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 97/23A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-second Session
Geneva, 23 - 28 June 1997

REPORT OF THE 21ST SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Budapest, Hungary, 10 - 14 March 1997

Note: This report incorporates Codex Circular Letter CL 1997/5-MAS.

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CX 4/50.2

CL 1997/5-MAS
March 1997

TO:
- Codex Contact Points
- Participants at the Twenty-first Session of the Codex Committee on Methods of Analysis and Sampling
- Interested International Organizations

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

SUBJECT: DISTRIBUTION OF THE REPORT OF THE TWENTY-FIRST SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (ALINORM 97/23A)

The report of the Twenty-first Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) is attached. It will be considered by the Twenty-second Session of the Codex Alimentarius Commission to be held in Geneva from 23 - 28 June 1997.

PART A: MATTERS FOR ADOPTION OR ENDORSEMENT BY THE 22ND SESSION OF THE CODEX ALIMENTARIUS COMMISSION

1. **Proposed Draft Guidelines for the Assessment of the Competence of Testing laboratories Involved in the Import and Export Control of Food** (ALINORM 97/23A, Appendix II & paras. 22-24)

Governments wishing to propose amendments or to submit comments regarding the implications which the Proposed Draft Guidelines or any provisions thereof may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Codex Standards (at Steps 5 and/or 8) (see *Codex Alimentarius Commission Procedural Manual*, Ninth Edition, pp. 28-29 and 33-35) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **not later than 15 May 1997.**

2. **Analytical Terminology for Codex Use** (ALINORM 97/23A, Appendix III & paras. 27-28)

3. **Amendments to the Terms of Reference of the Codex Committee on Methods of Analysis and Sampling** (ALINORM 97/23A, Appendix IV & para. 55)

4. **Methods of Analysis**

   (i) Methods of Analysis for Food Additives (ALINORM 97/23A, Appendix V, Part 1)
   (ii) Methods of Analysis Provisions of Codex Commodity Standards (ALINORM 97/23A, Appendix V, Parts 2-4 - methods marked with E or TE)

5. **Deletion of CAC/RM Numbering System** (ALINORM 97/23A, para. 44)

Governments wishing to propose amendments or to submit comments regarding the implications which the above matters have for their economic interests should do so in writing, in conformity with the Codex Alimentarius Commission Procedural Manual, to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome Italy, **no later than 15 May 1997.**

PART B: REQUEST FOR INFORMATION AND COMMENTS

1. Criteria for Evaluating Acceptable Methods of Analysis for Codex Purposes (ALINORM 97/23A, para. 15)

2. Measurement Uncertainty (ALINORM 97/23A, para. 37)

Member countries and interested international organizations are invited to send information on the above or comments on CX/MAS 97/3 and CX/MAS 97/7 directly to the Delegation of the United Kingdom (for address and contact numbers, see Appendix I of ALINORM 97/23A). For the item 1, the Committee agreed that information and comments should be sent as soon as possible.

3. Definitions of "Limits" (ALINORM 97/23A, paras. 26 & 28)

The Committee decided to request the Inter-Agency Meeting to recommend whether it would be appropriate to include "limits" in the selected terminology for Codex use and to elaborate their definitions. Member countries and interested international organizations are invited to send comments on the following to the IAM Secretariat, Mr. R. Christensen, Executive Director, General Counsel, AOAC International, 481 North Frederick Ave. Ste. 500, Gaithersburg, Maryland 20877-2417, USA (Fax: +1 301 924 7089) with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **no later than 31 July 1997**:

(a) Whether it is appropriate to include "limits" in the selected terminology for Codex use;
(b) Rationale for the above;
(c) If (a) is affirmative, what "limit" should be included; and
(d) Proposed definitions of the "limits" specified in (c) above, in accordance with internationally agreed definitions.

SUMMARY AND CONCLUSIONS

The Twenty-first Session of the Codex Committee on Methods of Analysis and Sampling reached the following conclusions:

MATTERS FOR CONSIDERATION BY THE COMMISSION

The Committee:

- redrafted the four criteria and a statement regarding laboratory accreditation into Proposed Draft Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food, sought approval of the elaboration of the guidelines and recommended the Commission to adopt the guidelines at Step 5 with omission of Steps 6 and 7 (paras. 22-24, Appendix II)
- decided to send the definitions of selected analytical teminology to the Commission for endorsement (para. 28, Appendix III);
- agreed to discontinue work on methods using ODS and that no further action was needed by the Committee (para. 42);
- in order to clarify its previous recommendation made at the last session to the Commission to delete the CAC/RM numbering system, provided the following information, "When the original reference is available, this reference should be included and the CAC/RM numbering system reference deleted. When the original reference is not available, the full text of the method should be included in *Codex Alimentarius* Volume 13 and the CAC/RM numbering system reference deleted." (para. 44);
- endorsed a number of methods of analysis for some food additives and contaminants and for 8 Codex commodity standards (paras. 45-47, Appendix V)
- agreed to request the Commission to adopt the corrected version of the Terms of Reference together with the amendment proposed by this Committee at its last Session (Para. 55, Appendix IV);
- agreed to propose to the Commission that new work on in-house method validation be undertaken (para. 61); and
- supported the proposal of the CCRVDF that the Commission request FAO and WHO to give consideration to convening an expert consultation on the question of methods validation for food control purposes (para. 18).

OTHER MATTERS OF INTEREST TO THE COMMISSION

The Committee:

- decided to return the Proposed Draft General Guidelines on Sampling to Step 3 for further revision by the Codex Secretariat, Australia, Austria, Canada, Czech Republic, France, Hungary, India, The Netherlands, Thailand, UK and USA in light of the decisions made at the Session (paras. 5-9);
- agreed that the paper on criteria for evaluating acceptable methods of analysis for Codex purposes be revised by Canada, France and the United Kingdom, with corrections as appropriate, for circulation to Member Countries and international organizations for comments (para. 15);
- agreed that it be kept informed of progress being made by IUPAC in the development of the Harmonized Guidelines for he Use of Recovery Factors in Analytical Measurement (para. 30);

- agreed to request a revised paper on measurement uncertainty in light of the decisions made by the Committee on this issue (paras. 36-37);
- deferred discussions on the Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts pending the developments on the Proposed Draft Guidelines on Sampling and the working procedure and selection of criteria in the criteria-based approach (para. 50);
- noted the report of the 12th Inter-Agency Meeting; and requested the Inter-Agency Meeting to recommend whether it would be appropriate to include "limits" in the selected terminology and to elaborate their definitions; and to review methods of analysis using ozone-depleting substances (paras. 28, 42 & 51-54);
- agreed to request the Codex Committee on General Principles to review items (d) and (e) of the Terms of Reference to enable this Committee to take more horizontal approach in elaborating sampling plans and to clarify the situations concerning discrepancy between these items and "assessment of microbiological quality and safety in food: (para. 56);
- agreed to recommend that the meetings of the *ad hoc* Working Group on Endorsement should continue to be utilized as an efficient means of accomplishing the important task entrusted to this Committee in the limited time frame it has for its Session (para. 57); and
- noted the request of Spanish-speaking countries to make Spanish interpretation available at future sessions (para. 59).

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REPORT OF TWENTY-FIRST SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling held its Twenty-first Session in Budapest, Hungary, from 10 - 14 March 1997, at the kind invitation of the Government of Hungary. Professor Péter Biacs, Director General of the Central Food Research Institute (KÉKI) chaired the Session. The Session was attended by 120 delegates and observers from 42 Member countries, 2 Observer countries and 8 international organizations. A complete list of participants is given in Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

2. The Session was opened by Mr. Lajos Buzássy, Deputy State Secretary of Ministry of Agriculture. He expressed the great interest of the Government of Hungary on the international harmonization of food standards and regulations because of the importance of the agricultural and food sectors in Hungary. He informed the delegations of the new Hungarian Food Law and the progress in preparation of the Hungarian Food Manual based on international regulations.

ADOPTION OF THE AGENDA (Agenda Item 2)

3. The Committee **adopted** the Provisional Agenda as presented in CX/MAS 97/1. It **agreed** to consider the following items under Agenda Item 14, Other Business and Future Work:

- Terms of Reference of the Committee;
- Coordination with other Codex Commodities; and
- Future of the *ad hoc* Working Group on Endorsement.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

4. The Committee concurred with the proposal of the Chairperson to appoint Mr. William J. Franks, Jr. (USA) as rapporteur.

PROPOSED DRAFT GENERAL GUIDELINES ON SAMPLING[1] (Agenda Item 4)

5. The Committee at its 20th Session in 1995 had agreed that the Proposed Draft Guidelines on Sampling be further revised to consist of two main parts: Part I - Discrete Lots Moving in International Trade and Part II - Control of Manufacturing Process; and that the revised document should identify its potential users[2]. The revised document had been circulated under CL 1996/38-MAS for comments. The comments submitted were considered to further improve the draft document.

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1 CL 1996/38-MAS; CX/MAS 97/2 (comments from Czech Republic, Hungary, Italy, South Africa, United Kingdom and International Dairy Federation); CX/MAS 97/2-Add. 1 (CRD 2) (comments from Canada and Denmark); CRD 7 (comments from Hungary); CRD 8 (report of the *ad hoc* Working Group); Written comments were submitted by France, the Netherlands and the USA at the Session.

