# CODEX ALIMENTARIUS COMMISSION old E





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**REP13/MAS** 

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX ALIMENTARIUS COMMISSION

Thirty sixth Session
Rome, Italy, 1-5 July 2013

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

Budapest, Hungary 4 - 8 March 2013

## CODEX ALIMENTARIUS COMMISSION $oldsymbol{\mathbb{E}}$





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CL 2013/6-MAS March 2013

**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 34th Session of the Codex Committee on Methods of

Analysis and Sampling (REP13/MAS)

## MATTERS FOR ADOPTION BY THE 36th SESSION OF THE COMMISSION:

## Proposed Draft Regional Standards at Step 8 of the Procedure

1. Draft Principles for the Use of Sampling and Testing in International Food Trade (para. 73, Appendix III)

## Other Amendments to the Standards

2. Methods of Analysis and Sampling in Codex Standards at different steps (paras 16 – 54, Appendix II)

## Amendment to the Procedural Manual

3. Proposed Amendment to the Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof in the Procedural Manual (para 9, Appendix IV)

Governments and interested international organizations wishing to comments on the above documents 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 15 May 2013.

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## **SUMMARY AND CONCLUSIONS**

The 34<sup>th</sup> Session of the Codex Committee on Methods of Analysis and Sampling reached the following conclusions:

## Matters for consideration by the 36<sup>th</sup> Session of the Codex Alimentarius Commission

## Draft and Proposed Draft Standards and Related Texts for adoption

#### The Committee forwarded:

- the Draft Principles for the Use of Sampling and Testing in International Food Trade for adoption at Step 8 (para.73, Appendix III);
- methods of analysis and sampling in Codex Standards at different steps for adoption (paras 16 54, Appendix II)
- The amendments to the Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof in the Procedural Manual (para. 9, Appendix IV)

## Other matters of interest to the Commission:

#### The Committee:

• agreed to return to Step 2/3 for redrafting, comments and further discussion at the next session the proposed draft principles for the Use of Sampling and Testing in International Food Trade – Other sections - Explanatory Notes (para. 78)

## Matters referred to other committees:

## The Committee agreed:

- to request CCCF to select appropriate methods of analysis for the provision (para. 8)
- to encourage CCFFP to provide information on the toxicity equivalent factors for all biotoxins listed in the Standard (para. 26) and to establish appropriate sampling plans (para. 54)
- to ask CCASIA to review the use of factor 5.71 (para. 30) and to encourage CCASIA to consider replacing the method of analysis for lipid content in the Standard for tempe with ISO 1211|IDF 1:2010 and to clarify whether the provision should be "lipid content" or "fat content" (para. 31)

REP13/MAS

## INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling held its Thirty-fourth Session in Budapest, Hungary, from 4 to 8 March 2013, by courtesy of the Government of Hungary. The Session was chaired by Professor Árpád Ambrus, Chief Scientific Advisor, National Food Chain Safety Office (NFCSO). Ms. Andrea Zentai, Food Safety Coordinator (NFCSO) acted as the Vice-Chairperson. The list of participants is attached to this report as Appendix I.

## **OPENING OF THE SESSION**

2. The session was opened by Dr Sándor Fazekas, Minister of Rural Development. The Minister welcomed participants to the 34<sup>th</sup> Session of the Committee, recalled the importance of Codex standards to ensure safety and quality of foods in international trade, and highlighted the celebrations for the 50<sup>th</sup> anniversary of the Commission. He drew the attention of the participants to the importance of the work of this Committee, which had been hosted by Hungary since 1972, and wished delegates success in their work. He also highlighted the excellent cooperation between Hungary and FAO.

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

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 2.

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

- 4. The Committee agreed to consider "Sampling in Codex Standards How should it be treated?" under Agenda Item 4 and adopted the Provisional Agenda with the amendment as its Agenda for the Session.
- 5. The Committee also agreed to establish an in-session working group, chaired by New Zealand and working in English, to consider the Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade: Section on Principles.

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

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

## **Committee on Contaminants in Foods (CCCF)**

## Proposed Draft Maximum Levels for Arsenic in Rice

- 7. Several delegations informed the Committee that some international collaborative studies for inorganic arsenic in rice were in progress in Japan and EU and national studies in Republic of Korea and that some methods of analysis had been validated by collaborative study in a country.
- 8. The Committee agreed to request CCCF to select appropriate methods of analysis for the provision, taking into account the results of these studies, and forward them to CCMAS for endorsement.

## **Committee on Fish and Fishery Products (CCFFP)**

Proposed draft Performance Criteria for Reference and Confirmatory Methods for Marine Biotoxins in the Standard for Live and Raw Bivalve Molluscs

9. The Committee clarified that methods should meet both the LOD and LOQ and agreed to propose correction of the Procedural Manual accordingly (Appendix IV).

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CRD 2

<sup>&</sup>lt;sup>2</sup> CX/MAS 13/34/1

<sup>&</sup>lt;sup>3</sup> CX/MAS 13/34/2; CRD 6 (comments of EU); CRD 10 (comments of Kenya); CRD 11 (comments of Chile); CRD 12

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

## Methods of Analysis for trans fatty acids (TFA)

10. One delegation informed the Committee that the work of NUGAG to review the definition of trans fatty acid was in progress and was of the view that the Committee should consider this matter after the review by NUGAG concluded.

