

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 97/23

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-second Session
Geneva, 23-28 June 1997

REPORT OF THE 20TH SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING Budapest, Hungary, 2-6 October 1995

Note: This report incorporates Codex Circular Letter CL 1995/46-MAS.

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CX 4/50.2

CL 1995/46-MAS
October 1995

To:

- Codex Contact Points
- Participants at the Twentieth Session of the Codex Committee on Methods of Analysis and Sampling
- Interested International Organizations

From: Chief, Joint FAO/WHO Food Standards Programme, FAO
Viale delle Terme di Caracalla, 00100 Rome, Italy

Subject: Distribution of the Report of the Twentieth Session, of the Codex Committee on Methods of Analysis and Sampling (CCMAS).

The report of the Twentieth Session of the above Committee (ALINORM 97/23) will be considered by the Twenty-second Session of the Codex Alimentarius Commission (Geneva, 23-28 June 1997).

PART A: MATTERS FOR ADOPTION BY THE COMMISSION

The following matters will be brought to the attention of the 22nd Session of the Codex Alimentarius Commission for adoption:

- i. The IUPAC/ISO/AOAC Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (ALINORM 97/23, para. 40) and
- ii. Amendment to the Committee's Terms of Reference (ALINORM 97/23, para. 64).

The Committee also endorsed provisions concerning methods of analysis for 10 commodity Codex Standards and also assigned type classification to 12 Codex General Methods for Contaminants (ALINORM 97/23, para 54 and Appendix IV).

Governments wishing to propose amendments or to submit comments regarding the implications which the above matters have for their economic interest should do so in writing, in conformity with the Codex Alimentarius Commission Procedural Manual, to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, **no later than 31st April 1996.**

PART B: DOCUMENTS TO BE ELABORATED FOR GOVERNMENT COMMENTS PRIOR TO THE NEXT SESSION OF THE COMMITTEE

- I. Proposed Draft Codex General Guidelines on Sampling (para. 10);
- ii. Development of objective criteria for assessing the competence of testing laboratories involved in the official import and export control of foods (para. 22) and
- iii. Harmonization of analytical terminology in accordance with international standards (para. 34).

PART C: REQUEST FOR COMMENTS AND INFORMATION

- I. Criteria for evaluating acceptable methods of analysis for Codex purposes (para. 18) and
- ii. Review of methods of analysis using ozone-depleting substances (para 61).

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATION BY THE COMMISSION AND THE EXECUTIVE COMMITTEE:

- Recommended the adoption of the IUPAC/ISO/AOAC Harmonized guidelines for internal quality control in analytical chemistry laboratories (paras. 37-40);
- Recommended amendments to the Committee's Terms of Reference (paras. 63 & 67);

OTHER MATTERS OF INTEREST TO THE COMMISSION

- Agreed in principle to accept the criteria approach for evaluating methods of analysis for Codex purposes (para. 17);
- Agreed that the following quality criteria be adopted by laboratories involved in the official import and export control of foods:
 - Comply with the general criteria for testing laboratories laid down in ISO/IEC Guide 25:1990
 - Participate in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in "The International Harmonized Protocol for the Proficiency testing of (Chemical) Analytical Laboratories",
 - Whenever available, use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission; and
 - Use internal quality control procedures, such as those described in the "Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories" (para. 21);
- Recommended the adoption of the IUPAC/ISO/AOAC Harmonized Protocol for the use of Recovery Factors for Codex purposes when the protocol was published by IUPAC (para. 27);
- Agreed to request Commodity Committees to identify how extensive the problem of indirect determinations was in Codex Standards (para. 30);
- Agreed to define selected core terms of direct relevance to the work of Codex and circulate to governments and international organizations for comments (para. 34);
- Noted the report of the Inter-Agency Meeting (para. 47);
- Noted the progress report on review of standard methods of analysis and sampling (para. 48);
- Requested commodity Committees to avoid selecting methods of analysis which use ozone-depleting solvents (paras. 61 & 62) and
- Proposed to undertake the following new work:
 - Review of methods of analysis using ozone-depleting substances and
 - Measurement uncertainty (para. 66).

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**REPORT OF THE TWENTIETH SESSION OF THE
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Budapest, Hungary, 2-6 October 1995**

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling held its Twentieth Session from 2 to 6 October 1995 in Budapest, by courtesy of the Government of Hungary. The Session was chaired by Professor Peter Biacs, Director General of the Central Food Research Institute (KEKI). The Session was attended by 109 delegates and observers from 41 countries and 5 International Organizations. A complete list of participants, including the Secretariat is provided in Appendix I to this report.

OPENING OF THE SESSION (Agenda Item 1)

2. At the opening session, the delegates were welcomed by Dr. E. Rácz, Director of Food Quality Division, Department of Food Industries and current Chairman of the Hungarian Codex Committee. The session was addressed by Dr. László Vajda, Head of the Department of International Economic Relations, Ministry of Agriculture.

ADOPTION OF THE AGENDA¹ (Agenda Item 2)

3. The Committee adopted the Provisional Agenda as proposed, and agreed to:
- appoint an *ad hoc* Working Group to consider Agenda item 4 - Proposed Draft Codex General Guidelines on Sampling, in order to facilitate its consideration;
 - discuss Agenda item 7 directly after Agenda item 5;
 - discuss, "Review of Methods of Analysis Using Ozone-Depleting Substances" after Agenda item 12; and
 - discuss amendment to the Terms of Reference of the Committee under Agenda item 13 - Other Business and Future Work.
4. Some delegations requested addition of an Agenda item on "Matters of interest". The Chairman informed the Committee that the Commission at its 21st Session approved the Committee's proposal for new work² and adopted the three items (two Protocols and the Codex Methods of Analysis for Contaminants).