2 ALINORM 97/23, paras. 8-9.

6. In introducing the revised document[3] as a member of the Codex Secretariat, Dr. Ray Coker stated that, in revising the document, materials from relevant ISO documents, i.e., ISO/TR 8550: 1994(E), ISO 2859-0:1995(E), ISO 2859-1:1989(E), ISO 2859/2:1985(E), and ISO 3951:1989(E), together with material[4] from the International Commission on Microbiological Specifications for Foods (ICMSF), were utilized and that a variety of worked examples had been included to assist in the clarification of the guidelines. Non-food examples provided in the text would be replaced with relevant ones in the food area. The Committee noted that most of the source materials were under revision.

7. The consensus opinion expressed after discussing the draft was that the document should be further revised in light of the comments made and the written comments submitted during the meeting. In order to facilitate consideration of the proposed revised text, the Committee agreed that an *ad hoc* Working Group comprising Australia, Austria, Canada, Czech Republic, France, Hungary, India, The Netherlands, Thailand, United Kingdom, the United States and the Codex Secretariat should convene outside the working hours of the Committee, to address the following issues.

- The nature of the target audience;
- The nature of the document; and
- The inclusion (or otherwise) of: (a) double, multiple and sequential sampling plans; (b) zero acceptance number sampling plans; (c) sampling from bulk material; (d) non-random sampling; (e) risk assessment issues; and (f) measurement error.

8. The Committee considered the proposals of the *ad hoc* Working Group which are summarized as follows:

- the primary target audience will be Member governments and Codex Committees;
- the guidelines should primarily address the acceptance sampling of isolated lots;
- the guidelines should include an introductory section confirming the nature of the target audience, the precise purpose of the document, and a summary of Codex Sampling Principles and their relationship with international organizations dealing with inspection;
- the standards referred to in the documents should be referenced and briefly summarized in an Appendix;
- the following items should be added:

  (a) brief introduction of double, multiple and sequential sampling plans;
  (b) brief introduction of zero acceptance number sampling plans;
  (c) sampling from bulk material (using ISO standards (ISO/WD 11648-0; ISO/CD 10725-2; ISO/CD 11648-1));
  (d) brief introduction of non-random sampling; and
  (e) all relevant figures and diagrams

- acceptance sampling plans for a continuous series of lots from a single process or source should be retained as a fully referenced, brief introduction;

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3 CL 1996/38-MAS.

4 *Microorganisms in Foods. 2. Sampling for Microbiological Analysis*, 1986, ISBN 0-632-015 67-5.

- reformulated worked examples relating to foodstuffs should be retained, utilizing existing sampling plans for food materials wherever possible;
- mention should be made of the relationship between perceived risk and sampling plan design; but an in-depth discussion of risk assessment should be avoided;
- the guidelines should be as simple and user-friendly as possible so that they can be readily understood by all participants in Codex Committees; and
- the guidelines should contain a brief introduction to the concept of measurement error, ensuring that the end-users are aware of the implications of measurement error on the efficiency of sampling plans.

9. The Committee **accepted** the proposals above and **requested** the Codex Secretariat to further revise the Proposed Draft General Guidelines on Sampling in light of the above points, with assistance provided by Australia, Austria, Canada, Czech Republic, France, Hungary, India, The Netherlands, Thailand, UK and USA. The revised guidelines should be circulated for comments well before the next session of the Committee.

Status of the Proposed Draft General Guidelines on Sampling

10. The Committee **decided** to return the Proposed Draft General Guidelines to Step 3 of the Codex Procedure for further revision and comments.

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS FOR CODEX PURPOSES[5] (Agenda Item 5)

11. The Committee at its 20th Session had agreed to: accept the criteria-based approach in principle; draw up detailed working guidelines for the operation of the criteria approach by the Committee, including the definitions and selection of the criteria to be used; clarify the procedures to be used in the dispute situation; and emphasize that procedures were to be used to ensure that laboratories are 'in control' and operating proficiently in all cases. The Committee had also agreed that there should be a clear indication that the problems related to Type II/Type III classification were not deliberately dealt with. The Committee had requested the Delegations of the United Kingdom and Canada to prepare a paper on working procedures for the new approach in horizontal manner, using Codex general methods for contaminants as examples for consideration at the current Session[6].

12. The Delegation of the United Kingdom presented the paper and stressed that this new approach was not intended to downgrade methods of analysis for Codex purposes; methods must still be collaboratively studied. In the new approach, Type I would remain the same as it was felt that the number of Type I methods submitted for endorsement would decrease and development of new Type I methods would be very limited in the future; whereas Type II/Type III methods would be converted into criteria as new proposals were submitted by Codex Committees. The Delegation introduced a set of selection criteria; assessment of the acceptability of the precision characteristics of a method; and two steps to be taken in cases of trade disputes. The examples of the conversion from methods to criteria using Codex general methods were explained. The Delegation indicated that five years experience in the UK with this approach had not cause significant problems.

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5 CX/MAS 97/3; CRD 5 (comments from IDF); written comments were submitted by Russia at the Session.

6 ALLINORM 97/23, paras. 17-18.

13. A majority of delegations welcomed and supported this approach. Several delegations proposed that "detection limit" and "determination limit" be deleted from the selection criteria as they were more related to laboratory equipment than method *per se*. Some delegations stated that the paper should specify that this approach was applicable to chemical analysis.

14. The Delegations of the United States and France stated that how to deal with trade dispute situations was not fully addressed. The Delegation of the United States stated while the "criteria"-based approach was acceptable for Type III methods, it was not for Type II methods because they were needed in cases of trade disputes. The Delegation of France offered to prepare a paper on trade dispute situations.

15. The Committee **agreed** that the paper should be revised by the Delegations of Canada, France and the United Kingdom, with corrections as appropriate, for circulation to Member Countries and international organizations for comments. Other delegations were invited to provide comments for the redrafting directly to the Delegation of the United Kingdom as soon as possible. The document would be further revised based on comments received in response to the circulated text for consideration by the Committee at its next Session. It was recognized that the terms and definitions used for criteria should be harmonized with those in the list of Analytical Terminology for Codex Use[7] (see para. 28.).

REFERRAL FROM THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF) - ESTABLISHING ROUTINE METHODS TO MEET CODEX MAXIMUM RESIDUE LIMIT REQUIREMENTS[8]

16. The CCRVDF referred to this Committee a paper on establishing routine methods to meet Codex Maximum Residue Limit requirements as it had felt that the content of the document had important implications for this Committee[9]. The CCRVDF was having difficulties selecting methods in relation to method validation by collaborative studies. The Delegation of Australia presented Appendix of CX/MAS 97/3-Add.1 explaining that in the case of veterinary drug residue analysis it was not possible to perform large scale method validations, a significant number of methods had not been collaboratively studied, and there would be more problems in the future. It was further stated that increasing use of third party laboratories would lead to problems concerning the use of proprietary methods. It was proposed that performance-based methods be utilized.

17. It was pointed out that until now this Committee had primarily dealt with compositional standards. As the levels of contaminants and residues were orders of magnitude lower than those of specifications contained in compositional standards, it was necessary to take variability into consideration and special consideration be given to sampling. It was recognized that there was a conflict between the Protocol[10], recommended by this Committee and adopted by the Commission, and practical problems in some Codex Committees. It was realized that this problem had not been considered so far by this Committee and that there might be a need to address this problem at future Sessions of the Committee.

18. The Committee **supported** the proposal of the CCRVDF that the Commission request FAO and WHO to give consideration to convening an expert consultation on the question of methods validation for food control purposes.

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7 Appendix III of this report.

8 CX/MAS 97/3-Add.1.

9 ALINORM 97/31A, para. 61.

10 *Protocol for the Design, Conduct and Interpretation of Method Performance Studies. Pure and Appl. Chem.* (1995) 67, 331-343.

19. The Delegation of the United Kingdom proposed to commence a new work item on the concept of in-house method validation based on international general guidelines. It was stated that a number of countries had already established instructions on this matter. Several delegations supported this proposal. The Delegation of the United Kingdom stated that criteria contained in Recommendation 6a of the paper would be taken into consideration in the redrafting of the paper on a "criteria"-based approach (see para. 15.). The Delegation of the United States added that variability should be included in the criteria.

DEVELOPMENT OF OBJECTIVE CRITERIA FOR ASSESSING THE COMPETENCE OF TESTING LABORATORIES INVOLVED IN THE OFFICIAL IMPORT AND EXPORT CONTROL OF FOODS[11] (Agenda Item 6)

20. The 19th Session of this Committee had considered the first draft of the paper on this issue and agreed that the paper be considered as a basis for recommendations to governments in this area. It had also agreed to request governments and interested international organizations for comments and to refer the paper to the Codex Committee on Food Import and Export Certification and Inspection Systems (CCFICS) for comments[12]. At its 20th Session the Committee had considered CX/MAS 95/4 and a major amendment made to the text was the inclusion of four criteria to be adopted by laboratories involved in the official import and export control of foods. The criteria were contained in the report of that session[13]. The Committee had agreed that the paper be revised, based on the comments and recommendations made during the session. Noting the work currently carried out by the CCFICS in the area of import and export control in general, the Committee had also agreed that a revised paper be referred to the CCFICS for its consideration, review and comments[14].

