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CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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REP 12/MAS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty fifth Session

Rome, Italy, 2-7 July 2012

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

Budapest, Hungary

5 – 9 March 2012

Note: This report includes Circular Letter CL 2012/4-MAS.

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CX 4/50.2

CL 2012/4-MAS
March 2012

TO: Codex Contact Points
Interested International Organizations

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

SUBJECT: Distribution of the Report of the 33rd Session of the Codex Committee on Methods of Analysis and Sampling (REP12/MAS)

A. MATTERS FOR ADOPTION BY THE 35th SESSION OF THE COMMISSION:

Draft Guidelines Step 5 of the Procedure

1. Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (section on Principles) (para. 20, Appendix IV).

Methods of Analysis and Sampling

2. Methods of Analysis in Codex Standards at different steps, including methods of analysis for food grade salt (paras 23 - 60, Appendix III)

Governments and interested international organizations wishing to comment on items 1, 2 and 3 above should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Procedural Manual of the Codex Alimentarius Commission), to the above address, before **15 May 2012**.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 33rd Session of the Codex Committee on Methods of Analysis and Sampling are as follows:

Matters for adoption by the 35th Session of the Commission:

The Committee:

- Forwarded to Step 5 the Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (section on Principles) (para. 20, Appendix IV)
- Endorsed or updated the status of several methods of analysis and sampling in Codex standards, including methods of analysis for food grade salt (paras 23 – 60, Appendix II)

Other Matters of Interest to the Commission

The Committee:

- Agreed to return to Step 2/3 the Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (except for the section on Principles) (para. 21)

Matters referred to other Codex Committees

Committee on General Principles

The Committee agreed on recommendations on the use of proprietary methods in Codex standards for inclusion in the Codex Procedural Manual (para. 78, Appendix V)

Committee on Fats and Oils

The Committee agreed to ask CCFO to review the methods for relative density in several standards and for erythrodiol+uvaol in olive oils and olive pomace oils as the current IUPAC methods were no longer available (para. 45, Appendix III)

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INTRODUCTION

1 The Codex Committee on Methods of Analysis and Sampling held its Thirty-third Session in Budapest, Hungary, from 5 to 9 March 2012, by courtesy of the Government of Hungary. The Session was chaired by Professor Árpád Ambrus, Deputy Director General, Hungarian Food Safety Office. Dr Béla Kovács, Professor, University of Debrecen, acted as the Vice-Chairperson. The Session was attended by 156 delegates and observers representing 56 Member Countries, one Member Organisation (EU) and 11 international organizations.

OPENING OF THE SESSION

2 The session was opened by Dr Endre Kardeván, Secretary of State, Ministry of Rural Development. He welcomed participants to the 33rd Session of the Committee and highlighted the importance of the work of the Committee as a basis of food safety and fair practices in food trade. He recalled that Hungary had hosted the Committee since 1972, which reflected its commitment to Codex work and, noting that several important items were scheduled for discussion, wished delegates all success in their work.

Division of Competence¹

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

ADOPTION OF THE AGENDA (Agenda Item 1)²

4 The Committee agreed to consider the update of references in the list of methods of analysis in Agenda Item 7 *Other business and Future Work* and adopted the Provisional Agenda with the amendment as its Agenda for the Session.

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

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

Maximum Levels for Deoxynivalenol (DON) and its Acetylated Derivatives in Cereals and Cereal-Based Products

6 The Committee noted that it was impossible to identify methods for acetylated derivatives of DON because no fully validated method of analysis was available at the moment. It was also noted that a maximum level was necessary to identify an appropriate method of analysis.

PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE (Agenda Item 3)⁴

7 The Committee recalled that its last session had agreed on the new work to develop the Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade and that an electronic working group chaired by New Zealand, with the assistance of the Netherlands and the United States, would develop a draft for circulation at Step 3 and consideration by the next session.

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

² CX/MAS 12/33/1

³ CX/MAS 12/33/2

⁴ CX/MAS 12/33/3, CX/MAS 12/33/3-Add.1 (Comments of Argentina, Australia, Canada, Colombia, Cuba, Kenya, New Zealand, Peru, Philippines, Republic of Korea, Thailand, ICUMSA, IDF), CRD 6 (Comments of the European Union), CRD 7 (Comments of Brazil), CRD 8 (Comments of Mali), CRD 9 (Comments of Argentina), CRD 12 (Comments of ICUMSA), CRD 15 (Report of the in-session working group)

8 The Committee thanked New Zealand, the Netherlands and the United States and the electronic working group for their work and noted that the Web-based system for the electronic working group was quite useful for the discussion.

9 The Committee agreed that it would consider at this session only the principles with additional notes only if essential and that further development of the document, such as explanatory notes and examples that would be useful, should be considered at a later stage.

General Discussion

10 The Committee considered whether the feed trade should be included in the scope. Although there are some Codex standards and texts that cover feeds insofar as they affect food safety in the food chain, it would be discussed by the Commission whether the terms of reference of Codex would include feed trade in general. It was also recalled that the project document referred only to foods. The Committee therefore agreed not to include feeds in the scope.

11 In reply to the question whether or not the principles should cover products intended for further processing and products intended to be incorporated into other foods but not to be put on sale, it was clarified that the principles were general and would be relevant for instance in the situation where a Codex standard covers such products.

12 The Committee noted that the relationship between sampling, testing and conformity assessment should be clearly stated and that it should be cautious in using the term “risk” and “protection” with a different meaning from other Codex standards and texts. It was also noted that definitions should be reviewed.

13 The Committee agreed to establish an in-session working group, working in English, French and Spanish, to consider and redraft the text in the light of the comments received. The Committee considered the revised text shown in CRD 15 section by section. Besides editorial amendments, the Committee agreed to the following changes.

Introduction

14 The Committee agreed to insert a new paragraph (numbered 5) to the effect that sampling and testing is only one of the methods by which an exporter can validly claim confidence that products meet specifications. This text was initially included in Principle 9 but was more appropriate in the introduction.

Definitions

15 The Committee agreed with the revised definitions proposed by the working group in CRD 15. It was noted that the definition of disputes had been deleted as the document was not intended to address dispute resolution, but to prevent occurrence of disputes.

Principle 1

16 The Committee noted some proposals to amend the text on “the specifications of the importing country” to delete the reference to the importing country and replace it with “Codex specifications”; to refer to “agreed specifications”, or to retain only “ specifications” as trade was not carried out by countries but by trading partners. The Committee however agreed that the import specifications were defined by governments and therefore retained the reference to the importing country in order to avoid confusion with private standards.