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

5. The Committee agreed with the proposal of the Chairman to appoint Mr. William J. Franks, (USA) as rapporteur.

¹ CX/MAS 95/1

² ALINORM 95/4, para. 8 & Appendix II; ALINORM 95/37, para. 12

PROPOSED DRAFT CODEX GENERAL GUIDELINES ON SAMPLING³ (Agenda Item 4)

6. It was noted that since the last Session of the Committee, the proposed draft guidelines had been circulated for comments and, taking into consideration the comments received, revised by a Consultant, Dr. R. Coker⁴. Dr. Coker presented the revised paper and emphasized that the main aim of the revision was to make the document more user-friendly and comprehensive.

7. After the introduction of the document, an *ad hoc* Working Group was convened in order to facilitate the discussion of the document. It was chaired by Dr. F. McClure of the USA and was composed of delegates from Canada, Finland, France, Hungary, The Netherlands, Norway and the USA. Dr. Coker was the rapporteur.

8. After much deliberation, the Working Group recommended to the plenary that the document should be further revised. The revised document would consist of two main parts as follows:

Part I: DISCRETE LOTS MOVING IN INTERNATIONAL TRADE

- (a) Two class attributes plans for proportion of non-conforming units;
- (b) Three class attributes plans (for microbiological assessments);
- (c) Variables plans for proportion of non-conforming units: unknown standard deviation; and
- (d) Attributes plans to detect at least one non-conforming unit in a lot.

Part II: CONTROL OF MANUFACTURING PROCESS

- (a) Two class attributes plans for proportion non-conforming units (ISO 2859);
- (b) Variables plans for proportion of non-conforming units: known and unknown standard deviation (ISO 3951);and
- (c) Switching Rules.

9. Additional changes would include:

- Use ISO definitions throughout the document (ISO 7002 as primary source);
- Include additional AQLs (0.16, 0.4, 1.6); and
- Make a number of other changes, such as removing Section 5.1.1, "The treatment of lots of varying size" and the associated Table 7.

10. The Committee agreed that the Secretariat should arrange for the present draft guidelines to be further revised, with review assistance provided by the members who served on the *ad hoc* Working Group. A new revised draft should be circulated to Member Countries for comments at

³ CX/MAS 95/2

Comment papers (Czech Republic & Hungary)

⁴ Ray Coker, Ph.D., Principal Natural Products Scientist, Natural Resources Institute, Chatham, UK.

Step 3 well before the next Session of the Committee. This revised draft should identify potential users of the document.

11. It was also suggested that the current document with the suggested revision should be brought to the attention of the Codex Committees on Residues of Veterinary Drugs in Foods and on Food Hygiene during their Sessions in November/December 1995, with an indication that the document is under revision, and that the revised document should be presented to the Codex Committee on Pesticide Residues which will meet next year.

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS FOR CODEX PURPOSES⁵ (Agenda Item 5)

12. The Committee recalled that this item had been discussed at the two previous sessions without reaching an agreement. The Delegation of the United Kingdom presented the paper. It was stated that in order to overcome disadvantages of the current system and to give analysts freedom of choice, an alternative approach was proposed - to define criteria and to choose methods which met criteria instead of specifying individual methods. The Committee noted that in the new approach Types I and IV would remain as at present whereas Types II and III would be converted into criteria.

13. The majority of delegations were in favour of this new approach. Nonetheless, several delegations foresaw the enormity of the task to convert these methods into criteria, including selection of criteria. Some delegations preferred to include other criteria such as "accuracy" ("trueness" or "bias"). It was pointed out that some criteria for selecting methods had already been adopted by the Commission⁶.

14. It was stressed that the methods which met criteria should be collaboratively studied and validated according to the protocol on inter-laboratory studies. Some delegations noted that an external standard, such as Horwitz curve, should be applied. The Delegation of Hungary stated that sample preparation be taken into consideration in addition to measurement of analytes.

15. The Delegation of the USA pointed out some discrepancies in Appendices I and II. The Delegation of the UK responded that these problems represent limitations of the current system of selecting methods.

16. The Delegation of the USA stated while it could accept this new approach for Type III methods, it was strongly opposed to the application of this approach to Type II methods. In the case of disputes, only one method should be chosen (current Type II methods) and used by all parties involved, especially when a dispute becomes a legal or administrative issue. It was stressed that the Committee should retain the prerogative to determine Type II methods.

17. The Committee agreed to recommendation 1⁷, to accept the approach in principle. The Committee also agreed to proceed along the line set out in the other recommendations with the understanding that there should be a clear indication that the problems related to TypeII/TypeIII

⁵ CX/MAS 95/3

Comment papers (USA, IDF & IUPAC)

⁶ "Recommendations for a Checklist of Information Required to Evaluate Methods of Analysis Submitted to the Codex Committee on Methods of Analysis and Sampling for Endorsement", *Codex Alimentarius*, Second Edition, Volume 13, pp. 129, and "Methods of Analysis Submitted for Endorsement by the Codex Committee on Methods of Analysis and Sampling: Precision Criteria", ALINORM 93/23, Appendix III.

⁷ Page 5, CX/MAS 95/3

classification were deliberately not dealt with. The Committee agreed to separate recommendation 3 into two i.e. new 3 and 4. The recommendations are cited below:

1. Accept the criteria approach in principle;
2. Draw up detailed working guidelines for the operation of the criteria approach by CCMAS. This would include the definitions and selection of the criteria to be used;
3. Clarify the procedures to be used in the 'dispute situation'; and
4. Emphasise that procedures are to be used to ensure that laboratories are 'in control' and operating proficiently in all cases.

18. The Committee requested the Delegations of the United Kingdom and Canada in collaboration with the Codex Secretariat to prepare a paper on working procedures for the new approach in horizontal manner, using Codex General Methods for Contaminants as examples, for consideration by the Committee at its next session and by its *ad hoc* Working Group on Endorsement. The Committee invited other delegations to make contribution.