21. The CCFICS, at its 4th Session, had considered the document, subsequently revised by the Delegation of Finland, and suggested that the document be further developed by this Committee by incorporating concrete proposals in the form of Guidelines or Principles based on other international texts recognized by the Commission and being consistent with corresponding CCFICS texts and other relevant Codex texts[15].

22. The Committee **agreed** with the views expressed by the CCFICS. The Delegation of Finland presented CX/MAS 97/4 and, in collaboration with the Delegations of Australia, Sweden and the United Kingdom, redrafted the four criteria and a statement regarding laboratory accreditation in the form of Guidelines. The document was entitled "Proposed Draft Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food".

23. The Committee considered the Proposed Draft Guidelines and **agreed** to recommend the Guidelines to the Commission for adoption as a final text. Regarding omission of the word "official" from the title of the Guidelines, the Committee noted that since the document was addressed to member governments which of themselves would use official laboratories or those certified by them, it would be superfluous to retain the word "official". This view was in keeping with that held by CCFICS in a similar document[16] prepared by that Committee and submitted to the Commission for adoption at Step 8. The Committee **decided** that, for consistency and

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11 CX/MAS 97/4.

12 ALINORM 95/23, para. 75.

13 ALINORM 97/23, para. 21.

14 ALINORM 97/23, para. 23.

15 ALINORM 97/30, paras. 27-28.

16 Draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (Appendix II of ALINORM 97/30A).

harmonization between this document and the one by CCFICS, the title should remain as was presented.

Status of the Proposed Draft Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food

24. The Committee **agreed** to seek the approval of the Commission to elaborate the guidelines and, at the same time, to advance the Proposed Draft Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food[17] to the Commission for adoption at Step 5 of the Procedure with recommendations to omit Steps 6 and 7.

HARMONIZATION OF ANALYTICAL TERMINOLOGY IN ACCORDANCE WITH INTERNATIONAL STANDARDS[18] (Agenda Item 7)

25. The Committee recalled that at its last Session it had agreed on the tentative list of terms, specifically related to the work of the Committee, to be defined and requested the Delegations of Finland and the United States to undertake the preparation of a paper for circulation for comments[19]. Based on comments received on the paper[20], a revised paper, CX/MAS 97/5, was prepared.

26. In introducing the paper, the Delegation of the United States explained that the paper was prepared through the search of available literature. ISO and IUPAC definitions were essentially used with some minor modifications to make them more appropriate for food analysis laboratories. It was stated that the definitions of limits, e.g., limit of detection and limit of determination, were not included as the statement of applicability of a method would indicate if the method had the capability of providing results in the vicinity of the Codex specification. However, several delegations stated that in the case of the analysis of trace contaminants there were not so many collaboratively studied methods available, which necessitated establishing the limit of determination (quantification) by laboratories and therefore, the definitions of limits were necessary.

27. There was a general agreement that internationally agreed terms and definitions should be utilized as much as possible, and if they were applied to chemical analysis as opposed to microbiological analysis, they were acceptable to the Committee except matters related to "limits". The Committee then considered the paper term by term and **made** the following amendments:

- inserted "by the same operator" in the definition of repeatability conditions as in the original ISO definition;
- inserted "(Proficiency)" after the term "Laboratory-Performance" in the term heading; and
- inserted at the end of Note 2 of Laboratory-Performance (Proficiency) Study the following term: "provided that the test samples cover the range of concentration of the analyte".

There were other proposals made at the Session to amend the definitions of result, accuracy, bias, precision, reproducibility conditions, and applicability; and to add texts to some Notes; nonetheless

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17 Appendix II of this report.

18 CX/MAS 97/5 (Revised document and comments from Czech Republic, Denmark, Hungary, Mexico, Spain, AOAC INTERNATIONAL and IDF); CRD 6 (comments from France); written comments were submitted by Australia and Russia at the Session.

19 ALINORM 97/23, paras. 34-35.

20 CL 1996/22-MAS.

the Committee **decided** to maintain the definitions of the above and Notes as contained in the paper in order not to change existing internationally agreed definitions.

28. The Committee **decided** to send the definitions of analytical terms as amended and contained in Appendix III of this report to the Commission for endorsement. It further **decided** to request the Inter-Agency Meeting to recommend whether it would be appropriate to include "limits" in the selected terminology and to elaborate their definitions. The Delegation of the USA would provide a background information paper as well as justification to the Inter-Agency Meeting. The Delegation of the United Kingdom stated that these terms and their definitions were to be taken into consideration when revising the paper on "criteria" approach (see para. 15.).

HARMONIZATION OF REPORTING OF TEST RESULTS CORRECTED FOR RECOVERY FACTORS[21] (Agenda Item 8)

29. The Committee recalled that it had first considered the concept of recovery factors in analytical work at its 19th Session[22]. The application of recovery can be a factor in obtaining meaningful analytical results. Currently the issue was of concern because the difference between a corrected and uncorrected result could mean that a specification (i.e., a legislative limit) is exceeded or not exceeded.

30. Some delegations considered the use of recovery factors to be routine. However it was pointed out that some methods, such as those for residues of pesticides, did not require correction for recovery. Recoveries had already been considered in setting up the maximum residue limit for the pesticide. The need for recovery should be established as part of method development and validation. The method clearly needs to describe the recovery procedure as part of the method and not as a separate protocol. A few delegations stressed the need to have more time to review the document.

31. The latest revised Harmonized Guidelines for the Use of Recovery Factors in Analytical Measurement (IUPAC) were made available to the Committee and delegations were invited to comment to IUPAC which planned to have the text further revised in June 1997, in light of comments to be received, for adoption in August 1997.

32. The Committee **agreed** that it be kept informed of progress being made by IUPAC in the development of the harmonized guidelines. Once finalized by IUPAC, the Committee would then consider whether or not to recommend the harmonized guidelines for use for Codex purposes.

MEASUREMENT UNCERTAINTY[23] (Agenda Item 9)

33. The Committee recalled that this Agenda Item had been proposed at the last Session due to a concern that a number of international organizations and accreditation agencies were developing recommendations and requirements regarding measurement uncertainty which were at variance with present practices of Codex[24]. The Committee had requested the Executive Committee to approve the initiation of work of this issue, which had been subsequently granted.

34. In the presentation of the paper, the Delegation of the United Kingdom introduced the problems encountered in the country in relation to the accreditation of laboratories which required an estimation of measurement uncertainty, and the possibility that the use of the term

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21 CX/MAS 97/6.
22 ALINORM 95/23, para. 78.
23 CX/MAS 97/7.
24 ALINORM 97/23, para. 66.

"measurement uncertainty" could be misleading. The Delegation introduced an ongoing project within the UK Ministry of Agriculture, Fisheries and Food to assess the ISO measurement uncertainty approach[25] which was complicated and time-consuming. The Committee was informed that EURACHEM was attempting to utilize the measurement uncertainty approach and it would review the ISO Guide[25] in July of this year.

35. Several delegations indicated that the ISO Guide was heavily oriented toward metrology and, as a result, was either too stringent in requirements or not suitable for application in food analysis. Several delegations expressed the opinion that food analysis laboratories accredited to ISO Guide 25 should be allowed to utilize method-performance data or, if it was not available, internal quality control or method validation data to estimate measurement uncertainty.

36. The Committee therefore **agreed** to the following:

1. The Committee will develop for Codex purposes an appropriate alternative term for measurement uncertainty, e.g. measurement reliability.

2. The precision of a method may be estimated through a method-performance study, or where this information is not available, through the use of internal quality control and method validation data.

3. Consideration should be given as to whether it is necessary to undertake an additional formal evaluation of a method of analysis using the ISO approach in addition to using information attained through a collaborative trial.

4. Governments should advise accreditation agencies that for national and Codex purposes the measurement uncertainty of a result need not be calculated using the ISO approach provided the laboratory is complying with the appropriate Codex principles.

37. The Committee **agreed** to request the Delegation of the United Kingdom to redraft the paper for consideration by the Committee at its next Session. The Delegation of the United Kingdom invited contributions of other delegations.

38. The Committee was informed that ISO Guide 25 was under revision and was currently receiving public comments. It was also informed of a forthcoming meeting of International Laboratory Accreditation Conference (ILAC) in Paris in April 1997, and that the Committee's interests would be conveyed at that meeting.

REVIEW OF METHODS OF ANALYSIS USING OZONE-DEPLETING SUBSTANCES (Agenda Item 10)

39. The Committee was informed that the document[26] was a follow-up to discussions held at its 20th Session on the implications to Codex endorsed methods of the phasing out of ozone-depleting substances (ODS) and environmental considerations. Following on this, the Codex Secretariat had prepared and provided to each international organization working in the field of analysis, a list of endorsed Codex methods which had been elaborated by the organization, with the express purpose of identifying which method(s) used ODS. The replies so far obtained identified ten methods using ODS (Annex II of the paper). Annex III of the paper contained a list of methods for which the reference documents were not available to the Codex Secretariat and the concerned organizations

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25 Guide to Expression of Uncertainty in Measurement, ISO, Geneva, 1993 (ISBN 92-67-10188-9).

26 CX/MAS 97/8.

were requested to provide the necessary information. The Committee was invited to consider actions to be taken in relation to the methods identified in Annex II, i.e., endorsed Codex methods using ODS. It was proposed that future work on this agenda item be undertaken by the Inter-Agency Meeting (IAM). This proposal was made as the Committee was interested in the potential impacts on the Codex endorsed methods of non-availability of ODS and the Committee does not develop analytical methods while the IAM is where organizations developing methods gather and therefore, the IAM was judged to be the best forum to continue work on this issue.