- 11. The observer of IDF informed the Committee that IDF and ISO were developing a method for fatty acids, including TFA, for milk products, infant formulae and adult nutritionals. The method is expected to be published in 2014 and will also be published by AOAC.
- 12. The observer of AOCS noted that they had developed AOCS Ce 1J-07 for trans fatty acids and that collaborative study of the method for complex matrix was ongoing.
- 13. Taking into account the information above, the Committee agreed not to endorse any new method for trans fatty acid at this session.

## **Committee on Fats and Oils (CCFO)**

## Matters Referred by CCMAS

14. The Committee noted that AOCS would re-submit the method for relative density from archive method reference.

## Proposed Draft Amendment to Parameters for Rice Bran Oil in the Standard for Named Vegetable Oils

15. The Committee agreed with the conclusion of the IAM that ranges in commodity tables should be only changed in response to the availability of the uncorrected results of analysis because although the approach, mean±3SD, might have merit if the total population of data was available for consideration, using this statistic on partial data might skew the values and give rise to misleading information.

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

## **Methods of Analysis**

## **Committee on Fish and Fishery Products**

Standard for Smoked Fish, Smoke Flavoured Fish and Smoked Dried Fish

- 16. For <u>water activity</u>, the Committee noted that NMKL had compared two instrumental methods applicable to water activity and that they provided equivalent results. The Committee agreed to delete the methods described in the standard and to replace it with the NMKL and ISO methods as Type III.
- 17. The Committee noted a comment concerning the application of criteria to this type of methods and it was agreed that further general discussion would be necessary on this question.
- 18. As regards <u>histamine</u>, some delegations did not support the reference to "other scientifically validated methods" as it was not clear and did not provide guidance to select methods. The Committee considered the proposed method performance criteria for histamine prepared by NMKL in CRD 15 to replace the current method with these criteria, while retaining the reference to the AOAC method and to the equivalent NMKL method, as well as NMKL 196, 2013 using HPLC, as examples of methods meeting the criteria. It was recognized that both methods were adequate for determining a level of 10 mg/kg of histamine. It was further agreed that the reference to criteria would apply to all relevant standards for fish and fishery products.
- 19. Some delegations proposed to extend the range of values for recovery as the current range was too restrictive. The Committee recalled that the values proposed were already adopted in the Procedural Manual and any change should be considered from a general point of view and not for specific analytes.

<sup>4</sup> CX/MAS 13/34/3, CX/MAS 13/34/3-Add.1, CRD 4 (comments of India), CRD 7 (comment of EU), CRD 13 , CRD 15 (comments of NMKL), CRD 19, CRD 20

## Standard for Live and Raw Bivalve Molluscs

#### **Biotoxins**

20. The Committee considered the proposal for the numerical criteria values for biotoxins in bivalve molluscs proposed by the CCFFP. In reply to a question, the Committee noted that the paragraph included after Table 1 were intended to provide guidance to governments in the selection of methods.

- 21. Some delegations pointed out that the AOAC 2005.06 method covered only 12 of the 16 toxins in the Saxitoxin group, and therefore it does not determine total toxicity. It was noted that the criteria in the Procedural Manual were applicable only for single analytes.
- 22. The Committee discussed several proposals intended to address this issue, asking the Committee on Fish and Fishery Products to provide information on toxicity equivalent factors, and applying the criteria for LOD and LOQ to the most toxic of the toxins in the Saxitoxin group. Some delegation also noted the difficulties related to analysis of these toxins due to the availability of reference materials.
- 23. Some delegations expressed the view that the criteria specified in the Procedural Manual were adequate for chemical methods but were not applicable for biological methods such as the mouse bioassay. It was however clarified that the mouse bioassay had been proposed for biotoxins as Type I and therefore the criteria were not applicable. It was also noted that it is not possible to endorse both Type I and Type II methods for the same provision.
- 24. Some delegations proposed to extend the range of values for recovery as the current range was too restrictive. The Committee recalled that the values proposed were already adopted in the Procedural Manual and should not be amended for specific analytes, as this would require a more general discussion.
- 25. The Committee agreed that the development of criteria in case of total toxicity should be considered from a general point of view at the next session (see General Issues below).
- 26. The Committee did not endorse the criteria and encouraged the CCFFP to provide information on the toxicity equivalent factors for all biotoxins listed in the standard.

## Standard for Live Abalone and for Raw Fresh Chilled or Frozen Abalone

27. As a result of the discussion on biotoxins in bivalve molluscs, the methods section in the Standard for Abalone was not endorsed.

## **FAO/WHO Coordinating Committee for Asia**

## Standard for Tempe

- 28. As regards <u>moisture content</u>, the Committee agreed to insert the AACCI method which is equivalent to the AOAC method (Type I).
- 29. The Committee noted that in the AOAC 955.04D method for <u>protein content</u> mercury is used as a catalyst and agreed that it should be replaced with safer alternative methods. After some discussion, it was agreed to refer to an alternative NMKL method and the equivalent AOAC and AACCI methods as Type I.
- 30. The Committee discussed the conversion factor of 5.71 listed for the determination of protein content. Some delegations pointed out that in trade of soybean products a conversion factor of 6.25 was used. Other delegations referred to scientific literature referred to a factor of 5.71 for soybean products. It was also noted that for infant formula the factor used was 5.71 for soy based products. The Committee agreed to ask the CCASIA to review the use of the factor of 5.71.
- 31. For <u>lipid content</u>, the Committee endorsed the method proposed but noted that it uses chloroform and encouraged CCASIA to consider replacing it with ISO 1211|IDF 1:2010, recalling that a similar change had been made for the determination of total fats in aqueous coconut products, and to clarify whether the provision should be "lipid content" or "fat content". The principle of the method was also corrected.
- 32. For crude fibre, equivalent AOAC and AACCI methods were inserted in addition to the ISO method and the principle was corrected.