DEVELOPMENT OF OBJECTIVE CRITERIA FOR ASSESSING THE COMPETENCE OF TESTING LABORATORIES INVOLVED IN THE OFFICIAL IMPORT AND EXPORT CONTROL OF FOODS⁸ (Agenda Item 6)

19. The document was prepared and introduced by the Delegation of Finland. It was emphasized that ISO/IEC Guide 25:1990 should form the basis of objective criteria for assessing the competence of testing laboratories involved in the import and export control of foods. In addition, such laboratories should participate in proficiency testing, and use validated methods. Some delegations preferred the deletion of the word "official" from the title of the text, while others preferred that testing laboratories remained within the framework of official control. The Committee agreed to include the word "official" in the title of the text. Some delegations stated that the reference to ISO/IEC Guide 25:1990 was sufficient and there was no need to refer to proficiency testing. However, it was pointed out that ISO/IEC Guide 25:1990 did not specifically address participation in proficiency testing in the field of food analysis, which is required to demonstrate competence in this field.

20. The Committee agreed to provide more general wording instead of referring to "third party" in the text and to include mailing addresses for each reference cited.

21. The Committee agreed that the following quality criteria be adopted by laboratories involved in the official import and export control of foods:

- Comply with the general criteria for testing laboratories laid down in ISO/IEC Guide 25:1990 "General requirements for the competence of calibration and testing laboratories"⁹,
- Participate in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in "The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories", *Pure & Appl. Chem.* 65 (1993) 2132-2144

⁸ CX/MAS 95/4.

Comment papers (USA, IDF & IUPAC)

⁹ Currently under revision.

(as adopted for Codex purposes by the Codex Alimentarius Commission at its 21st Session in July 1995);

- Whenever available, use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission; and
- Use internal quality control procedures, such as those described in the "Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories", *Pure & Appl. Chem.* 67 (1995) 649-666¹⁰.

22. The Committee noted that compliance with the criteria mentioned for laboratories involved in the official import and export control of foods needed to be assessed by suitable mechanisms. The bodies assessing the laboratories should comply with the general criteria for laboratory accreditation, such as those laid down in ISO/IEC Guide 58:1993, "Calibration and testing laboratory accreditation systems - General requirements for operation and recognition".

23. It was agreed that the paper be revised, based on the comments and recommendations made during the session. Noting the work currently carried out by the Codex Committee on Food Import and Export Certification and Inspection Systems in the area of import and export control in general, the Committee also agreed that the revised paper should be referred to the Codex Committee on Food Import and Export Certification and Inspection Systems for its consideration, review and comments.

PROGRESS REPORT ON THE DEVELOPMENT OF AN IUPAC/ISO/AOAC HARMONIZED PROTOCOL FOR RECOVERY FACTORS¹¹ (Agenda Item 7)

24. The paper was prepared and presented by the Delegation of the United Kingdom. The Committee was informed that the paper was comprised of a collection of informal discussions by analysts on the issue of recovery factors. The application of recovery factors was of particular interest especially where the difference between a corrected and uncorrected result affects a product's compliance with a specification provision.

25. The Committee noted that the Inter-Divisional Working Party of IUPAC was preparing questionnaires requesting information on the status of applying recovery factors. The Delegation of the United Kingdom requested that other delegations provide it comments concerning this initiative of IUPAC. It was noted that results of the survey would be the basis for an ISO/IUPAC/AOAC symposium, organized by AOAC International to be held during its annual meeting in Orlando, Florida. The Committee was informed that the protocol on recovery factors to be developed from the conclusions of the symposium might be published in 1998.

26. Many delegations felt the use of recovery factors to be an important topic. The Committee was informed that the paper did not address the factor of propagation of errors when using recovery factors. It was pointed out that some methods, such as those for residues of veterinary drugs and pesticides did not require correction for recovery. Recoveries had already been considered in setting up the maximum residue limit for the veterinary drug or pesticide as appropriate. It was also pointed out that it was necessary to know the nature of the analyte, whether it was free or non-free.

¹⁰ Being recommended to the Commission for adoption (see para. 40).

¹¹ CX/MAS 95/5
Comment papers (IDF & IUPAC)

27. The Committee indicated its interest in the work on the use of recovery factors being undertaken by IUPAC. The Committee requested to be kept informed by IUPAC of the progress being made on the development of an IUPAC/ISO/AOAC Harmonized Protocol for the Use of Recovery Factors. In the future, the Committee might recommend the document to the Commission for adoption by reference for Codex purposes when the protocol was published by IUPAC.

DEVELOPMENT OF UNIFORM CRITERIA FOR THE REPORTING OF TEST RESULTS ESPECIALLY WHEN THE PROVISION OR SPECIFICATION TO BE TESTED IS NOT IDENTICAL TO THE ANALYTE¹² (Agenda Item 8)

28. The Committee noted that the Commission at its 21st Session approved the initiation of this work that had been proposed by the Delegation of Austria at the last Session of the Committee. The Delegation of Austria submitted its comments and draft guidelines for reporting analytical results at the Session which contained sections on: name of the parameter; additional information; value and unit; and limit of detection or limit of determination/quantification (in relation to negative results). The Delegation proposed to elaborate the guidelines. The Committee noted that the IUPAC was currently investigating how to report low level results including negative signals and matters related to values and units.

29. It was felt that there were no significant problems for this Committee and therefore, no need to draw up guidelines. If there were problems, Commodity Committees were in better position than this Committee to identify them and they could solve the problems by modifying the specifications in the standards or request guidance from this Committee. When a provision or specification to be tested was not identical to the analyte, how to express the analytical results should be clearly stated in the standard in order to avoid the problem.

30. The Committee agreed to request Commodity Committees to identify how extensive the problem of indirect determinations was in Codex Standards. Based on responses from the Commodity Committees, the Codex Committee on Methods of Analysis and Sampling might consider elaborating guidance to these Commodity Committees, such as guidelines and appropriate factors. If there were no problems identified, the Committee should seek approval of the Commission to discontinue work in this area.

