIS AND SAMPLING PLAN

A. Proposed Method Criteria for DON in Raw Cereal grains (wheat, maize and barley)

(For consideration by CCCF)

Provision	ML (mg/kg)	LOD	LOQ	Precision on HorRat	Minimum applicable range (mg/kg)	Recovery	Applicable methods that meet criteria	Principle
deoxynivalenol	2	0.2	0.4	≤2	1 – 3	80 – 110%		

B. Proposed Sampling Plan for Fish and Fishery Products

(For consideration by CCFFP)

STANDARD FOR LIVE ABALONE AND FOR RAW, FRESH CHILLED OR FROZEN ABALONE FOR DIRECT CONSUMPTION OR FOR FURTHER PROCESSING

II-8.1 Sampling

II-8.2 Sensory and Physical Examination

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10 using AQL 6,5%.

Comments: Qualitative measures (defect/not defect) are assumed. For information about the probability of lot acceptance at AQL 6,5%, see Table 13 and Figure 8.

II-8.3 Determination of net weight

Sampling plans by variables with unknown standard deviation (s-method), CAC/GL 50 section 4.3, Table 14.

Comments: The mean value is measured, a quantitative measure, and therefore sampling plans by variables are appropriate.

II-8.4 Determination of Count per Unit Weight or Volume

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10 using AQL 6,5%.

Comments: Qualitative measures (complying/not complying) are assumed. For information about the probability of lot acceptance at AQL 6,5%, see Table 13 and Figure 8.

II-8.6 Determination of Biotoxins

To be considered by the next session of the CCMAS

STANDARD FOR SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKED-DRIED FISH

8.2 Sensory and Physical Examination

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10, using AQL 6,5%.

Comments: Qualitative measures (defect/not defect) are assumed. For information about the probability of lot acceptance at AQL 6,5%, see Table 13 and Figure 8.

8.4 Determination of net weight

Sampling plans by variables with unknown standard deviation (s-method), CAC/GL 50 section 4.3, Table 14.

Comments: The mean value is measured, a quantitative measure, and therefore sampling plans by variables are appropriate.

8.7 Determination of Parasites

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10, using AQL 6,5% and acceptance number=0.

DRAFT STANDARD FOR FRESH AND QUICK FROZEN RAW SCALLOP PRODUCTS

8.2 Sensory and Physical Examination

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10 using AQL 6,5%.

Comments: Qualitative measures (defect/not defect) are assumed. For information about the probability of lot acceptance at AQL 6,5%, see Table 13 and Figure 8.

8.3 Determination of pieces and count

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10 using AQL 6,5%.

Comments: Qualitative measures (defect/not defect) are assumed. For information about the probability of lot acceptance at AQL 6,5%, see Table 13 and Figure 8.

8.4 Determination of net weight

Sampling plans by variables with unknown standard deviation (s-method), CAC/GL 50 Section 4.3, Table 14.

Comments: The mean value is measured, and hence it is a quantitative measure and therefore sampling plans by variables are appropriate.

8.5 Determination of Parasites

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10, using AQL 6,5% and acceptance number=0.

8.6 Determination of the presence of viscera

No proposal (see Agenda Item 2)

Determination of added water

Attribute sampling plan, CAC/GL 50, Section 4.2, Table 10 using AQL 6,5%.

Comments: Qualitative measures (complying/not complying) are assumed. For information about the probability of lot acceptance at AQL 6,5%, see Table 13 and Figure 8.

** Comments in this paper are for information purpose only and not intended to be incorporated into the standards.*