## Standard for Non-Fermented Soybean Products

33. For <u>moisture content</u>, the equivalent AACCI method was inserted in addition to the AOAC method. For <u>protein content</u>, alternative methods were inserted in view of the decision taken for protein content determination in tempe (see above).

## **Committee on Processed Fruits and Vegetables**

## Standard for Canned Apple Sauce

34. The Committee noted a proposal to seek clarification on the need for two methods for <u>fill of containers</u> but noted that this was the general Codex method which had been reviewed and was widely used by the CCPFV. The methods were endorsed with an editorial correction.

#### Standard for Table Olives

- 35. The Committee endorsed the method proposed for drained weight and noted a proposal to ask the CCPFV to refer to the OIML Procedure R 87 2004, Annex C.
- 36. For the determination of <u>salt in brine</u>, an equivalent NMKL method was inserted. The general Codex methods for <u>lead</u> and <u>tin</u> were corrected, as already adopted, and all methods were endorsed with some editorial corrections.

## Aqueous coconut products

37. Several editorial corrections and updates were made to the current methods.

## **FAO/WHO Coordinating Committee for the Near East**

## Regional Standard for Date Paste

38. The Committee endorsed the methods as proposed with an editorial correction in the method for mineral matter content.

## Regional Standard for Halwa Tehenia

- 39. The Committee agreed that the method proposed for <u>sugars</u> was intended for the determination of sugars in syrup and was not adequate for halwa tehenia due to its oil content.
- 40. As a general issue, it was recalled that some methods had been referred back to the CCNEA earlier as they were not intended for the products covered by some regional standards. However, as no methods were specifically developed for these products, it was necessary to consider the suitability of methods developed for similar products for the purpose of food control.
- 41. The Committee agreed that the method developed by the International Starch Institute for sugars, available in the public domain, was applicable and it was endorsed as Type IV.
- 42. For <u>acidity</u> it was agreed to replace the current proposal with two AOAC methods which were applicable to a wide range of foods, as Type IV.

## **Committee on Fats and Oils**

43. The Committee agreed to replace the current IUPAC method for erythrodiol + uvaol content with COI/T.20/doc.No 30-2011 as proposed by the Committee on Fats and Oils. As regards the use of this method for the determination of sterol composition and total sterols, the Committee questioned whether the IOC method was equivalent to ISO 12228:1999 (current method) and agreed to ask CCFO for clarification in this respect.

## Foods for Special Dietary Uses - Milk and Milk Products

44. The Committee agreed with several updates and corrections, as proposed in CX/MAS 13/34/3-Add. 2.

## **Committee on Sugars**

## Diastase activity in honey

45. The Committee considered the proposal to amend the incubation time in the Phadebas method from 15 minutes to 30 minutes as the production of the method with a 15-minute incubation time has ceased. Some observers pointed out that this change was significant and should be put forward for amendment of the AOAC method through the AOACI procedure, and that currently both available methods, from AOACI and the International Honey Commission (IHC), referred to 15 minutes. After some discussion, the Committee agreed to endorse the IHC method with an incubation time of 30 minutes as Type IV, and invited IHC and AOACI to provide any relevant information for consideration at the next session.

## **General Issues**

- 46. The Committee agreed that in view of the discussion on the applicability of the criteria in this and earlier sessions, this issue should be addressed in a comprehensive manner.
- 47. The Committee generally supported further consideration of the criteria approach for multi analyte methods, and in cases where total toxicity resulted from toxicity of several substances, which would apply especially to biotoxins, dioxins and PCBs.
- 48. Some delegations supported consideration of the extension of criteria to Type I methods, as discussed earlier in the Committee and the IAM. One delegation pointed out that it was preferable to apply a stepwise approach to ensure that the mandate of the eWG remained achievable.
- 49. The Committee agreed to establish an electronic working group chaired by the United States of America, working in English with the following terms of reference:

The eWG will create a discussion paper to be presented at the 35<sup>th</sup> session of CCMAS.

The discussion paper will, in a stepwise approach, consider procedures for establishing criteria:

- i. For multi-analyte methods that are used for specifications that require a combination of components, or use toxicity equivalent factors;
- ii. Applicable to Type I methods.

Where there is considerable scientific or statistical overlap between (i) and (ii) these will be considered together.

## **Methods of Sampling**

## **Committee on Contaminants in Foods**

<u>Draft Maximum Level for Total Aflatoxins in Dried Figs including Sampling Plans</u>

- 50. The Committee agreed to endorse the sampling plan with an amendment to replace >20 with >120 for concentration range for  $RSD_R$  and to replace  $RSD_r$  with  $RSD_R$  in recommended value for precision or relative standard deviation  $RSD_r$  in table 2.
- 51. The Committee noted that as LOD and LOQ for total aflatoxins are sum of concentrations of several analogs they have similar problem to those for biotoxins. The Committee agreed not to request comments of CCCF as sampling plans for total aflatoxins in other commodities had already been endorsed and it was the responsibility of the Committee to consider this matter.
- 52. It was clarified that information on proficiency testing was available in the CCCF document.