HARMONIZATION OF ANALYTICAL TERMINOLOGY IN ACCORDANCE WITH INTERNATIONAL STANDARDS (Agenda item 9)

31. The Committee considered the paper prepared by AOAC INTERNATIONAL at the request of the Codex Secretariat. The paper provided a bibliography to assist the Committee in the harmonization of analytical terminology¹³, and also made recommendations on how to progress.

32. While the Committee recognized the usefulness of such a harmonized document, it was also noted that other bodies had abandoned the idea because of the enormity of the task.

33. The Committee therefore agreed to limit the scope of the work involved to defining a small number of terms specifically related to the work of the Committee. The Committee considered that those terms as contained in the Codex Alimentarius Procedural Manual, and the harmonized protocols adopted by the Commission should be ones to be defined. The Committee accepted the

¹² CX/MAS 95/6
Comment paper (Austria)

¹³ CX/MAS 95/7

recommendations made in the paper. The Delegations of the United States and Finland accepted the Committee's request to undertake the assignment and AOAC, ISO and IUPAC were requested to collaborate with them.

34. The Committee agreed to the proposal that the Delegations of USA and Finland in collaboration with AOAC INTERNATIONAL, ISO and IUPAC would, during the Session, provide core terms of direct relevance to the work of Codex, for inclusion in the report. Before the next session, the terms would be defined and circulated to governments and interested International Organizations. Based on the comments received, a revised paper would be prepared for consideration at its 21st Session and the IAM at its 12th meeting.

35. The Committee considered the list prepared, as requested above, and provided comments which were utilized in producing the revised tentative list below:

**TERMS PERTINENT TO THE CODEX COMMITTEE ON METHODS OF
ANALYSIS AND SAMPLING WHICH NEED TO BE DEFINED**

- Terms included in the Procedural Manual of the Codex Alimentarius Commission
- Terms included in the harmonized protocols
 - for method-performance studies,
 - for proficiency testing schemes, and
 - for internal quality control

The Term Final Value

Uncertainty (Reliability) Terms

- Accuracy (recovery)
 - error of single value
 - trueness
 - bias
- Precision (extremes)
 - repeatability (intermediate)
 - reproducibility

Method Characteristics Terms

- applicability?
- specificity
- sensitivity
- ruggedness (validation)
- limits
 - provision
 - decision
 - quantitation

Interlaboratory Studies Terms

- Method-performance Studies (validation of methods, outliers, invalid data)
- Laboratory-performance (Proficiency) Studies
- Material-performance Studies (including various kinds of reference materials)

Terms Related to Method Types (I - IV)

36. The Chairman thanked the Representative of AOAC INTERNATIONAL for the paper and also recognized the initiative of the Delegations of the United States and Finland.

PROGRESS REPORT ON THE DEVELOPMENT OF THE IUPAC/ISO/AOAC HARMONIZED PROTOCOL FOR THE QUALITY CONTROL OF (CHEMICAL) ANALYTICAL DATA¹⁴ (Agenda Item 10)

37. The Committee noted that at its 19th Session it had had for discussion the IUPAC/ISO/AOAC Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories. As it had been informed that the harmonized guidelines had been planned to be further considered by IUPAC in May 1994, the Committee had agreed that after a revised document was adopted by IUPAC, the Committee should consider the document with a view towards adopting it for Codex purposes.

38. The Committee was informed that IUPAC had adopted and published the finalized harmonized guidelines. Currently ISO and AOAC were reviewing the document with the goal of harmonization with IUPAC. The Delegation of the United Kingdom stated that the harmonized guidelines was the third of such documents that were elaborated by the IUPAC's Inter-divisional Working Party, the first two having been already adopted by the Codex Alimentarius Commission. The Delegation stressed that the document was intended to be of an advisory nature as opposed to a mandatory nature of protocol.

39. The Delegation of Sweden suggested that it was sufficient to include the harmonized guidelines into the recommendations made to the Codex Committee on Food Import and Export Certification and Inspection Systems on development of objective criteria for assessing the competence of testing laboratories involved in the import and export control of foods (see para. 23). However, the majority of delegations preferred formal adoption by the Commission so that there would be guidance on internal quality control procedures available to Codex.

Status of the Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories

40. Recognising the advisory nature of the document, the Committee recommended the Harmonized Guidelines¹⁵, to the Commission for adoption for Codex purposes.

REPORT OF THE ELEVENTH MEETING OF INTERNATIONAL ORGANIZATIONS WORKING IN THE FIELD OF METHODS OF ANALYSIS AND SAMPLING (INTER-AGENCY MEETING), AND PROGRESS REPORT ON REVIEW OF STANDARD METHODS BY INTERNATIONAL ORGANIZATIONS (Agenda Item 11)

(i) INTER-AGENCY MEETING

41. The Report was presented by Mr. K.-G. Lingner (ISO), Secretary of the Inter-Agency Meeting (IAM). The IAM was attended by representatives of 11 international organizations (AOAC, CAC, CEN, EOQ, ICC, ICUMSA, IDF, ISO, IUPAC, NMKL and OIV) and was chaired by Mr. G. Castan (ISO).

¹⁴ CX/MAS 95/8

Comment paper (IDF)

¹⁵ Appendix II of this Report

42. The IAM had considered matters of interest to Codex Committee on Methods of Analysis and Sampling, such as:

- international collaboration in the field of standard methods of analysis and sampling;
- methods of analysis and sampling required by the Codex Alimentarius Commission;
- proprietary laboratory techniques;
- ownership rights for methods and copyrights; and
- publication *in extenso* of a compendium of methods approved by the Codex Alimentarius Commission.