40. The Committee noted the obligations of member countries following Montreal Protocol. The Observer from the EC was requested to forward the information on the ongoing activities within the EC which was presented at the Session. The Committee was informed that IUPAC would consider the issue at its General Assembly to be held in August 1997. The Observer from AOAC INTERNATIONAL stated that two years ago it had started a programme to eliminate ODS from its methods. However, replacements were yet to be provided.

41. It was pointed out that, although the Committee had not endorsed methods proposed for standards for milk products, the Committee could request the Codex Committee on Milk and Milk Products to review such methods as were identified in Annex II, in light of the decisions made by this Committee on the issue. The Committee recalled the three options which were provided during the 20th Session i.e.:

(i) using less ODS solvent i.e., micro quantities;
(ii) replacement of the ODS solvent, which might necessitate re-validation of the method; and
(iii) using alternative methods.

42. The Committee to discontinue work on methods using ODS and that no further action was needed by this committee. It **requested** the IAM to take up this work item in collaboration with the Codex Secretariat. The Committee **requested** that it be kept informed whenever methods using ODS were identified or modified.

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS[27] (Agenda Item 11)

43. A report of the *ad hoc* Working Group on Endorsement was presented by its chairperson, Dr. W. Horwitz (USA). Dr. G. Diachenko (USA) served as rapporteur of the Group. The following countries and international organizations participated in the Group: Australia, Canada, Finland, France, Germany, Hungary, Republic of Korea, Malaysia, The Netherlands, Thailand, the United Kingdom, the United States, AOAC International, ISO and IUPAC.

44. In order to clarify the previous recommendation of the Committee to the Commission to delete the CAC/RM numbering system[28], the Working Group proposed and the Committee **accepted** the following wording: "The Committee provides the following clarifying information to assist the Commission in implementing the Committee's previous recommendation to delete the CAC/RM numbering system. When the original reference is available, this reference should be included and the CAC/RM numbering system reference deleted. When the original reference is not available, the full text of the method should be included in *Codex Alimentarius* Volume 13 and the CAC/RM numbering system reference deleted".

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27 CX/MAS 97/9; CX/MAS 97/9-Add.1 (CRD 3); and CRD 4 (report of the ad hoc Working Group on Endorsement).

28 ALINORM 97/23, para. 52.

45. The Committee **accepted** the proposal of the Working Group regarding the endorsement of a number of Type I methods based on the proposals of the commodity committees, historical and widespread satisfactory use of the methods by the industry, and the importance of these methods for trade purposes even though they had not been and were unlikely to be collaboratively studied.

46. During the discussions on methods of analysis submitted for endorsement, the Committee **agreed** that if a method had not been collaboratively studied, it could be temporarily endorsed as Type IV pending further information on collaborative studies, or if it met the criteria stated above, endorsed as Type I. The Committee **decided** to delete a reference to conversion factors for determination of relative density of fats and oils and classified IUPAC 2.101 method as Type II. The Committee also **decided** to endorse ISO 1742:1980, originally proposed by the Committee on Sugars, for determination of loss on drying of fructose rather than ISO 5381:1983 proposed by the Working Group as the latter method is a Karl Fischer method to determine H_2O. A list of methods considered along with their status and assigned Types is attached to this report as Appendix V.

47. Concerning appropriateness and practicality of the use of the commodity designation "all foods" for some methods, it was **felt** that for the time being the term be kept and, when necessary, an appropriate exclusion statement be introduced in the method.

48. The Committee was informed that AOAC 996.15 became available to be used for the determination of fish core in quick frozen fish sticks (fish fingers) and fish portions - breaded or in batter. As it was noted that AOAC 971.13 had been endorsed for the same commodity/provision combination, it was proposed that this information should be forwarded to the Codex Committee on Fish and Fishery Products for consideration of amending the method. The Committee was also informed that there was an IDF Standard available for the determination of sulphite in dried milk, yoghurt and fermented milks, which should be submitted to the Codex Committee on Food Additives and Contaminants for consideration.

REVIEW OF GUIDELINES FOR THE INCLUSION OF SPECIFIC PROVISIONS IN CODEX STANDARDS AND RELATED TEXTS[29] (Agenda Item 12)

49. The Committee noted that the Codex Committee on General Principles had been reviewing the texts of the *Codex Alimentarius Commission Procedural Manual*, including transferring certain sections to the relevant *Codex Alimentarius* volumes. The Committee had not considered this issue until now as it was elaborating the General Guidelines on Sampling and considering a "criteria"-based approach for evaluating acceptable methods of analysis.

50. The Committee deferred discussions to a future session pending the developments on the Proposed Draft Guidelines on Sampling and the working procedure and selection of criteria in the "criteria"-based approach.

REPORT OF INTER-AGENCY MEETING ON METHODS OF ANALYSIS[30] (Agenda Item 13)

51. The report of the 12th Inter-Agency Meeting (IAM) was presented by the Observer from AOAC INTERNATIONAL. The Committee was informed that the report would be available on the AOAC INTERNATIONAL World Wide Web home page (http://www.aoac.org)[31] and would

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29 CX/MAS 97/10.

30 CRD 1.

31 The report is also available from the following upon request: AOAC INTERNATIONAL, 481 North Frederick Ave. Ste. 500, Gaithersburg, Maryland 20877-2417, USA. Fax: +1 301 924 7089.

also link existing home pages of other IAM organizations through this site. The Committee noted that Dr. Roger Wood was elected to serve as chairman till the 13th Session of the IAM.

52. The Committee was informed that the Secretariat of the IAM would contact organizations which were once on the IAM roster, but did not participate in the IAM, to ascertain their interest. In this regard, the IAM requested the Codex Secretariat to provide a list of organizations, methods of which had been endorsed by the Commission but which did not appear on the IAM roster. Similarly, the Codex Secretariat was requested to periodically provide to the IAM secretariat a list of methods, by originating organization, which were endorsed for Codex purposes, with a request that these lists be reviewed and any changes or revocation of such standards were to be communicated to the Codex Secretariat. The IAM accepted to undertake the two new work items referred to it by the Committee, i.e., the harmonization of analytical terminology in accordance with international standards with specific reference to "limits" (see para. 28.) and the review of methods of analysis using ODS (see para. 42.).

53. The Committee was informed of the updated "Directory of Organizations Working in the Fields of Standard Methods of Analysis and Laboratory Quality Assurance for the Food Sector" which was prepared by the Delegation of UK. The Delegation stated that comments made on the first draft of the document which had been presented at the 20th Session had been reflected in the current version. As requested by the 20th Session of the Committee, preparation of the directory was an on-going exercise. The Delegation of the UK would therefore welcome updates to the document to enable it to prepare a revised version for the 22nd Session of the Committee and the 13th IAM.

54. The Committee **noted** the report of the IAM and the changes in its terms of reference. The Committee **appreciated** efforts by the IAM in providing technical support to the work of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

OTHER BUSINESS

(a) Terms of Reference of the Committee/Coordination with Other Codex Committees

55. The Committee noted that while at its 18th Session it had agreed on the proposal of the Codex Committee on General Principles (CCGP) to amend the Terms of Reference of this Committee by expanding item (b) and adding item (g), the incorrect version was adopted by the Committee and the Commission[32]. The Committee **confirmed** its previous concurrence with the proposal of the CCGP and **agreed** to request the Commission to adopt the corrected version of the Terms of Reference together with the amendment proposed by this Committee at its last Session (Appendix IV).

56. Several delegations expressed the view that coordination with other Codex Committees be strengthened and some delegations pointed out that there was discrepancy between items (d) and (e) as regards elaboration of sampling plans; and the term "assessment of microbiological quality and safety in food" was not clear. The Committee **agreed** to request the CCGP to review items (d) and (e) to clarify the situation and to enable this Committee to take more horizontal approach in elaborating sampling plans.

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32 CX/MAS 92/2-Add.1; ALINORM 93/23, paras. 28-33.

(b) *Ad Hoc* Working Group on Endorsement

57. The Committee was informed that at its next Session the *ad hoc* Working Group on Endorsement would probably not meet for reasons including increasing transparency and fairness of Committee activities, and financial implications to Codex and a number of Member countries. The Committee held the view that since specific method endorsement required substantial time and the meetings of the Working Group were open to all participants, so are transparent and fair, the Working Group should be allowed to meet to facilitate deliberations of the Committee. The Committee **agreed** to recommend that the meetings of the Working Group should continue to be utilized as an efficient means of accomplishing the important task entrusted to this Committee in the limited time frame it has for its Sessions.

(c) Others

58. The Delegation of India stated that special considerations were being given to developing countries under the WTO Agreements. The Committee noted that the CCGP would consider matters regarding the implementation of Codex provisions by developing countries at its next Session[33]. The Delegation of India, supported by that of Egypt, requested that Member countries provide new or continuing assistance in training and technical aids in the area of methods of analysis.

59. The Delegation of Cuba, on behalf of Spanish speaking countries, requested the Host Government that Spanish interpretation be provided at future sessions. The Chairperson responded that the Host Government would consider the use of Spanish interpretation.