## **Committee on Processed Fruits and Vegetables**

## Standard for Table Olives

53. The Committee endorsed the sampling plan as proposed.

## **Committee on Fish and Fishery Products**

Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish

Standard for live Abalone and for Raw Fresh Chilled or Frozen Abalone for Direct Consumption or for Further **Processing** 

The Committee reiterated that in individual standards, reference should not be made to the General Guidelines on Sampling as they do not provide sampling plans but instructions to select sampling plans, and encouraged individual committees to select appropriate sampling plans. Therefore, the sampling plans in the above standards should not be endorsed and the Committee encouraged CCFFP to establish appropriate sampling plans.

## PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN **INTERNATIONAL FOOD TRADE (Agenda Item 4)**

## DRAFT SECTION ON PRINCIPLES (Agenda Item 4a)<sup>5</sup>

- 55. The Committee recalled that its last session had advanced to Step 5 the Proposed Draft Principles (Section on Principles), subsequently adopted by the Commission and circulated for comments at Step 6.
- The Delegation of New Zealand introduced a revised version of the text which had been prepared by the in-session working group and took into account the comments made at Step 6 (CRD 16). The Committee considered the document section by section and made the following amendments and comments, in addition to editorial comments.

#### **Section 1. Introduction**

- The Committee agreed to delete the terms "consumers' risk" and "producers' risk" throughout the document, following earlier discussion on the confusion that may be introduced by the use of these terms, and recognised that the objective of the principles was to address the probabilities of incorrect decision.
- The first paragraph was amended to reflect that sampling and testing are not the only measures to determine whether food in trade meets particular requirements and was reordered for clarification purposes.
- In the fourth paragraph, the Committee considered a proposal to shorten the text to make it more general, highlighting the need for measures to be based on risk assessment. Some delegations however pointed out that import control was not intended only to address food safety aspects but also included fraud on the nature or quality of the product. It was agreed that promotion of fair practices in the food trade should also be taken into account and the text was amended accordingly.
- In the sixth paragraph, it was agreed to refer to "provisions" rather than "limits" as the text was of general application, and this term was amended throughout the text.

## Section 2. Scope

- The eighth paragraph was amended and transferred to a new paragraph 5 as it referred to the means of establishing whether foods meet specifications as related to Codex texts and was more relevant in the Introduction than in the Scope.
- The Committee noted a proposal to refer to Codex standards instead of "particular specifications". It was however recalled that the scope of the principle was of a general nature and applied to compliance with any type of specifications and the current text was retained.

## **Section 3. Definitions**

It was agreed to delete Note 1, following the earlier decision to delete "consumers' risk" and "producers' risk", and to delete the definition of "Probability" in "Note 2" as the probability of incorrect decisions was clearly described in the Principles section.

CX/MAS 13/34/4 (comments of Argentina, Australia, Brazil, Egypt, Japan, Philippines), CX/MAS 13/34/4-Add.1 (comments of European Union, Ghana, Jamaica, Republic of Korea), CRD 4 (comments of India), CRD 9 (comments of Iran), CRD 14 (comments of ISO), CRD 16 (redrafted version prepared by the in-session working group), CRD 18

## **Section 4. Principles**

64. The Committee considered a proposal to merge certain sections and to reduce the number of principles in order to avoid repetitions and follow a logical sequence.

- 65. The first and second principles were merged as a new Principle 1 "Transparency and Agreements before initiating trade".
- 66. It was clarified that the Agreements also applied "when introducing or modifying an import testing programme". It was agreed to refer to food in trade meeting Codex specifications in addition to the specifications of the importing country.
- 67. In the second paragraph (previously Principle 2) it was agreed that the criteria for acceptance of the product should also be documented. In the last sentence the reference to "failure" was replaced by "rejection", which was consistent with the terminology used in the Explanatory Notes.
- 68. A proposal was made to insert a new principle to address the criteria, but it was noted that this question would be addressed in the other sections (See item 4b).
- 69. The Committee agreed to merge Principle 5. "Selecting Appropriate Sampling and Testing Procedures" with Principle 6. "Practical Considerations", and Principle 8. "Product Variation" (as new Principle 4). As regards the need for procedures to be scientifically based, a reference was added to "taking into account the existing Codex standards". It was agreed to retain the other Principles as currently listed and to renumber the section accordingly.
- 70. The title of Principle 6 (new Principle 5) was amended to "Analytical Measurement Uncertainty" and it was agreed to refer also to the implications of measurement uncertainty in the Principle itself.
- 71. It was agreed that the title of Section 5 should be "Bibliography" and that it should include only the ISO CASCO publications and resources, which has been largely used in the development of the Principles, as both Codex Guidelines were already mentioned as references in the Introduction.
- 72. The Committee noted that all questions had been adequately addressed and expressed its thanks to the Delegations of Brazil, Germany and New Zealand, who had initially developed the document, and to the working groups held in the previous and current session for their excellent work.