43. As a result of its discussions, the IAM approved the following recommendations:

- that a summary of the IAM proceedings be included in the body of the Report of the Twentieth Session of Codex Committee on Methods of Analysis and Sampling;
- that the subject of quality assurance in food analysis be included in the agenda of the next IAM;
- that the document concerning proprietary laboratory techniques prepared by AOAC INTERNATIONAL be re-circulated and that all organizations participating in the IAM be invited to submit comments and information on their respective policies and practices to the IAM Secretariat;
- that the IAM Secretariat be requested to re-circulate a survey of member agencies of their procedures and practices concerning ownership rights (copyrights), including bilateral and multilateral agreements existing in the various organizations and that a first draft Code of Good Practice be prepared by AOAC INTERNATIONAL for consideration at the next IAM. Also, that organizations participating in the IAM be invited to consider the content and utility of such a Code of Good Practice in order to decide at the next IAM whether or not work on such a Code of Good Practice should be continued;
- that the IAM Secretariat be requested to inquire amongst the organizations participating in the IAM whether there is a preliminary interest participating in a comprehensive publication of a compendium of analytical methods of the Codex Alimentarius Commission;
- that the IAM Secretariat be requested to seek comments and prepare a review paper concerning the tasks, utility and future directions of the IAM for consideration at the next IAM; and
- that the IAM, noting the decision by ISO to relinquish the IAM Secretariat, requests CCMAS to recognise the re-assignment of the IAM Secretariat to AOAC INTERNATIONAL and that possible amendments to the Terms of Reference to be proposed by the IAM be considered at the next session of the Committee.

44. Several delegations, including international organizations were concerned that the report of the IAM would not be appended to the report of the Committee. As the report of the Committee would be widely distributed, the results of the work of the IAM, when appended to the report, would be available to other interested parties, which could not attend either the IAM or session of the Committee to listen to an oral report.

45. The Committee was informed that due to budgetary constraint, the Secretariat had to reduce its expenditure on publications. Not appending the full report of the IAM to the report of the Session was only one of the methods being taken by the Secretariat to reduce overall cost of publications. This action should not be seen as a reflection on the status of the IAM in the work of the Committee, rather the presence of the Codex Secretariat at the IAM should be seen as a fulfilment of the requirement of

the Commission that the CCMAS should maintain the closest possible relationship with all interested organizations working on methods of analysis and sampling.¹⁶

46. The Chairman said that the Host Government would be prepared to reproduce and circulate the Report of the IAM. Reflecting the views of the Committee, the Chairman said that he considered the IAM an integral part of the Committee and he would suggest that the Executive Committee discuss the importance of IAM at its next session.

47. The Committee noted the report of the Inter-Agency Meeting and expressed its appreciation for the assistance the IAM was providing to it.

(II) PROGRESS REPORT ON REVIEW OF STANDARD METHODS BY INTERNATIONAL ORGANIZATIONS ON METHODS OF ANALYSIS AND SAMPLING

48. The Committee also noted the progress¹⁷ report by the Delegation of the United Kingdom on review of standard methods by international organizations on methods of analysis and sampling. Some delegations made useful suggestions to improve on the information provided in the report.

49. The Committee was informed by the Delegation of the United Kingdom that the updated report would be available as an information paper at the next meeting of the IAM and the Session of the Committee.

50. The Committee expressed its appreciation and requested the Delegation of the United Kingdom to continue the preparation of the report.

ENDORSEMENT OF METHODS OF ANALYSIS IN CODEX STANDARDS¹⁸ (Agenda Item 12)

51. A report of the *ad hoc* Working Group on Endorsement was introduced by its chairman, Dr. W. Horwitz (USA). Dr. G. Diachenko (USA) served as rapporteur. The following Member Countries and International Organizations had been represented: Canada, Finland, France, Hungary, The Netherlands, Slovakia, Thailand, the United Kingdom, the United States, AOAC, IDF, ISO, IUPAC and OIV. The Group had considered: (i) Type of Codex General Methods for Contaminants adopted by the Commission at its 21st Session; (ii) Codex Methods of Analysis and Sampling (CAC/RMs); and (iii) Methods of Analysis for Commodity Standards (except those for sugars, fats and oils¹⁹).

52. Concerning Codex Methods of Analysis and Sampling (CAC/RMs), it was recommended that the Commodity Committees be advised to consider replacing some of the methods with more modern ones as appropriate and replace the CAC/RM numbers with the original literature references, if possible. The Committee agreed to recommend to the Commission the deletion of the CAC/RM numbering system. International organizations whose methods were contained in the list of CAC/RMs were invited to review their methods and to communicate any proposed updated reference citations to the Codex Secretariat as AOAC and ICUMSA had done.

¹⁶ Codex Alimentarius Procedural Manual, Eighth Edition, Page 108

¹⁷ Conference Room Document 3

¹⁸ CX/MAS 95/9, CX/MAS 95/9-Add. 1, and Conference Room Document 1.

¹⁹ See Appendix IV Notes.

53. The following remarks were made and agreed during the discussions on Codex General Methods and methods for Commodity Standards:

- (a) The method for iron in edible oils and fats (IUPAC (1988) 1st Suppl. 2.631, AOAC 990.05) should be classified as Type II;
- (b) The term "except edible oils and fats" should be added to the other method for iron (NMKL No. 139, 1991);
- (c) The reference to *Pure and Applied Chemistry* should be changed to IUPAC 7th Ed. (1988) 1st Suppl. for methods used for oils and fats;
- (d) ISO 8294:1994 (for Cu, Fe, Ni in edible oils) should be added in the list as it was equivalent to AOAC 990.05 and ISO 12193:1944 (for Pb in edible oils and fats) as it was equivalent to AOAC 994.02;
- (e) As the Guideline Level for aflatoxin in peanuts intended for further processing was currently at Step 6, it should be so indicated in the "provision" column; and
- (f) Literature references should be included in notes where other method(s) was (were) referred to in the text.

54. The Codex General Methods for Contaminants along with their assigned Types and the methods for Commodity Standards considered are attached as Part I and Part II, respectively, of Appendix IV, together with detailed notes for some of the methods.

55. The Committee agreed to set up a new *ad hoc* Working Group under the chairmanship of the Delegation of the USA at its next session.