FUTURE WORK

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

- Proposed Draft General Guidelines on Sampling;
- Criteria for evaluating acceptable methods of analysis for Codex purposes;
- Harmonization of analytical terminology in accordance with international standards - report of Inter-Agency Meeting on "limits" ;
- Harmonization of reporting of test results corrected for recovery factors;
- Measurement uncertainty;
- Endorsement of methods of analysis provisions in Codex Standards; and
- Report of Inter-Agency Meeting.

61. The Committee also **agreed** to propose to the Commission that the following new work be undertaken:

- In-house method validation (see para. 19.).

DATE AND PLACE OF NEXT SESSION (Agenda Item 15)

62. The Committee was informed that its 22nd Session was tentatively scheduled to be held in Budapest from 16-20 November 1998, subject to confirmation by the Hungarian and Codex Secretariats.

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33 ALINORM 97/33, para. 50.

ANNEX I

SUMMARY STATUS OF WORK

Subject	Step	Action by	Document Reference (ALINORM 97/23A)
Proposed Draft Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food	5/8	22nd CAC	Appendix II paras. 22-24
Analytical Terminology for Codex Use	(5/8)	22nd CAC	Appendix III paras. 27-28
Amendments to the Terms of Reference	-	22nd CAC	Appendix IV para. 55
Proposed Draft General Guidelines on Sampling	3	Codex Secretariat Australia, Austria, Canada, Czech Republic, France, Hungary, India, The Netherlands, Thailand, UK & USA 22nd CCMAS	paras. 8-10
Criteria for Evaluating Acceptable Methods of Analysis for Codex Purposes	2	Canada, France & UK Codex Secretariat Governments 22nd CCMAS	para. 15
Harmonization of Analytical Terminology in Accordance with International Standards - Report of Inter-Agency Meeting on "Limits"	2	Inter-Agency Meeting 22nd CCMAS	paras.26 & 28
Harmonization of Reporting of Test Results Corrected for Recovery Factors	2	IUPAC 22nd CCMAS	para. 32
Measurement Uncertainty	2	UK Governments 22nd CCMAS	para. 37
In-House Method Validation	1	22nd CAC Codex Secretariat 22nd CCMAS	paras. 19 & 61
Endorsement of Methods of Analysis Provisions in Codex Standards	-	Codex Secretariat 22nd CCMAS	
Review of Methods of Analysis Using Ozone-Depleting Substances	-	22nd CAC Inter-Agency Meeting	para. 41

ALINORM 97/23A
APPENDIX I

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PROPOSED DRAFT GUIDELINES FOR THE ASSESSMENT OF THE COMPETENCE OF TESTING LABORATORIES INVOLVED IN THE IMPORT AND EXPORT CONTROL OF FOOD

(Advanced to Step 5 of the Codex Procedure with recommendations to omit Steps 6 and 7 for adoption by the Commission at Step 8)

SCOPE

1. These guidelines provide a framework for the implementation of quality assurance measures to ensure the competence of testing laboratories involved in the import and export control of foods.

2. These guidelines are intended to assist countries in the application of requirements for trade in foodstuffs and in determining equivalency in order to protect the consumers and to facilitate fair trade.

REQUIREMENTS

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

- Compliance with the general criteria for testing laboratories laid down in ISO/IEC Guide 25:1990 "General requirements for the competence of calibration and testing laboratories;

- Participation in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in "The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories", Pure & Appl. Chem. 65 (1993) 2132-2144;

- 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) 649-666.

4. The bodies assessing the laboratories referred to above should comply with the general criteria for laboratory accreditation, such as those laid down in the ISO/IEC Guide 58:1993: "Calibration and testing laboratory accreditation systems - General requirements for operation and recognition".

ANALYTICAL TERMINOLOGY FOR CODEX USE
(sumbmitted to the Commission for endorsement)

PREAMBLE

The purpose of this document is to provide harmonized analytical terminology specifically related to the work of the Codex Committee on Methods of Analysis and Sampling. It was recognized that various disciplines, e.g., analytical chemistry and metrology, use the same terms in different ways and this causes confusion. Even within the chemical field the meaning of the same term may vary among commodity areas. Therefore, the Codex Committee on Methods of Analysis and Sampling/Codex Alimentarius Commission needs to harmonize core terminology with clear definitions to ensure that analysts mean the same thing when using a particular term.

VOCABULARY[1]

RESULT: The final value reported for a measured or computed quantity, after performing a measuring procedure including all subprocedures and evaluations. {IUPAC-1994}

NOTES: {VIM}

1 When a result is given, it should be made clear whether it refers to:
- the indication [signal]
- the uncorrected result
- the corrected result

and whether several values were averaged.

2 A complete statement of the result of a measurement includes information about the uncertainty of measurement.

ACCURACY (AS A CONCEPT): The closeness of agreement between the reported result and the accepted reference value.

NOTE: The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component. {ISO 3534-1} When the systematic error component must be arrived at by a process that includes random error, the random error component is increased by propagation of error considerations and is reduced by replication.

ACCURACY (AS A STATISTIC): The closeness of agreement between a reported result and the accepted reference value. {ISO 3534-1}

NOTE: Accuracy as a statistic applies to the single reported final test result; accuracy as a concept applies to single, replicate, or averaged values.

TRUENESS: The closeness of agreement between the average value obtained from a series of test results and an accepted reference value.

NOTES:

1 The measure of trueness is usually expressed in terms of bias. {ISO 3534-1}

2 Trueness has been referred to as "accuracy of the mean."

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1 The source of the definition, if identical or used with minor editorial revisions, is given in curly braces.

BIAS: The difference between the expectation of the test results and an accepted reference value. {ISO 3534-1}

NOTES:

1 Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value. {ISO 3534-1}

2 When the systematic error component(s) must be arrived at by a process that includes random error, the random error component is increased by propagation of error considerations and reduced by replication.

PRECISION: The closeness of agreement between independent test results obtained under stipulated conditions. {ISO 3534-1}

NOTES: {ISO 3534-1}

1 Precision depends only on the distribution of random errors and does not relate to the true value or to the specified value.

2 The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

3 "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

Repeatability [Reproducibility]: Precision under repeatability [reproducibility] conditions. {ISO 3534-1}

Repeatability conditions: Conditions where independent test results are obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time. {ISO 3534-1}

Reproducibility conditions: Conditions where test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment. {ISO 3534-1}

NOTE: When different methods give test results that do not differ significantly, or when different methods are permitted by the design of the experiment, as in a proficiency study or a material-certification study for the establishment of a consensus value of a reference material, the term "reproducibility" may be applied to the resulting parameters. The conditions must be explicitly stated.

Repeatability [Reproducibility] standard deviation: The standard deviation of test results obtained under repeatability [reproducibility] conditions. {ISO 3534-1}

NOTES: {ISO 3534-1}

1 It is a measure of the dispersion of the distribution of test results under repeatability [reproducibility] conditions.

2 Similarly "repeatability [reproducibility] variance" and "repeatability [reproducibility] coefficient of variation" could be defined and used as measures of the dispersion of test results under repeatability [reproducibility] conditions.

Repeatability [Reproducibility] limit: The value less than or equal to which the absolute difference between two test results obtained under repeatability [reproducibility] conditions may be expected to be with a probability of 95%. {ISO 3534-1}

NOTES:

1 The symbol used is r [R]. {ISO 3534-1}

2 When examining two single test results obtained under repeatability [reproducibility] conditions, the comparison should be made with the repeatability [reproducibility] limit

$$r\,[R] = 2.8\ s_r[s_R].$$ {ISO 5725-6, 4.1.4}

3 When groups of measurements are used as the basis for the calculation of the repeatability [reproducibility] limits (now called the critical difference), more complicated formulae are required that are given in ISO 5725-6:1994, 4.2.1 and 4.2.2.

APPLICABILITY: The analytes, matrices, and concentrations for which a method of analysis may be used satisfactorily to determine compliance with a Codex standard.

NOTE: In addition to a statement of the range of capability of satisfactory performance for each factor, the statement of applicability (scope) may also include warnings as to known interference by other analytes, or inapplicability to certain matrices and situations.

SPECIFICITY: The property of a method to respond exclusively to the characteristic or analyte defined in the Codex standard.

NOTES:

1 Specificity may be achieved by many means: It may be inherent in the molecule (e.g., infrared or mass spectrometric identification techniques), or attained by separations (e.g., chromatography), mathematically (e.g., simultaneous equations), or biochemically (e.g., enzyme reactions). Very frequently methods rely on the absence of interferences to achieve specificity (e.g., determination of chloride in the absence of bromide and iodide).

2 In some cases specificity is not desired (e.g., total fat, fatty acids, crude protein, dietary fibre, reducing sugars).

SENSITIVITY: Change in the response divided by the corresponding change in the concentration of a standard (calibration) curve; i.e., the slope, s_i, of the analytical calibration curve.

NOTE: This term has been used for several other analytical applications, often referring to capability of detection, to the concentration giving 1% absorption in atomic absorption spectroscopy, and to ratio of found positives to known, true positives in immunological and microbiological tests. Such applications to analytical chemistry should be discouraged.

NOTES: {IUPAC-1987}

1 A method is said to be sensitive if a small change in concentration, c, or quantity, q, causes a large change in the measure, x; that is, when the derivative dx/dc or dx/dq is large.

2 Although the signal may vary with the magnitude of c_i or q_i, the slope, s_i, is usually constant over a reasonable range of concentrations. s_i may also be a function of the c or q of other analytes present in the sample.