Principle 2

17 The Committee agreed to add “by all parties” at the end of the sentence and to add as the last sentence “All relevant information should be shared between governments using mutually agreed upon format and language(s)” for clarification.

Principle 3

18 One observer proposed to replace “product” with “food” as “product” was not defined. The Committee did not agree with it as the meaning of the text would be changed significantly.

Principle 8

19 It was noted that the Principle was so general in its application that it should be moved up in the document. After some discussion, the Committee agreed to move the Principle after Principle 3.

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

20 The Committee agreed to forward the Proposed Draft Principles to the 35th Session of the Commission for adoption at Step 5 (See Appendix IV).

21 The Committee agreed to return the commentary to Step 2/3 and to develop examples at a later stage. The Committee agreed to establish an electronic working group, working in English, to develop draft explanatory notes and consider what examples might be useful, for consideration at the next session.

22 The working group would be chaired by Germany with assistance of New Zealand (especially as regards the availability of a web-based work space), the United States, the Netherlands and Japan. Several delegations expressed their interest in participating in the working group.

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

23 The report of the working group was presented by its Chair, Dr Roger Wood (United Kingdom). The Committee considered the methods proposed for endorsement and in addition to editorial changes made the amendments and recommendations presented below (see Appendices II and III).

Fish and Fishery Products

Standard for Fish Sauce

24 For amino acid nitrogen, the references to both AOAC methods were corrected and the methods used to obtain the result by calculation were endorsed. The Committee noted the validation data provided by Thailand in CRD 5 for the extension of the scope of the method to fish sauce, as the method was originally designed for fertilisers, and encouraged Thailand to publish the data.

25 As regards pH, the Committee recalled that AOAC method 981.12 was already endorsed as Type III for processed fruits and vegetables. It was proposed to endorse it as Type IV because no collaborative studies existed for fish sauce and due to the dilution required for pH measurement. The Committee however noted that the dilution has no impact on the use of the method and endorsed it as Type III.

26 For sodium chloride, the reference to the 1981 FAO Technical paper 219 was not endorsed as it was not readily available. Although AOAC 937.09 was currently a Type II method, it was endorsed as Type IV as there were no collaborative studies for fish sauce. A consequential amendment was made to the status of this method for Boiled Dried Salted Anchovies. AOAC 976.18 was endorsed as Type II. As AOAC 976.19 is a proprietary method, it was not endorsed and the decision was deferred until the general issue of the proprietary methods had been addressed (see Agenda Item 5).

27 The method for the determination of histamine, which was already endorsed for fish and fishery products, was confirmed as Type II, and the reference to “other scientifically equivalent validated methods” was deleted as it was not consistent with the current approach to method endorsement.

Food Additives: Standard for Food Grade Salt

28 The Committee recalled that the Committee on Food Additives (CCFA) had asked for advice on the possibility of converting the methods for heavy metals and copper to criteria and retaining a list of methods for other provisions.

29 The Committee agreed to consider the specific methods for heavy metals and copper for endorsement and concurrently to propose criteria and to assess these methods on the basis of the MLs specified in the working document. The individual methods were therefore considered as described below.

⁵ CX/MAS 12/33/4, CX/MAS 12/33/4-Add.1, CRD 1 (Report of the working group), CRD 5 (comments of Thailand), CRD 11 (comment of ISO-methods for fats and oils), CRD 14 (comments of Australia-Natural Mineral Waters)

30 The Committee noted that several ESPA/CN methods had been updated and replaced with EuSalt Methods. The methods which are not discussed in the present section were endorsed as proposed. The following amendments and comments were made on the methods proposed.

31 One delegation proposed to reconsider the typing of methods as several Type II methods were not recent and consideration should be given to replacing them with more modern methods which were currently Type III. The Chair recalled that this was a general issue and that in the framework of Codex, reference methods should be widely available, which may not always be the case for more recent methods, and also noted that this question could be addressed through the criteria approach.

32 The Committee did not endorse the methods for halogens and asked the CCFA to clarify the need for these methods as there were no provisions for halogens in the standard.

33 The Committee did not endorse the following methods in view of the risk associated with the use of toxic chemicals: ISO 2481:1973 for halogens (mercury issues); EuSalt/AS 007-2005 for potassium (mercury issues); and EuSalt/AS 011-2005 for arsenic (pyridine issues). These methods were referred back to CCFA for further consideration of the risks associated with these reagents and the possibility of using alternative safer methods as Type II. The EuSalt/AS 005-2005 method for copper was also referred back to CCFA as the use of carbon tetrachloride is restricted in some countries.

34 The Committee endorsed EuSalt/AS 008-2005, proposed as Type III, as Type II because the method proposed as Type II, EuSalt/AS 007-2005, was not endorsed and among the Type III methods it was considered to be more widely available.

35 The Committee agreed on the method criteria presented in Table 1 (CRD 1) with a correction in the Recovery to 80-110 % for consistency with the values used in the Procedural Manual, and considered the methods proposed according to the criteria.

36 The Committee noted that the EuSalt/AS 015-2007 method met the criteria and endorsed it as Type III for copper, lead and cadmium. The Committee noted a comment that it may be difficult to use the ICP-OES method in some countries and asked the CCFA to consider if more widely available methods could be recommended. As regards the other methods for copper, arsenic, mercury, lead and cadmium, the collaborative study was performed at too low levels and thus the precision was poor; and collaborative study data was needed for the levels around the ML. These methods were therefore endorsed as Type IV.

37 For iodine, it was clarified that the WHO/UNICEF/ICDD method applied to products fortified with iodate only and it was endorsed as Type IV as no results of collaborative studies were available. The two other methods were endorsed.

Processed Fruits and Vegetables

Canned Bamboo Shoots

38 It was agreed to delete ISO 2447:1998 for tin and to endorse NMKL 126:1988| ISO 17240:2004 as Type III, as the reference method (Type II) is AOAC 980.19.

Coordinating Committee for the Near East

39 The methods proposed were endorsed with the following exceptions.

Harissa

40 The Committee noted that the Hunter scale of colours was described in a proprietary method and asked clarification from the Coordinating Committee for the Near East (CCNEA) on the reference of the method that should be used.

Halwa Tehenia

41 As the methods proposed for sugars and for acidity were not applicable to the provisions concerned, the Committee asked the CCNEA to propose relevant methods.

