codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 07/30/23

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirtieth Session
Rome, Italy, 2-7 July 2007

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

Budapest, Hungary
5 - 9 March 2007

Note: This document incorporates Codex Circular Letter CL 2007/10-MAS

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CX 4/50.2 **CL 2007/10-MAS**
March 2007

TO: - Codex Contact Points
- Interested International Organizations

FROM: - Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the 28th Session of the Codex Committee on Methods of Analysis and Sampling (ALINORM 07/30/23)**

A. MATTERS FOR ADOPTION BY THE 30th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

1. Proposed Amendment to the *Principles for the Establishment or Selection of Codex Sampling Procedures* (para. 117, Appendix II)

METHODS OF ANALYSIS AND SAMPLING

2. Methods of Analysis in Codex Standards at different steps (paras. 67-91, Appendix III)

Governments wishing to propose amendments or comments on items 1 and 2 above should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission) to the above address **before 10 May 2007.**

B. REQUEST FOR COMMENTS AND INFORMATION

DRAFT GUIDELINES AT STEP 6

3. Draft Guidelines for Settling Disputes on Analytical (Test) Results (para. 54, Appendix IV)

Governments and international organizations wishing to submit comments should do so in writing to the above address, with a copy to the Codex Contact Point of Hungary, Dr. Mária Váradi, Central Food Research Institute (KÉKI), H-1022 Budapest, Herman Ottó út 15 (Fax No. +361.212.9853; e-mail, m.varadi@cfri.hu), **before 15 September 2007**.

PROPOSED DRAFT GUIDELINE AT STEP 3

4. Proposed Draft Guideline on *Analytical Terminology* (para. 65, Appendix V)

Governments and international organizations wishing to submit comments should do so in writing to Dr. Michael D. Sussman, US Department of Agriculture, National Science Laboratory, 801 Summit Crossing Place, Suite B, Gastonia, NC 28054, USA, Fax 01-704-853-2800, E-mail:michael.sussman@usda.gov, with a copy to the above address, **before 30 June 2007**.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 28th Session of the Codex Committee on Methods of Analysis and Sampling are as follows:

Matters for adoption by the 30th Session of the Commission:

The Committee:

- agreed to propose an amendment to the *Principles for the Establishment or Selection of Codex Sampling Procedures* (para. 117, Appendix II);
- endorsed several methods of analysis in Codex standards at different steps of the Procedure (paras. 67-91, Appendix III);
- agreed to propose separate references for three texts already adopted by reference (para. 17).

Other Matters of Interest to the Commission

The Committee:

- agreed to retain at Step 7 the Draft Guidelines for Evaluating Acceptable Methods of Analysis (para. 27);
- agreed to return to Step 6 the Draft Guidelines for Settling Disputes on Analytical (Test) Results (para. 54, Appendix IV);
- agreed to return to Step 3 the Proposed Draft Guideline on Analytical Terminology (para. 65, Appendix V)
- agreed to consider at its next session the conversion of methods for trace elements into criteria (para. 101-102); the criteria for methods of analysis for foods derived from biotechnology (para. 111); and guidance on measurement uncertainty and sampling uncertainty (paras. 10 and 1234) with a view to proposing new work;
- agreed to consider at its next session discussion papers on the role and terms of reference of the Committee (para. 129) and on the reliability of analytical data (para. 137)

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INTRODUCTION

1) The Codex Committee on Methods of Analysis and Sampling held its Twenty-eighth Session in Budapest, Hungary, from 5 to 9 March 2007, by courtesy of the Government of Hungary. The Session was chaired by Professor Peter Biacs, Professor at the Corvinus University of Budapest. Professor Pál Molnar, Department of Food Science of the University of Szeged, acted as the Vice-Chairperson. The Session was attended by 155 delegates and observers representing 54 Member Countries, one Observer Country, one Member Organisation (EC) and 8 international organizations. A complete list of participants is given in Appendix I of this report. A minute's silence was held for Dr Horwitz, former member of the Delegation of the United States of America and previous chairperson of the Working Group on Endorsement of Methods in acknowledgment of his contribution to this Committee.