RUGGEDNESS: The ability of a chemical measurement process to resist changes in results when subjected to minor changes in environmental and procedural variables, laboratories, personnel, etc. {IUPAC-1995}

- The following set of definitions are from {IUPAC-1994-2}, with some minor revisions for clarity:

INTERLABORATORY STUDY: A study in which several laboratories measure a quantity in one or more "identical" portions of homogeneous, stable materials under documented conditions, the results of which are compiled into a single document.

NOTE: The larger the number of participating laboratories , the greater the confidence that can be placed in the resulting estimates of the statistical parameters. The IUPAC-1987 protocol (Pure & Appl. Chem., 66, 1903-1911(1994)) requires a minimum of eight laboratories for method-performance studies.

Method-Performance Study: An interlaboratory study in which all laboratories follow the same written protocol and use the same test method to measure a quantity in sets of identical test samples. The reported results are used to estimate the performance characteristics of the method. Usually these characteristics are within-laboratory and among-laboratories precision, and when necessary and possible, other pertinent characteristics such as systematic error, recovery, internal quality control parameters, sensitivity, limit of determination, and applicability.

NOTES:

1 The materials used in such a study of analytical quantities are usually representative of materials to be analyzed in actual practice with respect to matrices, amount of test component (concentration), and interfering components and effects. Usually the analyst is not aware of the actual composition of the test samples but is aware of the matrix.

2 The number of laboratories, number of test samples, number of determinations, and other details of the study are specified in the study protocol. Part of the study protocol is the procedure which provides the written directions for performing the analysis.

3 The main distinguishing feature of this type of study is the necessity to follow the same written protocol and test method exactly.

4 Several methods may be compared using the same test materials. If all laboratories use the same set of directions for each method and if the statistical analysis is conducted separately for each method, the study is a set of method-performance studies. Such a study may also be designated as a method-comparison study.

Laboratory-Performance (Proficiency) Study: An interlaboratory study that consists of one or more measurements by a group of laboratories on one or more homogeneous, stable, test samples by the method selected or used by each laboratory. The reported results are compared with those from other laboratories or with the known or assigned reference value, usually with the objective of improving laboratory performance.

NOTES:

1 Laboratory-performance studies can be used to support accreditation of laboratories or to audit performance. If a study is conducted by an organization with some type of management control over the participating laboratories – organizational, accreditation, regulatory, or contractual – the method may be specified or the selection may be limited to a list of approved or equivalent methods. In such situations, a single test sample is insufficient to judge performance. It is expected that the results from 1 of every 20 tests will be outside the value for the calculated mean ± twice the standard deviation, due solely to random fluctuations.

2 Sometimes a laboratory-performance study may be used to select a method of analysis that will be used in a method-performance study. If all laboratories, or a sufficiently large subgroup, of laboratories , use the same method, the study may also

be interpreted as a method-performance study, provided that the test samples cover the range of concentration of the analyte.

3 Separate laboratories of a single organization with independent facilities, instruments, and calibration materials, are treated as different laboratories.

Material-Certification Study: An interlaboratory study that assigns a reference value ("true value") to a quantity (concentration or property) in the test material, usually with a stated uncertainty.

NOTE: A material-certification study often utilizes selected reference laboratories to analyze a candidate reference material by a method(s) judged most likely to provide the least-biased estimates of concentration (or of a characteristic property) and the smallest associated uncertainty.

SOURCE MATERIALS

(1) VIM: "International Vocabulary of Basic and General Terms in Metrology" Second edition, 1993, International Organization for Standardization, Geneva, Switzerland, 58 pp.

(2) ISO 3534-1:1993: Statistics –Vocabulary and Symbols –Part 1: Probability and general statistical terms. International Organization for Standardization, Geneva, Switzerland, 47 pp.

ISO 3534-2:1993: Statistics –Vocabulary and Symbols – Part 2: Statistical quality control. International Organization for Standardization, Geneva, Switzerland, 33 pp.

(3) ISO 5725-6:1994: Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values. International Organization for Standardization, Geneva, Switzerland, 41 pp.

(4) IUPAC-1987: Freiser, H. and Nancollas, G.H. "Compendium of Analytical Nomenclature. Definitive Rules 1987." Second Edition, 1987. Blackwell Scientific Publications, Oxford UK, pp.

(5) IUPAC-1994: Currie L.A. and Svehla, G. "Nomenclature for the Presentation of Results of Chemical Analysis. (IUPAC Recommendations 1994)." *Pure & Appl. Chem.* 66, 595-608 (1994).

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(7) IUPAC-1995: Currie L.A. "Nomenclature in Evaluation of Analytical Methods Including Detection and Quantitation Capabilities. (IUPAC Recommendations 1995)." Pure & Appl. Chem. 67, 1699-1723(1994).

AMENDMENTS OF THE TERMS OF REFERENCE OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

(Submitted to the Commission for adoption)

Amended paragraphs (a), (b) and (d) of the Terms of Reference of the Committee (*Codex Alimentarius Commission Procedural Manual*, Ninth Edition, page 134) are as follows (struck-out text to be deleted and italicized text to be inserted):

(a) ~~to serve as a coordinating body for Codex with other international groups working in method of analysis and sampling and quality assurance systems for laboratories~~ *to define the criteria appropriate to Codex Methods of Analysis and Sampling*;

(b) ~~to serve as a coordinating body for Codex with other international groups working in method of analysis and sampling and quality~~ *to serve as a coordinating body for Codex with other international groups working in method of analysis and sampling and quality assurance systems for laboratories*;

(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].

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1 ALINROM 97/23, Appendix III.

METHODS OF ANALYSIS CONSIDERED BY THE COMMITTEE AT THE TWENTY-FIRST SESSION

This Appendix consists of four parts as follows:

Part 1. Methods of Analysis for Food Additives and Contaminants in Foods;
Part 2. Methods of Analysis for Commodity Standards Submittd for Endorsement;
Part 3. Amendment to the Previous Endorsement; and
Part 4. Methods of Analysis Temporarily Endorsed Previously

PART 1. METHODS OF ANALYSIS FOR FOOD ADDITIVES AND CONTAMINANTS IN FOODS

Commodity	Provision	Method	Principle	Note	Type	Status
Fats and oils	BHA, BHT, TBHQ, NDGA, propyl gallate	AOAC 983.15	Liquid chromatography		II	E
All foods	Cyclamates	NMKL 123 (1987)	Spectrophotometry	Collaborative study data on the NMKL methods were provided by the delegate from Finland.	II	E
Beverages and sweets	Saccharin	NMKL 122 (1987)	Liquid chromatography	See above.	II	E
All foods	Benzoic acid and its salt, sorbic acid and its salts	NMKL 103 (1984), AOAC 983.16	Gas chromatography	See above.	II	E
Cured meat	Nitrites	AOAC 973.31	Colorimetry	CEN and other groups have methods being developed for nitrites.	II	E
All foods	Sulphites $\geq$10 ppm sulphites	AOAC 990.28	Optimized Monier-Williams method	This method is recommended as Type II because of its wide acceptance and long history of use.	II	E
All foods	Sulphites $\geq$5 ppm total SO_2	AOAC 990.29	Flow injection analysis		III	E
All foods	Sulphites $\geq$10 ppm SO_2	AOAC 990.31	Ion exclusion chromatography		III	E

PART 2. METHODS OF ANALYSIS FOR COMMODITY STANDARDS SUBMITTED FOR ENDORSEMENT

A. Proposed by Codex Committee on Fats and Oils

Commodity	Provision	Method	Principle	Note	Type	Status
Fats and Oils	Acidity ≤10 mg-KOH/g	IUPAC 2.201 ISO 660:1996	Titrimetry		I	E
Palm Oil	Apparent density 0.8813-0.8977	ISO 6883:1995 with the appropriate conversion factor	Pyknometry		I	E
Fats and Oils	Arsenic ≤0.1 mg/kg	AOAC 942.17 (Codex general method)	Colorimetry (molybdenum blue)		III	E
Fats and Oils	Arsenic ≤0.1 mg/kg	AOAC 952.13 (Codex general method) IUPAC 3.136	Colorimetry (diethyldithocarbamate)		II	E
Fats and Oils	Arsenic ≤0.1 mg/kg	AOAC 985.16 (Codex general method)	Atomic absorption spectrometry		III	E
Fats and Oils	Baudouin test (modified Villavecchia or sesameseed oil test) +/-	AOCS Cb 2-40	Colour reaction		I	E
Fats and Oils	Copper and Iron ≤0.1 mg/kg	ISO 8294:1994 IUPAC 2.631 AOAC 990.05 (Codex general method)	Atomic absorption spectrometry (direct graphite furnace)		II	E
Fats and Oils	Crismer value 67-70	AOCS Cb 4-35	Turbidity		I	E
Fats and Oils	Fatty acid composition various levels	IUPAC 2.301+2.302+2.304, ISO 5509:1978+5508:1990	Gas chromatography of methyl esters		II	E
Fats and Oils	Halphen test +/-	AOCS Cb 1-25	Colorimetry		I	E
Fats and Oils	Insoluble impurities 0.05-0.1% (m/m)	IUPAC 2.604 ISO 663:1995	Gravimetry		I	E