Milk and Milk Products

Fermented Milks

42 The provision was corrected, the reference to the updated IDF and ISO method was inserted and the Type was amended from IV to I as total acidity is expressed as percentage of lactic acid, which involves a conversion factor. The IDF 24:1964 method was deleted as it was withdrawn by IDF.

Blend of sweetened condensed skimmed milk and vegetable fat

Reduced Fat Blend of sweetened condensed skimmed milk and vegetable fat

43 Recalling that the provision is for Milk solids-not-fat but that the endorsed methods determine Total solids-not-fat, the Committee agreed that the correct principle for Milk solids-not-fat (MSNF) was “Calculation from total solid content, fat content and sugar content” as proposed at the last session.

Other questions

44 The Committee agreed to revoke the EN method for Vitamin C for infant formula and for fruit juices and nectars in CODEX STAN 234 as it had been withdrawn and was no longer available.

Fats and Oils

45 The Committee agreed to endorse the updates of the references for several methods for fats and oils proposed by AOCS and ISO. It was further agreed to ask the Committee on Fats and Oils to review the methods for relative density in several standards and for erythrodiol+uvaol in olive oils and olive pomace oils as the current IUPAC methods were no longer available (see Appendix III).

46 It was noted that when IUPAC methods or other methods requiring updating were listed in standards developed by adjourned committees, they should be considered in the CCMAS.

Natural Mineral Waters

47 The Committee recalled that the 34th Session of the Commission had adopted several methods for natural mineral waters and agreed to make the following corrections as regards the principles:

- ISO 11885:2007 for borate: ICP-OES instead of ICP-MS
- ISO 10304-1:2007 for fluoride and nitrates: LC of ions instead of HPLC; for nitrites: LC of ions-UV instead of HPLC

Part 2. SAMPLING PLANS

Processed Fruits and Vegetables

Desiccated Coconut

48 The Committee endorsed the sampling plan and noted that it was based on the guidance in the *General Guidelines on Sampling* and that this approach should be generally followed by commodity committees.

49 As regards the sampling plan to be revoked, the Committee noted that the ICC Methods of Sampling No. 101.1960 was still current for grain sampling. It was agreed to ask CCPFV whether these instructions could be retained and applied to desiccated coconut.

Fish and Fishery Products: Fish Sauce

Regional Standards (Near East) for Harissa and for Halwa Tehenia

50 The Committee recalled that the CCMAS had clarified on several occasions 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. It was therefore agreed that the sampling provisions in the above standards should not be endorsed and that the committees should consider the development of specific sampling plans for the commodities concerned.

51 The Committee noted that this clarification applied to the question of CCNEA concerning the sampling plans in the Regional Standards for Humus with Tehena, Tehena and Foul Medames.

52 The Committee expressed its thanks to Dr Wood and to the working group for their excellent work. It was agreed that at the next session, the endorsement of methods of analysis and sampling would take place in the plenary session.

Nutrition and Foods for Special Dietary Uses⁶

Methods of analysis for dietary fibre

53 The Committee recalled that its last session had endorsed several methods of analysis for dietary fibre proposed by the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and had agreed that an electronic working group chaired by the United Kingdom would consider the elaboration of a decision tree to facilitate the selection of available methods for dietary fibre. The Committee considered the Discussion Paper on the Selection of Methods of Analysis for the Determination of Dietary Fibre through the Use of Decision Trees (CX/MAS 12/33/4-Add.2), taking into account the options put forward in the working group on endorsement to address this question.

54 The Committee agreed on the following amendments to the list of methods for dietary fibre included in CODEX STAN 234

55 The title of the last section of the Table of methods was amended to read “Other methods that have not been subjected to interlaboratory evaluation”, as there was no need to refer to the AOAC international guidelines. In this section it was also agreed that the first entry should refer to “yeast cell wall” instead of “all foods” as the Eurasyp method applies only to yeast cell wall.

56 Several delegations and some observers supported the development of guidance to facilitate the selection of methods, as the adoption of many Type I methods could cause some confusion for analysts, and several proposals were made as to the possible use of the recommendations presented in the working document: including the decision tree and the table with some explanatory text in a separate document; including the Table or part of it as an annex to the list of methods; or inserting footnotes to the list of methods to clarify their applicability on the basis of the information presented in Appendix IV of the working document.

57 Other delegations did not support such guidance in the framework of Codex as additional recommendations may create more confusion, limit the choice of laboratories and result in barriers to trade, and it was preferable to leave the selection of methods to the analysts, since adequate information on the scope was available in the description of each method. These delegations also recalled that as extensive efforts had been required to finalise the list of methods, the development of guidance on method selection was likely to be a long term process. They noted that the document could be useful as reference with some corrections and could be used as a basis for publication in a scientific journal, with the understanding that it should be freely and easily available. Some observers informed the Committee that their organisations could consider the publication of such a paper.

58 Some delegations noted that publication in a scientific journal, even if it was easily available, would not replace guidance on a Codex text in the list of methods or as a separate document. The Committee noted a proposal to refer only to the table in Appendix IV of the working document, which described the applicable sample types and the compounds determined by each method.

59 The Committee considered the Table in Appendix IV of the working document and agreed to make a number of corrections to the “Dietary Fibre Methodology - What is measured and what is not measured” for each of the methods listed in the Table and to present a revised version as a CRD so that it would be available to all delegates. It was agreed that no additional methods should be added as the purpose of the Table was to clarify the fibre components to be analysed for currently adopted methods.

60 The Committee acknowledged the value of the information presented in CRD 16 as a tool which could assist the selection of appropriate methods of analysis for dietary fibre in a particular product.

⁶ CX/MAS 12/33/4-Add.2, CRD 16 (methods of analysis for dietary fibre)

PROVISIONS ON THE USE OF PROPRIETARY METHODS IN CODEX STANDARDS (Agenda Item 5)⁷

61 The Committee recalled that its 32nd Session had agreed to initiate new work on the development of provisions for proprietary methods in the Procedural Manual and had agreed that an electronic working group, led by the United Kingdom and Germany, would define the term “proprietary method”, prepare a draft version of the criteria to be included in the Procedural Manual, and consider it at the next session.

62 The Delegation of the United Kingdom, as the chair of the electronic working group, explained the text, including a definition of proprietary methods and the text to be incorporated into the Procedural Manual to deal with these methods. The Delegation also informed the Committee that issues relevant to proprietary methods were also considered by the Inter-Agency Meeting because proprietary methods were submitted to standard setting organisations.