## Status of the Draft Principles for the Use of Sampling and Testing in International Food Trade

73. The Committee agreed to advance the Draft Principles to Step 8 for adoption by the 36<sup>th</sup> Session of the Codex Alimentarius Commission (see Appendix.III).

## OTHER SECTIONS (Agenda Item 4b)<sup>6</sup>

- 74. The Committee recalled that its last session had agreed to return the Other Sections (namely Explanatory Note) for redrafting by an electronic working group chaired by Germany and New Zealand.
- 75. The Delegation of Germany, on behalf of the eWG, introduced CX/MAS 13/34/5. The Delegation of Uruguay drew the attention of the Committee to its comments in CRD 3 for further consideration in development of the document. The Committee agreed that it would consider only key issues as it had made significant changes to the principles (See Agenda Item 4a).
- 76. The Committee noted that the document should be practicable; matters covered by other Codex Guidelines, i.e. GL 47 and GL 62, should not be included in this document but the focus should be on limiting the probability of incorrect decisions; the probabilities—of incorrect decision should be balanced for producers and importers; under Fitness for Purpose, if a method is not available in Codex standards, a fully validated equivalent alternative method could be used; when such methods are not available, some additional guidance should be provided; and general examples that could apply to different issues should be included.
- 77. With regard to Principle 7, the Committee noted that concrete procedures to estimate sampling uncertainty should be elaborated in future.

6 CX/MAS 13/34/5, CRD 3 (comments of Uruguay), CRD 5 (comments of Jamaica). CX/MAS 13/34/5-Add.1 was not prepared as no comments were requested due to time constraints.

## Status of the Proposed draft Principles for the Use of Sampling and Testing in International Food Trade – Other Sections

78. The Committee agreed to establish an eWG, chaired by Germany with the assistance of New Zealand for the platform on the web and working in English, to redraft this document, taking into consideration the discussion in the plenary and written comments which had been received. This revised version would be sent for comments at Step 3 and for consideration at the next session.

## SAMPLING IN CODEX STANDARDS – HOW IT SHOULD BE TREATED (Agenda Item 4c)<sup>7</sup>

79. The Observer from ICUMSA recalled that the 33<sup>rd</sup> session of the Committee had agreed to ask the IAM to provide a short discussion paper on sampling issues for consideration at the next session, and introduced CRD 8, recalling the evolution of sampling in the framework of Codex and earlier discussions on measurement and sampling uncertainty. The Observer noted that in some cases Codex Committees simply referred to the General Guidelines on Sampling instead of selecting specific sampling plans and that the current guidance to Codex committees and to governments needed to be reviewed. For this purpose the discussion paper considered the following possibilities:

## a. Acceptance Sampling

The present approach defined by the Codex Sampling Principles. It does require an understanding by the Codex Committees of the variability that is inherent with acceptance sampling plans, and in particular the relatively high probability of accepting a lot with unsatisfactory material in it. This is not currently understood by many Codex Committees.

## b. The Estimation of the total uncertainty from both analysis and sampling

Procedures for the quantification of the total uncertainty in the measurement process, including that from both analysis and sampling will be considered. Whether such uncertainty could be reduced to an "acceptable" level, normally by taking more sample increments (units) or reducing the variability within the lot being sampled will be assessed.

## c. Representative/Pragmatic Uncertainty

Whether to ignore all aspects of sampling uncertainty and define a practical plan on little scientific basis.

#### d. Auto-Control

A radically different approach, i.e. verifying the results obtained from continuous food production. This approach, called here "auto-control", has been considered in international Working Groups.

- 80. The Observer proposed to address this issue with the development of a discussion paper for consideration at the next session, to review existing and possible new approaches to the establishment of sampling plans within Codex.
- 81. Several delegations pointed out that the document had been made available only at the session and therefore discussion should be postponed to the next session. Several other delegations stressed the importance of addressing sampling issues, especially uncertainty, and noted that CRD 8 provided a good basis for further discussion. The Committee discussed whether to establish an electronic working group and its possible terms of reference, as presented in CRD 19. Some delegations expressed the view that the mandate of the working group and purpose of the discussion paper should be more clearly defined before proceeding with further work.
- 82. The Observer from AOCS, speaking as Secretariat of the IAM, recalled that the last session of the Committee had agreed that the IAM would develop a discussion paper and proposed to follow this process again. The Committee welcomed this proposal and agreed that the IAM would develop a paper on sampling and would invite interested delegations to participate in the process. The Committee noted that in practice, all members and observers would be informed of the initiative of the IAM through the Codex lists of distribution and they could provide their contribution directly to the IAM (through AOCS). The Committee also welcomed the offer of New Zealand to make a web based platform available to facilitate the development of the document in a transparent and interactive manner. The result would be a paper on sampling issues to be presented by the IAM for consideration at the next session of the Committee.

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<sup>&</sup>lt;sup>7</sup> CRD 8, CRD 19

## DISCUSSION PAPER ON THE UPDATE REFERENCES OF METHODS OF ANALYSIS AND RELATED TEXTS (Agenda Item 5)<sup>8</sup>

83. The Committee recalled that at its last session it had agreed that Brazil would prepare a discussion paper on the update of references to methods of analysis for consideration at this session, noting that several adopted methods had been no longer in use or required an update.