Commodity	Provision	Method	Principle	Note	Type	Status
Fats and Oils	Iodine value 6.3-148 % m/m absorbed iodine	AOCS Cd 1b-1987	Calculation from the fatty acid profile	The Commodity Committee (CC) is requested to specify the oils that each method is applicable to.	I	TE
Fats and Oils	Iodine value 6.3-148 % m/m absorbed iodine	IUPAC 2.205/1 ISO 3961:1996 AOAC 993.20 AOCS Cd 1d-1992	Wijs-titrimetry	The Commodity Committee (CC) is requested to specify the oils that each method is applicable to.	I	TE
Fats and Oils	Iron 1.5-3.0 mg/kg	ISO 8294:1994 IUPAC 2.631 AOAC 990.05 (Codex general method)	Atomic absorption spectrometry (direct graphite furnace)		II	E
Fats and Oils	Lead $\leq$0.1 mg/kg	IUPAC 2.632 AOAC 994.02 ISO 12193:1994 (Codex general method)	Atomic absorption (direct graphite furnace)		II	E
Fats and Oils	Matter volatile at 105°C $\leq$0.3% (m/m)	IUPAC 2.601 ISO 662:1996	Gravimetry (open-drying)		I	E
Fats and Oils	Peroxide value 0-20 meq-active oxygen/kg	IUPAC 2.501 (as amended) AOCS Cd 8b-90	Titrimetry using *iso*-octane		I	E
Fats and Oils	Refractive index 1.447-1.470	IUPAC 2.102 ISO 6320:1995	Refractometry		II	E
Fats and Oils	Reichert & Polenske values 6-8.5 (Reichert value) 8-18 (Polenske value)	IUPAC 2.204	Tritrimetry		I	E
Fats and Oils	Relative density 0.881-0.927	IUPAC 2.101	Pyknometry		II	E
Fats and Oils	Saponification value 168-265 mg-KOH/g-oil	IUPAC 2.202 ISO 3657:1988	Titrimetry		I	E
Fats and Oils	Slip point	ISO 6321:1991	Open ended capillary tube		I	E

Commodity	Provision	Method	Principle	Note	Type	Status
Palm oil	Slip point 24-44°C for palm oil	AOCS Cc 3-25 (1992)	Open ended capillary tube (for 60°C)		I	E
Fats and Oils	Soap content 0.005% (m/m)	BS 684 Section 2.5	Gravimetry		I	E
Fats and Oils	Sterol composition -	ISO 6799:1991 IUPAC 2.403	Gas chromatography		II	E
Fats and Oils	Titre 32-49°C	IUPAC 2.121 ISO 935:1988	Thermometry		I	E
Fats and Oils	Tocopherol composition -	IUPAC 2.432	HPLC	ISO/DIS reference was deleted. When the final method reference becomes available its inclusion will be considered.	II	E
Fats and Oils	Total carotenoids 300-2000 mg-β-carotene/kg	BS 684 Section 2.20	Spectrophotometry		II	E
Fats and Oils	Unsaponifiable matter 0-30 g/kg	IUPAC 2.401 (part 1-5) ISO 3596-1:1996	Titrimetry after extraction with diethyl ether		I	E

B. Proposed by Codex Committee on Sugars

Commodity	Provision	Method	Principle	Note	Type	Status
Honey	Acidity ≤40 meq-acid/kg	*J. Assoc. Public Analysts* (1992) **28** (4) 171-175 MAFF Validated V19 for Acidity in Honey			I	E
Sugars (lactose)	Anhydrous lactose ≥99.0%	ICUMSA GS 4/3-3 (1994)	Titrimetry		II	E
Sugars (powdered sugar)	Anti-caking agents <1.5% m/m	ICUMSA GS 3-21 (1994) to be amended to incorporate a method for the determination of starch to meet the requirements of the Standard		ICUMSA is requested to provide needed information on methods and the status of collaborative studies.		NE

Commodity	Provision	Method	Principle	Note	Type	Status
Honey	Apparent reducing sugar ≥45%	Stated in the Standard (Annex 2 of CX/MAS 97/9)	Titrimetry (Lane & Eynon)		I	E
Honey	Apparent sucrose ≤10%	FAO Manuals of Food Quality Control, Food and Nutrition Monograph 14/3 (1979) 150	Walker Inversion		I	E
Honey	Arsenic free from As	AOAC 952.13 (Codex general method)	Colorimetry (diethyldithiocarbamate)	The CC should provide a quantitative provision for As rather than "free from As". It was assumed that the <1 mg/kg As in the sugars specification would be adequate for method sensitivity.	II	E
Sugars	Arsenic <1 mg/kg	AOAC 952.13 (Codex general method)	Colorimetry (diethyldithiocarbamate)		II	E
Sugars	Arsenic <1 mg/kg	ICUMSA GS 2/3-25 (1994)	Colorimetry (diethyldithiocarbamate)	If this method is identical to AOAC 952.13, it should be put together with the AOAC method.	IV	TE
Sugars (soft white sugar and soft brown sugar)	Colour -	ICUMSA GS 1-7 (1994)	Photometry		I	E
Sugars (powdered sugar)	Colour ≤60 ICUMSA units	ICUMSA GS 2/3-9 (1994)	Photometry		I	E
Sugars (plantation or mill white sugar, soft white sugar and soft brown sugar)	Conductivity ash ≤0.2% m/m	ICUMSA GS 1/3/4/7/8-13 (1994)	Conductimetry		I	E
Sugars (white sugar)	Conductivity ash ≤0.04% m/m	ICUMSA GS 2/3-17 (1994)	Conductimetry		I	E
Sugars (powdered sugar)	Conductivity ash ≤0.04% m/m	ICUMSA GS 2/3-17 (1994)	Conductimetry		I	E
Honey	Copper free from Cu	AOAC 971.20 (Codex general method)	Atomic absorption spectrophotometry	The CC should specify a quantitative level of Cu for the provision so CCMAS can be sure the method is adequately sensitive.	II	E

Commodity	Provision	Method	Principle	Note	Type	Status
Sugars (dextrose anhydrous, dextrose monohydrate)	D-glucose ≥99.5% m/m on a dry basis	ISO 5377:1981	Titrimetry		I	E
Honey	Diastase activity ≥3	AOAC 958.09	Photometry		II	E
Honey	Diastase activity ≥3	Stated in the Standard (CX/MAS 97/9-Add.1) Other commercially available calibrated substrate preparations can also be used.	Photometry	Use of a proprietary reagent in the method requires the change noted in the principle section.	III	E
Honey	hydroxymethylfurfural ≤80 mg/kg	AOAC 980.23	Spectrophotometry		II	E
Honey	hydroxymethylfurfural ≤80 mg/kg	Stated in the Standard (CX/MAS 97/7-Add.1)	HPLC		III	E
Honey	hydroxymethylfurfural ≤80 mg/kg	Stated in the Standard (CX/MAS 97/7-Add.1)	Photometry (Winkler)	This method uses p-toluidine which is carcinogenic.	III	E
Sugars (plantation or mill white sugar)	Invert sugar ≤0.1% m/m	ICUMSA GS 1/3/7-3 (1994)	Titrimetry (Lane & Eynon)		I	E
Sugars (soft white sugar and soft brown sugar)	Invert sugar 0.3-12.0% m/m	ICUMSA GS 1/3/7-3 (1994)	Titrimetry (Lane & Eynon)		I	E
Sugars (white sugar)	Invert sugar ≤0.04% m/m	ICUMSA GS 2/3-5 (1997)	Titrimetry		I	E
Sugars (powdered sugar)	Invert sugar ≤0.04% m/m	ICUMSA GS 2/3-5 (1997) after filtration if necessary to remove any anticaking agents	Titrimetry		I	E
Honey	Lead free from Pb	AOAC 972.25 (Codex general method)	Atomic absorption spectrophotometry	The CC should specify a quantitative level of Pb for the provision so CCMAS can be sure the method is adequately sensitive.	II	E

Commodity	Provision	Method	Principle	Note	Type	Status
Honey	Lead free from Pb	Miller-Ihli method (JAOAC International(1994) 77(5), 1288-1292)		The method was not endorsed because it had no collaborative study data submitted and no official AOAC International status.		NE
Sugars	Lead <0.5 mg/kg	AOAC 972.25 (Codex general method)	Atomic absorption spectrophotometry		II	E
Sugars	Lead <0.5 mg/kg	Miller-Ihli method (JAOAC International (1994) 77(5) 1288-1292)		The method was not endorsed because it had no collaborative study data submitted and no official AOAC International status.		NE
Sugars (lactose)	Loss on drying ≤6.0% m/m	USP method (1995)	Gravimetry (drying at 120°C for 16 h)	Previous reference: CAC/RM 2-1969.	I	E
Sugars (soft white sugar, soft brown sugar, white sugar, plantation or mill white sugar and powdered sugar)	Loss on drying ≤4.5% m/m	ICUMSA GS 2/1/3-15 (1994)	Gravimetry		I	E
Sugars (fructose)	Loss on drying ≤0.5% m/m	ISO 1742:1980	Gravimetry		I	E
Honey	Mineral (ash) ≤1.0%	*J. Assoc. Public Analysts* (1992) **28** (4) 177-181 MAFF Validated Method V20 for Mineral (ash) in Honey	Gravimetry (ignition at 600°C)		I	E
Honey	Moisture ≤23%	AOAC 969.38B *J. Assoc. Public Analysts* (1992) **28** (4) 183-187 MAFF Validated Method V21 for Moisture in Honey	Refractometry		I	E
Sugars (fructose and lactose)	pH 4.5-7.0	ICUMSA GS 1/2/3/4/7/8-23 (1994)	Potentiometry		I	E
Sugars (plantation or mill white sugar)	Polarization ≥99.5°Z	ICUMSA GS 1/2/3-1 (1994)	Polarimetry		II	E