63 The Committee thanked the United Kingdom and the electronic working group for their work.

General Consideration

64 The Committee noted the views that caution should be exercised when considering proprietary methods, taking into account that a proprietary method endorsed as Type I or II would give a significant commercial advantage to the manufacturer. Some delegations were of the view that a proprietary method should not be endorsed as Type I or II due to difficulties for analysts and concern about the availability of the method and/or reagent to be used in the method in some countries. It was noted that the typing of such methods would be carefully considered on a case-by-case basis during endorsement of the methods in CCMAS.

65 The Committee noted that in the absence of any other method, consideration should be given to adequate proprietary methods as at least one method of analysis should be endorsed to enforce labelling, such as in the case of gluten determination.

66 Some delegations asked whether the principle was applicable to the work of other committees such as CCRVDF, CCPR and CCFH. It was clarified that the principle would directly be applied to endorsement of methods of analysis for which CCMAS is responsible, although it might have some relevance for the work of other committees.

67 With regard to a question on how to deal with more than one proprietary method to be submitted for one provision, the Committee noted that they should be endorsed as type III and one of them would be type II if they would give the same analytical value and that only one of them should be endorsed as type I in case that they would give different values.

68 The Committee agreed to redraft the document taking into account the comments and to consider the redrafted document shown in CRD 10 section by section. Besides editorial amendments, the Committee agreed to the following changes.

Definition of a Proprietary Method of Analysis

69 As regards disclosure of information about the method, the Committee agreed to replace “without express permission or licensing” with “such that no alternative source of these would be available” because the original definition was so broad that a method using “normal” chemicals might be included in the scope. It was also agreed to replace “restricting or limiting” with “where the intellectual property owner restricts” for clarification.

Requirements

70 The introductory paragraph was slightly reworded to make it clear that the requirements are of a general nature and not specific tasks of CCMAS.

⁷ CX/MAS 12/33/5, CRD 4 (Comments of Chile and EU), CRD 10 (Redrafted document), CRD 13 (Comments of China)

Paragraph a)

71 The Committee agreed to amend the beginning of the sentence as “A proprietary method should not be endorsed if ...” and the following paragraphs accordingly. The Committee also agreed that the last sentence should be a new paragraph with an amendment of the last part as “the status of the previously endorsed proprietary method should be reviewed and may be revised”.

Paragraph c)

72 The Committee agreed to replace “lot-to-lot variability” with “the effect of manufacturing variability” for clarification.

73 One delegation proposed to include that changing the content of a kit could effect the performance characteristic and should be reported. The Committee, noting that this document describes general principles, agreed to add a new paragraph after paragraph c) as follows: “After endorsing, any changes that influence performance characteristics must be reported to CCMAS for consideration”.

Paragraph d)

74 One delegation was of the view that a proprietary method to be endorsed must be validated. The Committee did not agree with the proposal because the amendment made it too difficult to endorse a proprietary method, noting that such methods would not be endorsed as Type I, II or III as written in the latter sentence.

75 The Committee agreed to add “Results of such studies should be made available for CCMAS” after the first sentence to ensure that CCMAS could examine the status of the method.

Paragraph e)

76 The Committee agreed to replace “proprietary information” with “intellectual property”.

Paragraph g)

77 The Committee agreed to change the paragraph to what CCMAS would do to read “CCMAS may decline to endorse a proprietary method if intellectual property unduly restricts research into determining the method properties, scope of claim and validity or the development of improvements to the technology”, noting that endorsement of any method of analysis, including proprietary methods, does not prohibit any further research.

Status of Provisions on the Use of Proprietary Methods in Codex Standards

78 The Committee agreed to submit the amended text to the Committee on General Principles for endorsement to be added after the Section of the *General Criteria for the Selection of Methods of Analysis* in the *Principles for the Establishment of Codex Methods of Analysis* of the Procedural Manual (See Appendix V).

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 6)⁸

79 The Secretary of the Inter-Agency Meeting, Dr Richard Cantrill (AOCS), introduced the report of the 24th meeting of international organisations working in the field of methods of analysis and sampling (IAM) held on 2nd March 2012. In addition to the matters on the agenda of the Committee, the meeting had considered the activities of the organisations concerned, some of which are highlighted below.

80 The Committee noted that the publication of the Eurachem Guide to VIM Terminology posted on the Eurachem website and that IAM recognised the need to provide a list of other sources of terms.

81 The IAM had considered the criteria approach such as practical implications of criteria approach to the adoption of methods, validation of a semi-criteria method and extension of the criteria approach to Type I methods except for trueness.

82 The Committee noted that the IAM/MoniQA workshop on choosing the right laboratories for official control organized prior to the meeting had been very successful and attended by more than 60 delegates, and participants were invited to make proposals for a future workshop which might be held in 2013.

⁸ CRD 2 (Report of an Inter-Agency Meeting)

83 The Committee noted that a report of recent activities of CEN TC 275 WG 0 would be available shortly for comment prior to a forthcoming meeting of CEN/TC 275.

84 With regard to the guidelines for the validation of qualitative methods, it was noted that under the leadership of AOAC, the output from the work of two groups of experts from ISO/TC 34/SC 16 and AOAC Intl., and MoniQA/IUPAC would be made available on their website for public comment.

85 The Committee was informed that ISO 5725, redeveloped as ISO 15725, was in an early phase of development. It was noted that a new draft of part 1 would be in time for discussion at the June meeting of TC 69 and that the outline of part 2 would appear to contain reference to intermediate precision determination.

86 The IAM reminded the members of IAM that they should update and maintain their entries in CODEX STAN 234-1999 where necessary.

87 The Committee expressed its appreciation to the international organisations participating in the interagency meeting for their contribution to its work and the organisation of the IAM/MoniQA workshop, and to the Hungarian Food Safety Office for hosting the IAM. It was noted that the next IAM meeting would be held prior to the 34th Session of the Committee.

88 The Committee noted that the document on “The Codex criteria approach applied to operationally defined methods” attached to CRD 2 provided some helpful information and that this question may be considered in the future in the Committee.

89 The Committee agreed to ask IAM to provide a short discussion paper on sampling issues for consideration at the next session taking into consideration the information in CRD 12.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 7)

Update of references in the list of methods of analysis

90 The Delegation of Brazil indicated that several adopted methods were no longer in use or otherwise required an update and that the reference to documents developed by other organisations in some Guidelines should also be revised, and proposed to consider this issue at the next session.

91 The Secretariat recalled that while updates of methods were the responsibility of the relevant committee if it is active, CCMAS could review the methods when the committees were adjourned, as was currently the case for the methods for milk and milk products that were regularly updated. It was also noted that the standard setting organisations provided their updates to the Committee for consideration under the item on endorsement.