- 84. The Delegation of Brazil introduced CX/MAS 13/34/6, highlighted that the *Guidelines for the Assessment of the Competence of testing Laboratories Involved in the Import and Export Control of Foods* (CAC/GL 27-1997) recommend the application of ISO/IEC 17025:2005 that require the use of the most updated version of methods of analysis and recommended to the Committee that the mechanisms for updating methods of analysis should be established.
- 85. The Committee considered each of the recommendations in the document and reached the following conclusions.

## Recommendation 1

- 86. The Committee noted that in case that the method changes substantially, the reference number for the method of analysis, not only the year of publication, will change. The Observer of ISO clarified that there was no need to include the year of publication in the reference. The Committee therefore agreed to remove the publication date from the reference of the methods of analysis in Codex Standards, the Procedural Manual and relevant documents of CCMAS. The Delegation of India expressed their reservation as it might have legal consequences.
- 87. The Secretariat indicated that this proposal would be included in the document on amendments to Codex standards which is prepared every year for adoption by the Commission.
- 88. It was clarified that the publication date in the reference to ISO 17025 should be retained as it is not a method of analysis.

#### Recommendation 2

89. The Committee agreed that when possible, it was advisable to use the criteria approach, in addition to referring to specific methods. The Committee noted that criteria approach for Type I methods should be considered in future, noting that it would help modernization of old Type I methods (See also Agenda Item 3).

## Recommendation 3

90. The Committee agreed with the recommendation on how methods of analysis were mentioned in Codex Standards should be harmonized.

## Recommendation 4

91. The Committee agreed with the recommendation that the commodity Codex Standards could just make reference to a general document with all the methods of analysis, which allows permanent and dynamic revision.

## Recommendation 5

- 92. The Committee generally agreed with the following recommendation: "before each CCMAS, the Codex Secretariat would issue a list of all methods from the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) whose endorsement date is older than 5 years for consideration by the method endorsement session. For each method in this list, CCMAS should re-endorse, withdraw or suggest an alternative method. In case where a commodity committee is still active, the CCMAS will either propose to the committee an appropriate new method or motivate the committee to make a proposal; where the commodity committee was adjourned, CCMAS will perform the update under its responsibility".
- 93. The Committee noted that the IAM had worked on the update of methods in the Standard and would continue playing a significant role in the process; that a procedure for the work should be clearly defined; that a unified database for methods of analysis in Codex system should be elaborated to facilitate this work; and that the 5-year period to review methods was derived from the current practices in ISO.

EX/MAS 13/34/6; CRD 4 (comments of India), CRD 10 (comments of Kenya), CRD 11, CRD 17

94. The Secretariat indicated that proposals which affected the standards developed by other committees may require some consultation with these committees and that amendments to the format of Codex standards or any other section in the Procedural Manual would need to be referred to the Committee on General Principles.

## Conclusion

- 95. The Committee agreed to establish an eWG on elaboration of procedures for regular updating of methods, chaired by Brazil and working in English, to facilitate the discussion on the matter with the following mandate:
- Propose a format for a single source (document, database) to capture all methods in the scope of CCMAS
- Propose a process to update the reference to methods of analysis. Include work to be done by commodity committees, IAM and Codex Secretariat
- Propose a plan to prioritize the (re)endorsement of current methods in the CODEX STAN 234 list and commodity committees. (e.g. methods of adjourned/ abolished committee first)

## REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 6)9

96. The Observer of AOCS as secretariat of IAM introduced the report of the IAM in CRD 1 and explained that several matters of interest to the Committee had been considered, including the extension of the criteria approach to type I methods, the validation of methods containing prescriptive and criteria based sections, the revision of ISO 5725 and matters arising from CCMAS.

## OTHER BUSINESS AND FUTURE WORK (Agenda Item 7)

97. There was no proposal to consider under this agenda item.

## DATE AND PLACE OF THE NEXT SESSION (Agenda Item 8)

98. The Committee was informed that its 35<sup>th</sup> Session was tentatively scheduled to be held in Hungary from 3 to 7 March 2014, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

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<sup>9</sup> CRD 1

<u>REP13/MAS</u> 11

## **SUMMARY STATUS OF WORK**

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP13/MAS)
Draft Principles for the Use of Sampling and Testing in International Food Trade	8	Governments 36th CAC	para. 73 Appendix III
Proposed draft Principles for the Use of Sampling and Testing in International Food Trade – Explanatory notes	2/3	eWG chaired by Germany Governments 35 <sup>th</sup> CCMAS	para. 78
Methods of Analysis and Sampling in Codex Standards at different steps	-	Governments 36 <sup>th</sup> CAC	paras 16 – 54 Appendix II
Proposed Amendment to the Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof in the Procedural Manual	PM*	Governments 36 <sup>th</sup> CAC	para 9 Appendix IV
Discussion paper on considering procedures for establishing criteria	-	eWG chaired by US 35 <sup>th</sup> CCMAS	para. 49
Discussion paper on elaboration of procedures for regular updating of methods	-	eWG chaired by Brazil 35 <sup>th</sup> CCMAS	para. 95
Discussion paper on Sampling in Codex Standards	-	${\rm IAM} \atop {\rm 35^{th}~CCMAS}$	paras 79 – 82

## Procedural Manual

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## **Appendix II**

## ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS

- A. Committee on Fish and Fishery Products
- B. FAO/WHO Coordinating Committee for Asia
- C. Committee on Processed Fruits and Vegetables
- D. FAO/WHO Coordinating Committee for the Near East
- E. Committee on Fats and Oils
- F. Committee on Nutrition and Foods for Special Dietary Uses
- G. Committee on Milk and Milk Products
- H. Committee on Sugars
- I. Committee on Contaminants in Foods