REVIEW OF METHODS OF ANALYSIS USING OZONE-DEPLETING SUBSTANCES (Agenda item 12a)

56. The Committee had for discussion the document²⁰ prepared by the Representative of AOAC INTERNATIONAL as a result of discussions²¹ held at the 19th Session of the Committee.

57. The Committee was informed by the Representative of AOAC that, under the Montreal Protocol of Substances that Deplete the Ozone Layer, production and supply of halogenated hydrocarbons would be phased out. It was pointed out that there were methods of analysis including those already endorsed by the Commission which use halogenated hydrocarbons, such as chlorofluorocarbons and carbon tetrachloride. When these solvents are phased out, there would be a need for other solvents to replace the ozone depleting solvents. This might affect the status of the method and replacing a solvent may cause a need for the re-validation of such a method.

58. The Representative of IDF informed the Committee that a change in solvent in methods developed by its organization would not require re-numbering of the method. The Representative of ISO said that if the principle of the method is unchanged re-numbering was unnecessary. The Representative of AOAC said that replacement of a solvent that affected method performance necessitated a re-evaluation of the method and hence a new number.

²⁰ CX/MAS 95/10

²¹ ALINORM 95/23, para 79

59. The Delegation of Canada said that as the criteria approach was recommended, any method which met the criteria could be used. Furthermore a criterion prohibiting the use of ozone-depleting substances should be considered. The delegation further proposed that it could be included in the criteria that any Type III method using ozone-depleting substances might be withdrawn.

60. The Delegation of Hungary suggested the investigation of certain methods using micro-volumes of ozone-depleting substances in order to minimize their adverse effect to the environment.

61. The Committee requested that international organizations working in the field of analysis and sampling identify methods elaborated by them which had been endorsed by the Commission and which use ozone-depleting substances. This information should be communicated to the Codex Secretariat, which should present the identified methods to the *ad hoc* Working Group on Endorsement, based on the information received.

62. The Codex Committee on Methods of Analysis and Sampling would urge the Commodity Committees to avoid selecting methods of analysis which use ozone-depleting substances.

OTHER BUSINESS AND FUTURE WORK (Agenda item 13)

(I) OTHER BUSINESS

63. The Committee was informed that the Codex Committee on Milk and Milk Products at its First Session in 1994 decided that in the future it would be appropriate to seek the endorsement of methods of analysis for milk products by the Codex Committee on Methods of Analysis and Sampling (ALINORM 95/11, para. 29). The Executive Committee at its 42nd Session recommended that the Commission make the appropriate changes to the Terms of Reference of the Codex Committee on Methods of Analysis and Sampling to enable it to consider methods of analysis proposed by the Codex Committee on Milk and Milk Products (ALINORM 95/4, para. 37).

64. On the basis of the above recommendations the Committee agreed to recommend that the Commission amend its Terms of Reference as indicated in Appendix III.

(II) FUTURE WORK

65. The Committee agreed to continue work on the following items:

- Proposed Draft Codex General Guidelines on Sampling;
- Criteria for evaluating acceptable methods of analysis for Codex purposes;
- Development of objective criteria for assessing the competence of testing laboratories involved in the official import and export control of food;
- Harmonization of reporting of test results corrected for recovery factors;
- Harmonization of analytical terminology in accordance with international standards;
- Report of the IAM on methods of analysis; and
- Endorsement of methods of analysis for Codex purposes.

66. The Committee agreed to propose that the following new work be undertaken by the Commission:

- Review of methods of analysis using ozone-depleting substances (See paras. 56-62); and

– Measurement uncertainty.

This new work was proposed by the Delegation of the United Kingdom, who expressed concern that a number of international organizations and accreditation agencies were developing recommendations and requirements regarding measurement uncertainty which were at variance with present practice of the Committee on Methods of Analysis and Sampling. Other delegations requested that consideration of such recommendations and requirements be addressed by the Committee.

67. Several delegations were desirous that the Commission consider further amendment(s) to the Committee's Terms of Reference to enable it undertake other related work, such as endorsement of microbiological methods to assess safety of food and the development of methods of analysis for the detection of foods produced by biotechnology.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 14)

68. The Committee was informed that its 21st Session was tentatively scheduled to be held in Budapest in the 4th week of March 1997, the exact dates will be determined by the Hungarian and the Codex Secretariats.

SUMMARY STATUS OF WORK

SUBJECT	ACTION TO BE TAKEN BY	DOCUMENT REFERENCE ALINORM 97/23
Adoption of the IUPAC/ISO/AOAC Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories	22 nd Session CAC	para. 40 & Appendix II
Amendment to the Committee's Terms of Reference	22 nd Session CAC	para. 64 & Appendix III
Proposed Draft Codex General Guidelines on Sampling (At Step 3 of the Procedure)	Codex Secretariat, Governments, CCRVDF, CCFH & 21 st Session CCMAS	paras. 10 & 11
Review of Methods of Analysis using Ozone-Depleting Substances	43 rd Session Executive Committee, International Organizations, 21 st Session CCMAS	paras. 61,62 & 66
Measurement Uncertainty	43 rd Session Executive Committee, 21 st CCMAS, UK	para. 66
Criteria for Evaluating acceptable Methods of Analysis for Codex purposes	UK & Canada Codex Secretariat 21 st Session CCMAS	para. 18
Development of Objective Criteria for Assessing the Competence of Testing Laboratories involved in the Official Import and Export Control of Foods	Finland, CCFICS & 21 st Session CCMAS	paras. 22 & 23
Report on the Development of an IUPAC/ISO/AOAC Harmonized Protocol for Recovery Factors	IUPAC 21 st session CCMAS	para. 27
Endorsement of Codex Methods and their Classification	21 st Session CCMAS	para. 55
Harmonization of Analytical Terminology in accordance with International Standards	USA, Finland, AOAC, ISO, IUPAC, Codex Secretariat, Governments & 21 st Session CCMAS	para. 34

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**RECOMMENDED HARMONIZED GUIDELINES FOR INTERNAL QUALITY
CONTROL
IN ANALYTICAL CHEMISTRY LABORATORIES
(At Step 8 of the Procedure)**

The following document is recommended for adoption for Codex purposes by the 22nd Session of the Commission.

Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories
(Pure and Appl. Chem., Vol. 67, No. 4, pp. 649-666, 1995).

**AMENDMENT OF THE TERMS OF REFERENCE OF THE
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**
(Submitted to the Commission for adoption)¹

Amend paragraph (d) of the Terms of Reference of the Committee (*Codex Alimentarius Procedural Manual*, Eighth Edition, page 133) as follows (struck-out text to be deleted and italicized text to be inserted):

- (d) to consider, amend, if necessary, and endorse, as appropriate, methods of analysis and sampling proposed by Codex (Commodity) Committees, except that methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of microbiological quality and safety in food, *and* the assessment of specifications for food additives, ~~and those methods elaborated by the Codex Committee on Milk and Milk Products,~~ do not fall within the terms of reference of this Committee.

¹ ALINORM 95/4, para. 37.

**LIST OF METHODS OF ANALYSIS CONSIDERED
BY THE TWENTIETH SESSION OF THE CODEX COMMITTEE ON METHOD OF
ANALYSIS AND SAMPLING**

Part I: Codex General Methods for Contaminants

Part II: Methods of Analysis for Commodity Standards

Notes on Parts I and II.

PART I - CODEX GENERAL METHODS FOR CONTAMINANTS

PROVISION	METHOD	PRINCIPLE	TYPE
Cadmium	AOAC 982.23	Anodic stripping voltammetry	III
Cadmium	NMKL No. 139, 1991	Atomic absorption spectrometry	III
Chromium	NMKL No. 139, 1991	Atomic absorption spectrometry	II
Copper (in edible oils and fats)	IUPAC 7th ed. (1988) 1st Suppl. 2.631 AOAC 990.05 ISO 8294:1994	Direct graphite furnace atomic absorption spectrometry	II
Iron (in edible oils and fats)	IUPAC 7th ed. (1988) 1st Suppl. 2.631 AOAC 990.05 ISO 8294:1994	Direct graphite furnace atomic absorption spectrometry	II
Iron (except in edible oils and fats)	NMKL No. 139, 1991	Atomic absorption spectrometry	II
Lead	AOAC 982.23	Anodic stripping voltammetry	III
Lead (in edible oils and fats)	IUPAC 7th ed. (1988) 1st Suppl. 2.632 AOAC 994.02 ISO 12193:1994	Direct graphite furnace atomic absorption spectrometry	II
Lead	NMKL No. 139, 1991	Atomic absorption spectrometry	III
Nickel (in edible oils and fats)	IUPAC 7th ed. (1988) 1st Suppl. 2.631 AOAC 990.05 ISO 8294:1994	Direct graphite furnace atomic absorption spectrometry	II
Tin (in canned foods)	AOAC 985.16	Atomic absorption spectrometry	III
Zinc	NMKL No. 139, 1991	Atomic absorption spectrometry	III

PART II - METHODS OF ANALYSIS FOR COMMODITY STANDARDS

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Serial No.	Commodity Standard No.	Provision	Method	Principle	Type	Status
249	Special foods 980	Copper, manganese, zinc, magnesium, iron Cu: >60 mg, Mn: >5 µg, Zn: >0.5 mg, Mg: >6 mg and Fe: >0.15 mg/100 kcal	AOAC 984.27	ICP emission spectrometry		NE
251	Foods with low-sodium content (including salt substitutes) 053-1981	Sodium and potassium Na: < 120 mg/100 g, K: No limit	AOAC 984.27	ICP emission spectrometry		NE
252	Foods with low-sodium content (including salt substitutes) 053-1981	Calcium and magnesium Mg: < 20 % of sum of potassium, calcium, ammonium cations	AOAC 965.09	Atomic absorption spectrophotometry		NE
253	Foods with low-sodium content (including salt substitutes) 053-1981	Ammonium < 3 % (m/m)	AOAC 920.03	Magnesium oxide		NE
254	Foods with low-sodium content (including salt substitutes) 053-1981	Phosphorous < 4 % (m/m)	AOAC 984.27	ICP emission spectrometry		NE
580	Guidelines for nutrition labelling CAC/GL 2-1985	Polyunsaturated fat	AOCS Ce 1c-89	Gas liquid chromatography	IV	TE
581	Guidelines for nutrition labelling CAC/GL 2-1985	saturated fat	AOCS Ce 1c-89	Gas liquid chromatography	IV	TE
634	Quick frozen fish sticks (fish fingers) Fish portions & fish fillets - breaded or in batter 166-1989	Histamine 10 mg/100 g	AOAC 977.13	Fluorimetry	II	E
635	Infant formula and follow-up formula 72-1981 & 156-1987	Total dietary fibre	J. Publ. Analysts (1993) 29 (2)	Englyst method		NE

PART II - METHODS OF ANALYSIS FOR COMMODITY STANDARDS

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Serial No.	Commodity Standard No.	Provision	Method	Principle	Type	Status
636	Quick frozen fish sticks (Fish fingers) Fish portions & fish fillets - breaded or in Batter 166-1989	Fish core	AOAC 971.13	Immersion and weighing	I	E
637	Milk	Aflatoxin M1 0.05 µg/kg	IDF STD. 171:1995	Immunoaffinity column & LC	II	E
638	Milk & dried milk A-5 (milk powder)	Aflatoxin M1 0.05 µg/kg	IDF Std. 111A:1990	TLC/LC		NE
639	Fluid milk	Aflatoxin M1 0.05 µg/kg	AOAC 986.16	HPLC		NE
640	Peanuts (intended for further processing)	Aflatoxin, total 15 µg/kg (Step 6)	AOAC 975.36	Romer mini colmn	III	E
641	Peanuts (intended for further processing)	Aflatoxin, total 15 µg/kg (Step 6)	AOAC 979.18	Holaday-Velasco mini column	III	E
642	Corn	Aflatoxin, total	AOAC 979.18	Holaday-Velasco mini column	II	E
643	Peanuts	Aflatoxin, total 15 µg/kg (Step 6)	AOAC 990.34	ELISA		NE
644	Peanuts & peanut products	Aflatoxin, total 15 µg/kg (Step 6)	AOAC 968.22	CB Method		NE
645	Peanuts & peanut products	Aflatoxin, total 15 µg/kg (Step 6)	AOAC 970.45	BF method		NE
646	Peanuts (Raw)	Aflatoxin, total 15 µg/kg (Step 6)	AOAC 993.17	TLC	III	E
647	Peanuts (Raw)	Aflatoxin, total 15 µg/kg (Step 6)	AOAC 991.31	Immunoaffinity column (Aflatest)	II	E