92 The Committee agreed that Brazil would prepare a discussion paper on the update of references to methods of analysis and other texts for consideration at the next session.

Other issues

93 In reply to a question on the information provided in the report of the IAM on the work initiated in BIPM on the role of metrology in microbiology, it was noted that this could also be relevant for general issues on methods of analysis and sampling, while work on microbiological methods was the responsibility of the Committee on Food Hygiene. It was noted that an update on the work of BIPM would be provided through the IAM at the next session.

94 The Delegation of Morocco expressed the view that practical guidance was needed on the application of the General Guidelines on Sampling, or that the Guidelines should be simplified in order to facilitate their use. The Chair indicated that the development of examples in the framework of the Principles for Sampling and Testing in International Food Trade was intended to address this need to provide guidance on sampling to member countries.

DATE AND PLACE OF NEXT SESSION (Agenda Item 8)

95 The Committee noted that its next session was scheduled to be held in Hungary from 4 to 8 March 2013, subject to final confirmation from the host country and Codex Secretariat.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP12/MAS)
Endorsement of methods of analysis in Codex Standards, including methods of analysis for food grade salt	-	Governments 35 th CAC	paras 23 – 60 Appendix II
Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (section on Principles)	5	Governments 35 th CAC	para. 20 Appendix IV
Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (except for the section on Principles)	2/3	Governments electronic working group 34 th CCMAS	para. 21
The Use of Proprietary Methods in Codex Standards	PM	27 th CCGP Governments 35 th CAC	para. 78 Appendix V

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Appendix II**STATUS OF ENDORSEMENT OF METHODS OF ANALYSIS AND SAMPLING**

- A. Fish and Fishery Products
- B. Food Additives
- C. Processed Fruits and Vegetables
- D. Coordinating Committee for the Near East
- E. Milk and Milk Products
- F. Nutrition and Foods for Special Dietary Uses
- G. Fats and Oils
- H. Natural Mineral Waters
- I. Methods that are no longer available

A. COMMITTEE ON FISH AND FISHERY PRODUCTS**Standard for Fish Sauce**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Fish sauce	total nitrogen	AOAC 940.25	digestion	type I
Fish sauce	amino acid nitrogen	AOAC 920.04 and AOAC 920.03	determining formaldehyde titration method subtracting by ammoniacal nitrogen (magnesium oxide method)	type I
Fish sauce	pH	AOAC 981.12	electrometry	type III The pH shall be measured in a sample of fish sauce diluted with water to 1:10 using a pH meter. The dilution of fish sauce is necessary because of the high ionic strength in the undiluted sauce.
Fish sauce	sodium chloride	AOAC 937.09	Titrimetry	type IV
Fish sauce	sodium chloride	AOAC 976.18	potentiometry	type II
Fish sauce	sodium chloride	AOAC 976.19	Indicating strip method	Not endorsed as this is a “proprietary method” and alternative methods are available
Fish sauce	histamine	AOAC 977.13	Fluorimetry	type II

Note: Consequential amendment to the methods for sodium chloride in Boiled Dried Salted Anchovies (AOAC 937.09)

B. COMMITTEE ON FOOD ADDITIVES**Draft Revision of the Standard for Food Grade Salt**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
food grade salt	sulphate	ISO 2480:1972	gravimetric	type II
food grade salt	sulphate	EuSalt/AS 015-2007	ICP-OES	type III
food grade salt	sulphate	EuSalt/AS 018-2005	Ion chromatography	type III
food grade salt	halogens	ISO 2481:1973	mercurimetry	Not endorsed. Refer back to CCFA due to no provision for halogen in the Standard and safety concerns with a reagent in the method
food grade salt	halogens	EuSalt/AS 016-2005	potentiometry	Not endorsed. Refer back to CCFA due to no provision for halogen in the Standard
food grade salt	halogens	EuSalt/AS 018-2005	ion chromatography	Not endorsed. Refer back to CCFA due to no provision for halogen in the Standard

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
food grade salt	calcium and magnesium	ISO 2482:1973	complexometric titrimetry	type II
food grade salt	calcium and magnesium	EuSalt/AS 009-2005	Flame atomic absorption spectrometry	type III
food grade salt	calcium and magnesium	EuSalt/AS 015-2007	ICP-OES	type III
food grade salt	potassium	EuSalt/AS 007-2005	volumetry	Not endorsed. Refer back to CCFA due to safety concerns with a reagent in the method
food grade salt	potassium	EuSalt/AS 008-2005	Flame atomic absorption spectrometry	type II
food grade salt	potassium	EuSalt/AS 015-2007	ICP-OES	type III
food grade salt	copper	EuSalt/AS 005-2005	photometry	Not endorsed. Concern on availability of carbon tetrachloride; See annex
food grade salt	copper	EuSalt/AS 015-2007	ICP-OES	type III; See annex
food grade salt	arsenic	EuSalt/AS 011-2005	photometry	Not endorsed. Refer back to CCFA due to safety concern on the use of pyridine in the method; See annex
food grade salt	arsenic	EuSalt/AS 015-2007	ICP-OES	type IV; See annex
food grade salt	mercury	EuSalt/AS 012-2005	cold vapour atomic absorption spectrometry	type IV; See annex
food grade salt	lead	EuSalt/AS 013-2005	flame atomic absorption spectrometry	type IV; See annex
food grade salt	lead	EuSalt/AS 015-2007	ICP-OES	type III; See annex
food grade salt	cadmium	EuSalt/AS 014-2005	flame atomic absorption spectrometry	type IV; See annex
food grade salt	cadmium	EuSalt/AS 015-2007	ICP-OES	type III; See annex
food grade salt	iodine	EuSalt/AS 002-2005	Titrimetry using sodium thiosulphate	type II
food grade salt	iodine	WHO/UNICEF/ICCIDD method ¹	Titrimetry using sodium thiosulphate	type IV Only applicable to a product which has been fortified with iodate
food grade salt	iodine	EuSalt/AS 019-2009	ICP-OES	type III

¹ Assessment of iodine deficiency disorders and monitoring their elimination. A guide for programme managers. Third edition, Annex 1: Titration method for determining salt iodate and salt iodine content. World Health Organization, Geneva, 2007. The report is available from http://www.who.int/nutrition/publications/micronutrients/iodine_deficiency/WHO_NHD_01.1/en/index.html