OPENING OF THE SESSION

2) The Session was welcomed by Ms. Ágnes Szegedyné Fricz, Deputy Head of the Food Safety Chain, Animal and Plant Health Department, Ministry of Agriculture and Regional Development, who expressed the honour of Hungary to host this important committee for many years. She informed the Committee of the record attendance of member countries and international organisations at this Session, which reflected the increasing relevance and importance of the work of Codex in protecting consumer health and facilitating international food trade and its recognition in terms of the Agreements of the WTO. Ms Fricz also informed the Committee that the Hungarian food industry had been privatized and modernized and had increased production and that a new food law had been enacted which requires that food regulations should be harmonized with the standards of Codex. In addition, she highlighted the importance of the need for reliable methods of analysis and sampling and of their harmonization to ensure effective food safety control and wished delegates a fruitful and pleasant meeting.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

3) The Delegation of the European Community presented CRD 3 on the division of competence between the European Community and its Member States according to Rule of Procedure II Paragraph 5 of the Codex Alimentarius Commission.

4) The Committee agreed to the proposal of the Delegation of the European Community to consider Agenda Item 3(a) and 3(b) after Item 4 to allow more time for consideration of these items and with this amendment adopted the Provisional Agenda as presented in CX/MAS 07/28/1.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[2]

5) The Committee noted the recommendation of the Commission to give due regard to methods of analysis that could be used world wide both in developed and developing countries, where applicable.

Measurement Uncertainty

6) The Committee noted that when adopting the recommendations on the Use of Analytical Results: Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards, the Commission had referred to the Committee the request made by some delegations for further guidance to address measurement uncertainty.

7) The Committee considered the document on Guidance on Measurement Uncertainty prepared by the Delegation of the United Kingdom in order to address the issues raised at the last session of the Committee and the Commission. The Delegation indicated that the purpose of the paper was to provide simple explanations on the nature of measurement uncertainty, the procedures for its estimation, and to consider its relationship with analytical results and the method used to obtain the result. The document also provided information on the procedures developed by several international organizations for the estimation of measurement uncertainty. The Delegation noted that some laboratories might underestimate uncertainty and report it unrealistically to their customers, and stressed the importance of addressing uncertainty for the purpose of export control and in case of dispute situations.

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1 CX/MAS 07/28/1

2 CX/MAS 07/28/2, CX/MAS 07/28/2-Add.1 and CX/MAS 07/28/2-Add.2 (Guidance on Measurement Uncertainty), CRD 14 (comments of Chile)

8) Several delegations expressed their appreciation to the Delegation of the United Kingdom for this useful paper and supported further work in this area. Some delegations supported the development of recommendations to Commodity Committees, while other delegations stressed the importance of guidance to national authorities on how to address measurement uncertainty, especially in order to prevent problems in international trade.

9) In view of these comments, some delegations sought clarification on the scope of the document that could be developed, and whether it was intended for governments or in the framework of Codex. The Delegation of the United Kingdom indicated that the main objective was to provide guidelines to national governments on how to address measurement uncertainty but it was also important to give additional guidance to commodity Committees as to how to take into account the uncertainty when setting provisions in Codex standards.

10) The Committee agreed that an electronic working group coordinated by the United Kingdom and open to all interested members and observers, would prepare proposals for guidance on measurement uncertainty, as guidelines intended for governments and as recommendations to Codex committees, as appropriate. The Committee would consider these proposals at its next session in order to decide what type of new work should be undertaken.

Methods of Analysis for Dioxins

11) The Committee recalled that while considering the adoption of the Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds, some delegations had expressed some concerns on the methods used and suggested to refer the provisions on methods of analysis and sampling in the Code to the CCMAS.

12) The Delegation of the European Community pointed out that at this stage further revision of the Code of Practice was unnecessary and therefore the Code should remain as adopted.