PART II - METHODS OF ANALYSIS FOR COMMODITY STANDARDS

Serial No.	Commodity Standard No.	Provision	Method	Principle	Type	Status
648	Corn	Aflatoxin, total	AOAC 990.34	ELISA		NE
649	Cotton Seed	Aflatoxin, total	AOAC 990.34	ELISA		NE

NOTES

Part I Codex General Methods for Contaminants

Cadmium: The WG considered that there was already a Type II Codex general method for Cadmium and so classified the two new methods (AOAC 982.23 and NMKL 139) as Type III.

Copper: This method (AOAC 990.05) had already been classified as Type II for fats and oils. It was recommended that the Codex Committee on Methods of Analysis and Sampling agreed to change the colorimetric method (AOAC 960.40), which had been classified as Type II for fats and oils to Type III, in order to avoid having more than one Type II method for fats and oils. The Committee noted that ISO 8294:1994 is identical to the IUPAC method. It was also proposed that the appropriate IUPAC numbering be used for references to IUPAC methods.

Iron: The WG recommended that the IUPAC method and AOAC 990.05 be classified as Type II for fats and oils and the Atomic absorption method (NMKL No. 139), be classified as Type II.

Lead: The IUPAC method had already been classified as Type II for fats and oils. The WG noted that AOAC 994.02 and ISO 12193:1994 were equivalent methods. It was also observed that there was already in place a colorimetric dithizone method (AOAC 934.07) for lead in fats and oils. The WG therefore proposed that the Committee on Fats and Oils should consider deleting the method because the method is not sensitive enough to detect lead at the specification level. If however, the Commodity Committee would rather retain the method, it should be classified as Type III.

Nickel: The IUPAC method and AOAC 990.05 were recommended as Type II for fats and oils.

Tin: The method (AOAC 985.16) had previously been classified as Type III for a canned food, therefore the WG retained this classification.

Zinc: The method (NML No. 139) was classified as Type III.

Part II Methods of Analysis for Commodity Standards

The following comments were made:

66-128, 689-861 The methods for Sugars and Fats and Oils respectively, were not considered because the respective Commodity Committees were in the process of considering comments to circular letters which were circulated. The Working Group therefore recommended that consideration of these methods be suspended, pending the results of the actions taken by the respective Commodity Committees. The Working Group urged the Codex Committee on Methods of Analysis and Sampling to request its members to provide comments on CL 1995/22-FO directly to the Codex Committee on Fats and Oils.

138 The Secretariat was requested to contact the secretariat of AIIBP to obtain the necessary information, regarding the applicability of the method.

249, 251-254 It was noted that these methods have not been collaboratively studied for these commodities which contain salt substitutes and that there were no methods applicable to these matrices that meet the criteria of the Codex Committee on Methods of Analysis and Sampling. In view of this,

the WG recommended the withdrawal of the temporary endorsement earlier granted to the reference methods and their deletion from being considered for endorsement.

353, 354, 475 & 489 The temporary endorsements were retained. The Secretariat was requested to bring the status and previous concerns of the Codex Committee on Methods of Analysis and Sampling to the attention of the Codex Committee on Natural Mineral Water.

435 & 503: The WG recommended that the Secretariat of the Codex Committee on Cereals, Pulses and Legumes be contacted to consider the comments earlier made and request their recommendations or concurrence with the proposals of the WG. If action was not taken the WG would recommend the withdrawal of the temporary endorsement.

509: Same recommendation as for 435 & 503, except that the Secretariat should contact the Codex Committee on Processed Fruits and Vegetables.

580 & 581 The WG temporarily endorsed these methods as Type IV and requested the Secretariat to contact the American Oil Chemists Society for method validation information which if available and found to be satisfactory, would enable the WG to recommend full endorsement.

635 The WG observed that there was already a Type I method (AOAC 991.43) for the determination of dietary fibre. The request by the Delegation of the United Kingdom for the WG to consider the Englyst method was not supported because the WG observed that the method and indeed the already endorsed one, could not determine the specified level for carrageenan and there was no specification for the level of the of carry-over fiber.

638 & 639 The WG did not recommend endorsement of these methods because, the WG noted that the IDF methods could not detect down to the limits prescribed. It was noted that this information should be transmitted to the IDF/ISO/AOAC Tripartite Working Group on Methods of Analysis, which recommend methods for milk products to the Codex Alimentarius Commission through the Codex Committee on Milk and Milk Products.

640, 641, 646 & 647 The WG recommended Type III classification for all except 647 which it classified as Type II. It was also noted that CEN had specified the size of the column and the method was no longer a proprietary one.

642 Recommended for endorsement as Type II method since it can measure levels higher than 10 $\mu\text{g}/\text{kg}$ which is adequate for the guideline level.

643, 644, 645 & 648 All were not recommended for endorsement because they are not sensitive enough for analyses at the guideline levels. It was also noted that 648 was a proprietary method and one of the solvents used in 644 is chloroform - an ozone-depleting substance.

649 Cottonseed, not being for direct human consumption as food, the WG did not find this reference appropriate for consideration and so recommended its deletion.