C. COMMITTEE ON PROCESSED FRUITS AND VEGETABLES**Standard for Canned bamboo Shoots**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Canned Bamboo Shoots	Tin	NMKL 126:1988 ISO 17240:2004	Flame atomic absorption spectrometry	type III

Note: The 24th CCPFV (2006) agreed to delete method ISO 2447:1998 in the Standard for Pickled Fruits and Vegetables following the request from CCMAS to clarify why this method was used and to consider using the General Codex Method AOAC 980.19 (Type II) (ALINORM 07/30/27, Appendix II)

D. COORDINATING COMMITTEE FOR THE NEAR EAST**Regional Standard for Harissa**

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
harissa	acidity	ISO 750:1998	titrimetry	type I
harissa	dry extract – soluble solids	ISO 2173:2003	refractometry	type I
harissa	acid insoluble ash	ISO 763:2003	gravimetry	type I
harissa	colour	“Hunter” method		Not endorsed. CCNEA to be asked to propose an appropriately referenced method

Regional Standard for Halwa Tehenia

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
halwa tehenia	moisture	AOAC 925.45 AACC Intl 44.60.01	gravimetry	type I
halwa tehenia	fat	AOAC 963.15	gravimetry	type I
halwa tehenia	ash	AOAC 900.02 AACC Intl 8.14.01	gravimetry	type I
halwa tehenia	sugars (estimated as sucrose)	AOAC 930.15		Method proposed not endorsed. CCNEA to be asked to propose an appropriate method
halwa tehenia	acidity	AOAC 900.02		Method proposed not endorsed. CCNEA to be asked to propose an appropriate method

E. COMMITTEE ON MILK AND MILK PRODUCTS

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type proposed
Fermented milks	total acidity expressed as percentage of lactic acid	ISO/TS 11869 IDF/RM 150: 2012	Potentiometry, titration to pH 8.30	type I
Blend of sweetened condensed skimmed milk and vegetable fat	Milk solids-not-fat (MSNF) ²	ISO 6734 IDF 15:2010	Calculation from total solids content, fat content and sugar content	type IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	MSNF ²	ISO 6734 IDF 15:2010	Calculation from total solids content, fat content and sugar content	type IV

F. COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**Methods of analysis for dietary fibre: Guidelines for Use of Nutrition and Health Claims: Table of Conditions for Claims**

Other methods⁽²⁾ that have not been subjected to interlaboratory evaluation				
Yeast cell wall	Insoluble glucans and mannans of yeast cell wall (for yeast cell wall only)	Eurasyp (European association for specialty yeast product) – LM Bonanno. Biospringer- 2004 – online version : http://www.eurasyp.org/public.technique.home.screen .	Chemical & HPAEC-PAD	Type IV

² Milk total solids and Milk solids-not-fat content include water of crystallization of lactose.

G. COMMITTEE ON FATS AND OILS

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Fats and oils	Butylhydroxy-anisole, butylhydroxy-toluene, tert-butylhydroquinone, & propyl gallate	AOAC 983.15; or AOCS Ce 6-86 (09)	Liquid chromatography	type II
Fats and oils not covered by individual standards	Acid Value	ISO 660:2009; or AOCS Cd 3d-63 (09)	Titrimetry	type I
Fats and oils not covered by individual standards	Copper and Iron	AOAC 990.05 ISO 8294:2007 or AOCS Ca 18b-91 (09) (Codex general method)	Atomic absorption Spectrophotometry (direct graphite furnace)	type II
Fats and oils not covered by individual standards	Peroxide value	AOCS Cd 8b-90 (11) ISO 3961:1996	Titrimetry using <i>iso</i> -octane	type I
Named Animal Fats	Iodine value (IV)	ISO 3961: 1996; or AOAC 993.20; or AOCS Cd 1d-92 (09)	Wijs-Titrimetry	type I
Named Animal Fats	Peroxide value	AOCS Cd 8b-90 (11) ISO 3961:1996	Titrimetry using <i>iso</i> -octane	type I
Named Animal Fats	Saponification value	ISO 3657:2002; or AOCS Cd 3-25 (11)	Titrimetry	type I
Named Animal Fats	Unsaponifiable matter	ISO 3596:2000 or ISO 18609: 2000; or AOCS Ca 6b-53 (11)	Titrimetry after extraction with diethyl ether	type I
Named Vegetable Oils	Acidity	ISO 660: 2009 or AOCS Cd 3d-63 (09)	Titrimetry	type I
Named Vegetable Oils	Apparent density	ISO 6883: 2007, with the appropriate conversion factor; or AOCS Cc 10c-95 (09)	Pycnometry	type I

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Named Vegetable Oils	Crismer value	AOCS Cb 4-35 (09) and AOCS Ca 5a-40 (12)	Turbidity	type I
Named Vegetable Oils	GLC ranges of fatty acid composition	ISO 5508: 1990 and ISO 12966-2:2011; or AOCS Ce 2-66 (09) and Ce 1-62 (09) or Ce 1h-05 (09)	Gas chromatography of methyl esters	type II
Named Vegetable Oils	Insoluble impurities	ISO 663:2007	Gravimetry	type I
Named Vegetable Oils	Iodine value (IV)	Wijs - ISO 3961:2009; or AOAC 993.20; or AOCS Cd 1d-92 (09); or NMKL 39 (2003)	Wijs-Titrimetry ³	type I
Named Vegetable Oils	Peroxide value (PV)	AOCS Cd 8b-90 (11); or ISO 3960: 2007	Titrimetry	type I
Named Vegetable Oils	Saponification value (SV)	ISO 3657: 2002; or AOCS Cd 3-25 (11)	Titrimetry	type I
Named Vegetable Oils	Sterol content	ISO 12228: 1999; or AOCS Ch 6-91 (11)	Gas chromatography	type II
Named Vegetable Oils	Unsaponifiable matter	ISO 3596: 2000; or ISO 18609: 2000; or AOCS Ca 6b-53 (11)	Gravimetry	type I
Olive Oils and Olive Pomace Oils	Acidity, free (acid value)	ISO 660:2009 or AOCS Cd 3d-63 (09)	Titrimetry	type I
Olive Oils and Olive Pomace Oils	Difference between the actual and theoretical ECN 42 triglyceride content	COI/T.20/Doc. no. 20 or AOCS Ce 5b-89 (11)	Analysis of triglycerides of HPLC and calculation	type I
Olive Oils and Olive Pomace Oils	Fatty acids in the 2-position of the triglycerides	ISO 6800:1997 or AOCS Ch 3-91 (11)	Gas chromatography	type I