## A. COMMITTEE ON FISH AND FISHERY PRODUCTS

## Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Smoked Fish,	Water phase salt	AOAC 952.08		Type I
Smoke-Flavoured		AOAC 937.09		
fish and Smoke-		Described in standard <sup>1</sup>	Calculation	
dried fish				
Smoked Fish,	Water activity	NMKL 168, 2001   ISO 21807:2004	Electrometry	Type III
Smoke-Flavoured				
fish and Smoke-				
dried fish				

## Method Performance Criteria for histamine in smoked fish, smoke-flavoured fish and smoke-dried fish

Provision	ML (mg/100 g)	Minimum applicable range (mg/100 g)	LOD (mg/100 g)	LOQ (mg/100 g)	RSD <sub>R</sub> (%)	Recovery	Applicable methods that meet the criteria	Principle
Histamine	10 (average)	8 – 12	1	2	16.0	90 – 107	AOAC 977.13   NMKL 99, 2013 NMKL 196, 2013	Fluorometric HPLC
Histamine	20 (each unit)	16 – 24	2	4	14.4	90 – 107	AOAC 977.13   NMKL 99, 2013 NMKL 196, 2013	Fluorometric HPLC

## Standard for Live Abalone and for Raw Fresh Chilled or Frozen Abalone for Direct Consumption or for Further Processing

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
frozen abalone	Net weight	AOAC 963.18	Gravimetry	Type I
(covered by glaze)				

## B. FAO/WHO COORDINATING COMMITTEE FOR ASIA

## **Regional Standard for Tempe**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Tempe	Moisture content	AOAC 925.09   AACCI 44-40.01	Gravimetry (vacuum	type I
			oven)	
Tempe	Protein content	NMKL 6, 2004 or AOAC 988.05 or AACCI 46-16.01	Titrimetry, Kjeldahl	type I
		(Nitrogen factor 5.71)	digestion	
Tempe	Lipid Content	AOAC 983.23	Gravimetry	type I
Tempe	Crude fibre	ISO 5498:1981 or AOAC 962.09 or AACCI 32-10.01	Gravimetry	type I

 $<sup>^{1}</sup>$  % salt × 100 / (% water + % salt)

.

## Regional Standard for Non-Fermented Soybean Products

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Non-fermented	Moisture content	AOAC 925.09   AACCI 44-40.01	Gravimetry (vacuum	type I
soybean products			oven)	
Non-fermented	Protein content	NMKL 6, 2004 or AACCI 46-16.01 or AOAC 988.05 or AOCS Bc 4-91 or	Titrimetry, Kjeldahl	type I
soybean products		AOCS Ba 4d-90 (Nitrogen factor 5.71)	digestion	

## C. COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

## 1. Methods of Analysis

## **Standard for Canned Apple Sauce**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Canned Apple	Fill of containers	CAC/RM 46-1972* (for glass containers)	Weighing	Type I
Sauce		(Codex general method for processed fruits and vegetables)		
		and		
		ISO 90-1.1:1997 (for metal containers)		
		(Codex general method for processed fruits and vegetables)		
Canned Apple	Soluble solids	AOAC 932.12	Refractometry	Type I
Sauce		ISO 2173:2003 (Codex general method for processed fruits and vegetables)		

## **Standard for Table Olives**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Table olives	Drained weight	AOAC 968.30 (Codex general method for processed fruits and vegetables)	Sieving	Type I
			Gravimetry	
Table olives	Fill of containers	CAC/RM 46-1972* (for glass containers)	Weighing	Type I
		(Codex general method for processed fruits and vegetables)		
		and		
		ISO 90-1.1:1999 (for metal containers)		
		(Codex general method for processed fruits and vegetables)		
Table olives	pH of brine	NMKL 179:2005 (Codex general method for processed fruits and vegetables)	Potentiometry	type II
Table olives		AOAC 981.12 (Codex general method for processed fruits and vegetables)		Type III
Table olives		ISO 1842:1991		Type IV
Table olives	Salt in brine	AOAC 971.27   NMKL 178, 2004 (Codex general method)	Potentiometry	Type II
Table olives		ISO 3634:1979 "chloride expressed as sodium chloride"		Type III
		(Codex general method for processed fruits and vegetables)		
Table olives	Lead	AOAC 999.11   NMKL 139, 1991 (Codex general method)	AAS (Flame absorption)	Type II
Table olives	Tin	NMKL 190:2009   EN 15764:2009	AAS	Type II
		NMKL 191:2009   EN 15765:2009	ICP-MS	Type III

## \* DETERMINATION OF WATER CAPACITY OF CONTAINERS (CAC/RM 46-1972)

#### 1. SCOPE

This method applies to glass containers.

## 2. **DEFINITION**

The water capacity of a container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

#### 3. PROCEDURE

- 3.1 Select a container which is undamaged in all respects.
- 3.2 Wash, dry and weigh the empty container.
- 3.3 Fill the container with distilled water at 20°C to the level of the top thereof, and weigh the container thus filled.