Commodity	Provision	Method	Principle	Note	Type	Status
Sugars (white sugar)	Polarization ≥99.7°Z	ICUMSA GS 2/3-1 (1994)	Polarimetry		II	E
Sugars (powdered sugar)	Polarization ≥99.7°Z	ICUMSA GS 2/3-1 after filtration in necessary to remove any anti-caking agents	Polarimetry		II	E
Sugars (dried glucose syrup and glucose syrup)	Reducing sugar ≥20.0% m/m on a dry basis expressed as D-glucose	ISO 5377:1981	Titrimetry		I	E
Honey	Sample preparation	AOAC 920.180	-	The Committee proposed to use AOAC 920.180 as it is identical to the method currently stated in the Standard and to change the provision from sampling to sample preparation.	-	E
Sugars (fructose)	Specific rotation -89° - -93.5°	Zuckerindustrie 113 (1988); 1, 49-50	Polarimetry	Status retained pending further information.	II	TE
Sugars (soft white sugar and soft brown sugar)	Sucrose plus invert sugar ≥88.0% m/m expressed as sucrose	ICUMSA GS 4/3-7 (1994)	Titrimetry		I	E
Sugars (soft white sugar and soft brown sugar)	Sulphated ash ≤3.5% m/m	ICUMSA GS 1/3/4/7/8-11 (1994)	Gravimetry		I	E
Sugars (lactose)	Sulphated ash ≤0.3% m/m on a dry basis	ICUMSA GS 1/3/4/7/8-11 (1994)	Gravimetry		I	E
Sugars (dextrose anhydrous, dextrose monohydrate, dried glucose syrup and glucose syrup)	Sulphated ash ≤1.0% m/m on a dry basis	ISO 5809:1982	Single sulphonation		I	E

Commodity	Provision	Method	Principle	Note	Type	Status
Sugars (powdered dextrose)	Sulphated ash ≤0.25% m/m on a dry basis	ISO 5801		The Committee was informed of the proposal to use ISO 5801 but postponed discussions pending the information on the ISO method.		
Sugars (white sugar and plantation or mill white sugar)	Sulphur dioxide <20 mg/kg	ICUMSA GS 2/7-33 (1994)	Colorimetry	The CC Secretariat should provide clarification of ICUMSA method numbers, collaborative study data and clarification concerning applicability of		
Sugars (white sugar and plantation or mill white sugar)	Sulphur dioxide <20 mg/kg	ICUMSA GS 2/3-35 (1994)	Enzymatic method	both sulphur dioxide methods to powdered sugar with and without anti-caking agents.		
Sugars (powdered sugar without anti-caking agents)	Sulphur dioxide <15 mg/kg	ICUMSA GS 2/7-33 (1994)	Colorimetry	See above and only listed as applicable for white sugar in ICUMSA methods book.		
Sugars (powdered sugar without anti-caking agents)	Sulphur dioxide <15 mg/kg	ICUMSA GS 2/3-35 (1994)	Enzymatic method	.		
Sugars (powdered sugar with anti-caking agents)	Sulphur dioxide <15 mg/kg	ICUMSA GS 2/3-35 (1994)	Enzymatic method	The CC Secretariat should confirm that the colorimetric method is not applicable to this commodity.		
Sugars (dextrose anhydrous, dextrose monohydrate, glucose syrup, dried glucose syrup and fructose)	Sulphur dioxide <20 mg/kg	ISO 5379:1983	Acidimetry and nephelometry		IV	TE
Sugars (dextrose anhydrous and dextrose monohydrate)	Total solids ≥90.0% m/m	ISO 1741:1980	Gravimetry (vacuum oven)		I	E

Commodity	Provision	Method	Principle	Note	Type	Status
Sugars (dried glucose syrup and glucose syrup)	Total solids ≥70.0% m/m (glucose syrup) ≥93.0% m/m (dried glucose syrup)	ISO 1742:1980	Gravimetry (vacuum oven)		I	E
Honey	Water-insoluble solids ≤0.5%	*J. Assoc. Public Analysts* (1992) **28** (4) 189-193 MAFF Validated Method V22 for Water-Insoluble Solids in Honey	Gravimetry		I	E

C. Proposed by the Codex Committee on Fish and Fishery Products

Commodity	Provision	Method	Principle	Note	Type	Status
Quick Frozen Fish Sticks (Fish Fingers)	Proportion of fish fillet/minced fish flesh not specified	Stated in the Standard (Annex 3 of CX/MAS 97/9)	Gravimetry	No decision was made pending submission of UK collaborative study data.		
Salted Fish and Dried Salted Fish of the *Gadidae* Family	Salt not specified	Stated in the Standard (Annex 4 of CX/MAS 97/9)	Titrimetry (Mohr)	The CC should be requested to consider the General Method for Salt AOAC 971.27 instead of the proposed method and questioned whether a method was needed since no specification was listed.		

D. Proposed by the Codex Coordinating Committee for Asia

Commodity	Provision	Method	Principle	Note	Type	Status
Canned Bamboo Shoot	Colour, flavour, texture	Stated in the Standard (Annex 5 of CX/MAS 97/9)	Organoleptic measurement	The CC Secretariat should be informed that items such as organoleptic measurements of colour, flavour and texture are not ordinarily considered as methods of analysis.		NE
Canned Bamboo shoot	Net weight and drained weight drained wt/net wt ≥60%	AOAC 968.30	Gravimetry	CC should be informed that WG endorsed the AOAC method which appears to be identical to the method stated in the Standard (Annex 6 of CX/MAS 97/9).	I	E

Commodity	Provision	Method	Principle	Note	Type	Status
Canned Bamboo Shoot	pH ≥4.0; 4.0-4.6 (if acid is added)	AOAC 981.12	Potentiometry		I	E
Dried Salted Anchovies	Acid insoluble ash ≤1.5% m/m (dry basis)	Stated in the Standard (Annex 7 of CX/MAS 97/9)	Gravimetry	It was recommended that the CC consider adopting a more generally applicable method such as AOAC 938.08.		
Dried Salted Anchovies	Sodium chloride ≤15% m/m (dry basis)	AOAC 937.09	Volumetry		II	E
Dried Salted Anchovies	Water activity ≤0.75	AOAC 978.18 or methods using any instruments equivalent to the instruments described in AOAC 978.18	Measurement of vapour pressure, dew point or physical or electric characteristics of sensors using instruments		I	E
Fish Crackers	Crude protein (Nx6.25) ≥5% m/m	AOAC 920.87	Titrimetry (Kjeldahl)		I	E
Fish Crackers	Crude protein (Nx6.25) ≥2% m/m	AOAC 960.52	Titrimetry (micro-Kjeldahl)	CC should be requested to consider the more general method AOAC 920.87 given potential sampling problems and that method 960.52 has been surplused by AOAC.		
Fish Crackers	Moisture 8-14% m/m	AOAC 950.46B	Gravimetry (air-drying)	CC needs to select one of the two drying conditions specified in the method or provide data indicating their comparability.		

APPENDIX III

PART 3. AMENDMENT TO THE PREVIOUS ENDORSEMENT

Commodity	Provision	Method	Principle	Note	Type
Processed Meat and Poultry Products and Soups and Broths	Nitrite	ISO 2918:1975	Colorimetry	Previously endorsed as Type II. Reclassification recommended based on the lack of collaborative study data.	IV

APPENDIX IV

PART 4. METHODS OF ANALYSIS TEMPORARILY ENDORSED PREVIOUSLY

1. The Committee extended the temporarily endorsed status of the following methods.

Commodity	Provision	Method	Principle	Note	Type
Edible cassava flour	Ash < 3 % (m/m)	AOAC 923.03	Gravimetry	It was proposed to extend the temporary endorsement of AOAC 923.03 working at 550°C and requested the ISO information on the temperature used in ISO 2171:1993 whether it is only 900°C. CC should be contacted concerning the necessary oven temperature.	I
Grated desiccated coconut	Granularity Extra fine, fine and medium	ISO 2591-1:1988 Test Sieving According to British Standard Mesh Nominal Test Sieves: BS 410-1986	Sieving		I
Guidelines for nutrition labelling	Polyunsaturated fat	AOCS Ce 1c-89	Gas liquid chromatography	It was noted that AOAC 996.06 became available and the method should be submitted to the CCNFSDU for consideration.	IV
Guidelines for nutrition labelling	saturated fat	AOCS Ce 1c-89	Gas liquid chromatography	It was noted that AOAC 996.06 became available and the method should be submitted to the CCNFSDU for consideration.	IV

2. The Committee replaced the previously proposed method with the following method with temporary endorsement.

Commodity	Provision	Method	Principle	Note	Type
Durum wheat semolina and durum wheat flour	Particle size	AFNOR NFV 03721	Sieving	It was proposed to temporarily endorse the AFNOR method with the understanding that when it is finalized as an ISO method, it will be replaced by the ISO method reference.	I