³ It is possible to calculate the Iodine Value from fatty acid composition data obtained by gas chromatography e.g. using AOCS Cd 1b-87 (09)

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Olive Oils and Olive Pomace Oils	Insoluble impurities in light petroleum	ISO 663:2007	Gravimetry	type I
Olive Oils and Olive Pomace Oils	Iodine value	ISO 3961:2009 or AOAC 993.20 or AOCS Cd 1d-92 (97) or NMKL 39 (2003)	Wijs-Titrimetry	type I
Olive Oils and Olive Pomace Oils	Peroxide value	ISO 3960:2007 or AOCS Cd 8b-90 (11)	Titrimetry	type I
Olive Oils and Olive Pomace Oils	Saponification value	ISO 3657:2002 or AOCS Cd 3-25 (11)	Titrimetry	type I
Olive Oils and Olive Pomace Oils	Sterol composition and total sterols	COI/T.20/Doc. no. 10 or ISO 12228:1999 or AOCS Ch 6-91 (11)	Gas chromatography	type I
Olive Oils and Olive Pomace Oils	<i>trans</i> fatty acids content	COI/T.20/Doc no. 17 or ISO 15304:2002 or AOCS Ch 2a-94 (11)	Gas chromatography of methyl esters	type II
Olive Oils and Olive Pomace Oils	Unsaponifiable matter	ISO 3596:2000 or ISO 18609:2000 or AOCS Ca 6b-53 (11)	Gravimetry	type I
Olive Oils and Olive Pomace Oils	Wax content	COI/T.20/Doc. no. 18 or AOCS Ch 8-02 (11)	Gas chromatography	type II

H. NATURAL MINERAL WATERS**Criteria applicable to health-related substances in the Standard for Natural Mineral Waters**

Provision	ML (mg/L)	Min. applicable range (mg/L)	LOD (mg/L)	LOQ (mg/L)	Precision RSDR (%) No more than	Recovery (%)	Suggested methods meeting the criteria	Principle
Borate	5	3.1	0.5	1	25	97-103	ISO 9390:1990 ISO 11885:2007 ISO 17294-2:2003	Spectrophotometry ICP-OES ICP-MS ⁴
Fluoride	1.0	0.52	0.1	0.2	32	97-103	ISO 10304-1:2007 ISO 10359-1:1992 (dissolved fluoride) ISO 10359-2:1994 (inorganic bound)	LC of ions Electrochemical probe Digestion, distillation
Nitrate	50	37	5	10	18	98-102	ISO 10304-1:2007 ISO 13395:1996 ISO 7890-3:1988	LC of ions CFA, FIA, Spectrophotometry Spectrophotometry
Nitrite	0.1	0.03	0.01	0.02	44	95-105	ISO 10304-1:2007 ISO 13395:1996 ISO 6777:1984	LC of ions UV CFA, FIA, Spectrophotometry Spectrophotometry

I. METHODS TO BE REVOKED FROM CODEX STAN 234

COMMODITY	PROVISION	METHOD	PRINCIPLE	Note
Milk fat products	Milk fat	IDF 24:1964	Gravimetry (calculation from solids-not-fat content and water content)	
Fruit juices and Nectars	Vitamin C	EN 14130:2004	HPLC	
Infant Formula	Vitamin C	EN 14130:2003	HPLC	

⁴ Total Boron is determined

Method Criteria Values for Copper, Arsenic, Mercury, Lead and Cadmium in Food Grade Salt

Table 1: Criteria approach including appropriate methods

Provision	ML (mg/kg)	Min. applicable level (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	Precision RSD _R (%)	Recovery (%)	Suggested methods meeting the criteria	Principle
Copper	2	1.1	0.2	0.4	29	80-110	EuSalt/AS 015-2007	ICP-OES
Arsenic	0.5	0.2	0.05	0.1	36	80-110		
Mercury	0.1	0.03	0.01	0.02	45	80-110		
Lead	2	1.1	0.2	0.4	29	80-110	EuSalt/AS 015-2007	ICP-OES
Cadmium	0.5	0.2	0.05	0.1	36	80-110	EuSalt/AS 015-2007	ICP-OES

Table 2: Methods, suggested for endorsement, but for which further documentations/validations are needed:

Provision	Method	Principle	Results from the collaborative study	Comments
Copper	EuSalt/AS 005-2005	Photometry Note: use of carbon tetrachloride is restricted	13 laboratories 4 <u>low</u> levels: 0.02 – 0.054 mg/kg thus RSD _R high (43-77%)	The collab study is not valid as it has been performed on too low levels, and thus the precision is poor. The method might be ok, however, documentation is needed for the levels around ML.
Arsenic	EuSalt/AS 011-2005	Photometry	17 laboratories 3 <u>low</u> levels: 0.005-0.0024 mg/kg thus RSD _R high (210-680%)	See above.
Arsenic	EuSalt/AS 015-2007	ICP-OES	16 laboratories 5 levels: 0.08 – 20.76 mg/kg RSD _R : 5.4-270% Lowest validated level with ok prec. 0.84 mg/kg	The precision is not satisfactory for the levels around ML.
Mercury	EuSalt/AS 012-2005	cold vapour AAS	Several laboratories 3 levels below LOQ thus RSD _R very high (>350%)	The collab study is not valid as it has been performed on too low levels, and thus the precision is poor. The method might be ok, however, documentation is needed for the levels around ML.
Lead	EuSalt/AS 013-2005	Flame AAS	15 laboratories 3 levels below LOQ, thus RSD _R very high (>125%)	See above.
Cadmium	EuSalt/AS 014-2005	Flame AAS	15 laboratories 3 levels below LOQ (highest 0.011mg/kg) RSD _R : > 93%	See above.