## 4. CALCULATION AND EXPRESSION OF RESULTS

Subtract the weight found in 3.2 from the weight found in 3.3. The difference shall be considered to be the weight of water required to fill the container. Results are expressed as mL of water.

## **Standard for Aqueous coconut products**

Products		Provisions	Method	Principle	Type
Aqueous	coconut	Total Fats	ISO 1211 IDF 1:2010	Gravimetry (Röse-	I
products				Gottlieb)	
Aqueous	coconut	Totals Solids	ISO 6731 IDF 21:2010	Gravimetry	I
products				Gravilletry	
Aqueous	coconut	Non-fat solids	ISO 1211 IDF 1:2010	Calculation:	I
products			ISO 6731 IDF 21:2010	Gravimetry (Röse-	
				Gottlieb)	
				Gravimetry	
Aqueous	coconut	Moisture	ISO 6731 IDF 21:2010	Gravimetry	I
products				Gravimeny	

## 2. Sampling

Commodity	Sampling Plan	Status
Table Olives	Described in the Standards	Endorsed

## D. FAO/WHO COORDINATING COMMITTEE FOR THE NEAR EAST

## **Regional Standard for Date Paste**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Date Paste	Moisture	AOAC 934.06	Gravimetry	Type I
Date Paste	Mineral impurities	ISO 762:2003	Gravimetry	Type I
Date Paste	Ash	AOAC 940.26	Gravimetry	Type I
Date Paste	Acid Soluble Ash	AOAC 900.02D	Gravimetry, Calculation	Type I

## Regional Standard for Halwa Tehenia

COMMODITY	PROVISION	METHOD	PRINCIPLE	Type
Halwa Tehenia	Sugars	ISI 28-1e <sup>2</sup>	Titrimetry	Type IV
Halwa Tehenia	Acidity	AOAC 924.53, AOAC 942.15	Titrimetry	Type IV

## E. COMMITTEE ON FATS AND OILS

## Standard on Olive Oil and Olive Pomace Oil

COMMODITY	PROVISION	METHOD	PRINCIPLE	Туре
Olive Oils and	Erythrodiol + uvaol	COI/T.20/doc.No 30-2011	Gas chromatography	Type II
Olive Pomace Oils				

## F. COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Products	Provisions	Method	Principle	Type
Special foods	Loss on drying (milk	AOAC 925.23	Gravimetry	Type I
	based)	-ISO 6731 IDF 21:2010		
Special foods	Sodium and	ISO 8070 IDF 119:2007	Flame atomic absorption	Type II
	Potassium		spectrometry	Type II
Infant formula	Moisture/Total	AOAC 990.20	Gravimetry	Type I
	Solids	ISO 6731 IDF 21:2010		Type I

## G. COMMITTEE ON MILK AND MILK PRODUCTS

Products	Provisions	Method	Principle	Type
Edible Casein	Casein in protein	ISO 17997 1 IDF 29 1:2004	Titrimetry, Kjeldahl	T
Products				†

<sup>&</sup>lt;sup>2</sup> http://www.starch.dk/isi/methods/28luff.htm

## H. COMMITTEE ON SUGARS

Products	Provisions	Method	Principle	Type
Honey	diastase activity	IHC Method for Determination of Diastase activity with		T IV
		Phadebas, 2009 except that the incubation time should be increased from 15 to 30 minutes.		Type IV

## I. COMMITTEE ON CONTAMINANTS IN FOODS

Commodity	Sampling Plan	Status
Dried Figs	Described in the Standard (See para. 50)	Endorsed

AACCI	American Association of Cereal Chemists International
AOCS	American Oil Chemists' Society
AOAC	AOAC International
COI	International Olive Council
IDF	International Dairy Federation
IHC	International Honey Commission
NMKL	Nordic Committee on Food Analysis

**Appendix III** 

# Draft Principles for the Use of Sampling and Testing in international Food Trade (Step 8)

## **SECTION 1 - INTRODUCTION**

- 1. 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. 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.
- 2. 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.
- 3. 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.
- 4. 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.
- 5. 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.
- 6. 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)

## **SECTION 2 - SCOPE**

7. 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.

## **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.<sup>1</sup>

## 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<sup>1</sup>

Lot1

Sample<sup>1</sup>

Sampling<sup>1</sup>

Sampling plan<sup>1</sup>

Result<sup>2</sup>

## Measurement uncertainty<sup>3</sup>

## **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).

## 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)); and
- 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.

## 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.

<sup>&</sup>lt;sup>1</sup> General Guidelines on Sampling (CAC/GL 50-2004)

<sup>&</sup>lt;sup>2</sup> Guidelines on Analytical Terminology (CAC/GL 72-2009)

<sup>&</sup>lt;sup>3</sup> Guidelines on Measurement Uncertainty (CAC/GL 54-2004)

## Principle 5: Analytical measurement uncertainty

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

## **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.

## **Principle 7: Review of procedures**

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

## **BIBLIOGRAPHY**

Publications and resources of the ISO Committee on Conformity Assessment (ISO CASCO) at http://www.iso.org/iso/resources/conformity\_assessment.htm. (2013)

Appendix IV

## Proposed Amendment to the Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance Thereof in the Procedural Manual (for adoption)

Third box at the left in the flow chart

YES.

Is the method validated at 0.03 mg/kg, or is the LOD or and LOQ determined to be 0.01 mg/kg and 0.02 mg/kg or lower?