APPENDIX III

**METHODS OF ANALYSIS OR PROVISIONS TO BE CONSIDERED
BY THE COMMITTEE ON FATS AND OILS**

COMMODITY	PROVISION	METHOD	PRINCIPLE
Named Animal Fats	Relative Density		
Named Vegetable Oils	Relative Density	IUPAC 2.101 with appropriate conversion factor	Pycnometry
Olive Oils and Olive Pomace Oils	Erythrodiol +uvaol content	IUPAC 2.431	GC
Olive Oils and Olive Pomace Oils	Relative Density	IUPAC 2.101, with the appropriate conversion factor	Pycnometry

APPENDIX IV

PROPOSED DRAFT PRINCIPLES FOR THE APPLICATION OF SAMPLING AND TESTING ACTIVITIES IN INTERNATIONAL FOOD TRADE

(Step 5 of the procedure)

SECTION 1 - INTRODUCTION

1. Sampling and testing procedures are utilized to determine if foods in trade are compliant with particular specifications. These procedures establish the level of protection afforded to exporters and producers, and importers and consumers. The procedures used should be such as to ensure that Consumers' Risk and Producers' Risk are both considered. 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. In 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." As for methods of analysis, those endorsed by Codex should be considered first.
3. Sampling and testing procedures in international food trade are often used 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 the economic consequences and feasibility of risk management options. Risks due to conditions during storage and transport should be considered by all business operators in the food distribution chain. In order to achieve this there should be an understanding of the impacts of sampling and testing options on all affected parties. Risk management itself should be a continuing process that takes into account all new information, including scientific information, in the evaluation and review of risk management decisions based on sampling and testing.
5. It should be recognised that end-product sampling and testing is only one of the methods by which an exporter can validly claim confidence that product meets specifications.
6. This document does not affect existing Codex limits or the current way of setting those limits. These responsibilities are set out in committees' terms of reference.

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.
8. These principles do not :
 - a) address other uses of sampling and testing;
 - b) address other means of establishing that foods in trade meet specifications;
 - c) give guidance on choosing appropriate levels of Consumers' Risk and Producers' Risk.

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.

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:

Consignment¹**Lot¹****Sample¹****Sampling¹****Sampling plan¹****Result²****Measurement uncertainty³****Consumers' Risk and Producers' Risk¹***Note 1*

The definitions of Consumers' Risk and Producers' Risk refer to the probabilities of wrongly accepting or wrongly rejecting a lot or consignment, respectively.

Note 2

The word “probability” should be interpreted as the proportion or percentage of times that lots or consignments identical to the given lot or consignment would be incorrectly decided by the specified sampling and testing procedures.

SECTION 4 - PRINCIPLES**Principle 1: Agreements before initiating trade**

Before starting trading activities, the parties concerned should reach agreement related to the sampling and testing procedures that will be applied to determine whether the food in trade meets the specifications of the importing country and also on the sampling and testing procedures to be followed in the case of a dispute.

Principle 2: Transparency

The selection of sampling and testing procedures and the process for comparing test results to specifications should be documented, communicated and agreed upon by all parties. All relevant information should be shared between governments using mutually agreed upon format and language(s).

Principle 3: Components of a product assessment procedure

Sampling and testing of food in trade to determine 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 4: Consumers' Risk and Producers' Risk

Whenever food is sampled and tested, the probability of wrongly accepting or wrongly rejecting a lot or consignment affects both exporters and importers and can never be entirely eliminated. The Consumers'

¹ *General Guidelines on Sampling (CAC/GL 50)*

² *Guidelines on Analytical Terminology (CAC/GL 72)*

³ *Guidelines on Measurement Uncertainty (CAC/GL 54)*

Risk and Producers' Risk should be evaluated and controlled, preferably using methodology described in internationally recognized standards.

Principle 5: Selecting appropriate sampling and testing procedures

The sampling and testing procedures selected should be scientifically based and appropriate to the commodity and lot or consignment to be sampled and tested, fit for intended purposes and applied consistently.

Principle 6: Practical considerations

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 Consumers' Risk is not compromised.

Principle 7: Taking account of analytical measurement uncertainty and its implications

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

Principle 8: Product variation

The selection of sampling and testing procedures should take into account the potential variations within a lot or consignment.

Principle 9: Fitness for purpose

A testing procedure is fit for purpose in a given product assessment procedure, if, when used in conjunction with the sampling plan and the decision criteria, it has accepted probabilities of wrongly accepting or wrongly rejecting a lot or consignment.

Principle 10: Review procedures

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

SECTION 5 - REFERENCES

- *Guidelines for Food Import Control Systems* (CAC/GL 47-2003)
- Publications and resources of the ISO Committee on Conformity Assessment (ISO CASCO) at http://www.iso.org/iso/resources/conformity_assessment.htm.

APPENDIX V

PROVISIONS ON THE USE OF PROPRIETARY METHODS IN CODEX STANDARDS**(To be added to the procedural manual)*****Definition of a Proprietary Method of Analysis***

For Codex purposes a proprietary method of analysis is one that contains protected intellectual property preventing full disclosure of information about the method and/or where the intellectual property owner restricts the use or distribution of the method or materials for its performance such that no alternative source of these would be available. It does not extend to a method which is subject only to copyright.

Requirements

Codex Committees may occasionally submit methods of analysis which are proprietary, or are based on proprietary aspects, to the Codex Committee on Methods of Analysis and Sampling for endorsement. CCMAS encourages the method sponsors to provide data for CCMAS assessment.

- a) A proprietary method should not be endorsed if there is available a suitable non-proprietary method of analysis which has been or could be endorsed and which has similar or better performance characteristics. This should ensure that no approach is taken such that it appears as if a proprietary method is endorsed by Codex to the detriment of other potential methods; if possible preference should be given to adopting appropriate method criteria rather than endorsing a specific proprietary method of analysis.
- b) Preference should be given to endorsing those methods of analysis where the reagents and/or apparatus are described in the method to the degree that either laboratories or other manufacturers could produce them themselves.
- c) Method performance criteria established for proprietary methods are the same as those for non-proprietary methods. Performance criteria should be those stipulated above. If appropriate, information on the effect of manufacturing variability of the proprietary method on the method performance should be provided.
- d) After endorsing, any changes that influence performance characteristics must be reported to CCMAS for consideration.
- e) A proprietary method should be either fully collaboratively validated or validated and reviewed by an independent third party according to internationally recognised protocols. The results of such studies should be made available for CCMAS. If a proprietary method has not been validated by a full collaborative trial, it may be eligible for adoption into the Codex system as a Codex Type IV method, but not as a Type I, II or III method.
- f) Whilst respecting the necessity for reasonable protection of intellectual property, sufficient information should be available to enable reliable use of the method by analysts and to enable evaluation of the performance of the method by CCMAS. In any particular case this may extend beyond performance data, for example to include details of operating principle, at the sole discretion of CCMAS.
- g) The supplier or submitter of a proprietary method should demonstrate to CCMAS's satisfaction that the method will be readily available to all interested parties.
- h) CCMAS may decline to endorse a proprietary method if restrictions by intellectual property unduly restrict research into determining the method properties, scope of claim and validity or development of improvements to the technology.
- i) If suitable nonproprietary methods become available and endorsed, the status of the previously endorsed proprietary method should be reviewed and may be revised.