13) The Delegation of Thailand recalled the importance of monitoring the level of dioxins and expressed the view that the methods for the determination of dioxins were a new challenge as the techniques involved were sophisticated and too costly, and that it was difficult for developing countries to use them. These views were supported by several delegations. The Delegation of Cuba expressed the view that when methods requiring high technology were proposed, alternative methods should also be considered.

14) The Delegation of Thailand proposed to apply the criteria approach to the determination of dioxins and Dioxin-like PCBs and the committee agreed that this could be discussed under Agenda Item 5b while considering the conversion of methods to criteria.

15) The Chair recalled that the Committee had considered the methods for the determination of dioxins at its last session and had forwarded a request for clarification on the purpose of the methods to the Committee on Contaminants in Foods (CCCF) (ALINORM 06/29/3, para. 95). Further consideration of the methods for dioxins would therefore depend on the reply that would be received from the CCCF, to be held in April 2007.

Reference to the IUPAC/ISO/AOAC Protocols

16) The Committee recalled that the Commission, while considering the update of the reference to the International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories, had noted that the Food Control Laboratory Management Recommendations (CAC/GL 28-1995) mentioned the above Protocol together with two other texts adopted by reference in 1997 and had asked the CCMAS to clarify whether these texts should be identified separately or under a single reference.

17) The Committee agreed that it would be easier for the purposes of reference to identify each text separately and therefore proposed to the Commission to identify as separate Guidelines the following texts:

- International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories (1995, revised 2006)
- Protocol for the Design, Conduct and Interpretation of Method Performance Studies (1997)
- Harmonised Guidelines for Internal Quality Control in Analytical Chemistry Laboratories(1997)

DRAFT GUIDELINES FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS (Agenda Item 3a)[3]

18) The Committee recalled that its last session had agreed to return the draft Guidelines to Step 6 for redrafting by an electronic Working Group led by the Delegation of New Zealand and for consideration by this session of the Committee.

19) The Delegation of New Zealand indicated that the revised draft took into account the comments made at the last session especially with regards to the need for simplification of the document and the removal of the scientific and technical detail, but that due to the late revision of the document it had not been circulated for comments prior to the current session of the Committee and proposed that the guidelines be circulated at Step 6 for further comments.

20) The Delegation drew the attention of the Committee to its recommendations proposed in CX/MAS 07/28/3 to consider the core Guidelines and to provide the electronic working group with guidance as to the scope and general principles; to consider the criteria set out for acceptance of methods; agree that the working group continue work on additional annexes to the guidelines giving recommendations on statistical procedures and that the Codex guidelines for method-performance studies should be updated.

21) In addition the Delegation informed the Committee of its intention to publish three papers on methods of providing confidence intervals for estimates of precision parameters; considerations relating to the estimation of bias and its uncertainty of estimation in method performance studies; and the impact of uncertainty relating to estimates of bias and precision on producer's risks in tests for product compliance, the incorporation into compliance tests and tests for method acceptability of suitable controls of this possible impact.

22) The Committee had a general discussion on the recommendations as proposed. Several delegations expressed the view that it was not clear who the document was aimed at and that only once this had been clarified the document could be further developed. Some delegations were of the opinion that the guidelines could serve as a valuable tool for competent authorities on how to select methods that were fit-for-purpose. Other delegations proposed that if the guidelines were intended for the purpose of endorsement, an approach similar to that proposed for uncertainty as stipulated in CX/MAS 07/28/2-Add.2 be followed.

23) It was also suggested to clarify how the guidelines would affect the criteria approach and the conversion of methods for trace elements into criteria. Some delegations expressed the view that the application of the approach outlined in the revised text would entail considerable changes to the current practice in the evaluation of acceptable methods and therefore did not support further development of the guidelines at this stage.

24) In addition, the Observer of AOCS speaking as secretary to the IAM requested clarification on whether ISO 5725:1996 and IUPAC Harmonization Protocol to Determine Performance Criteria for Methods of Analysis had been taken into account in the development of the guidelines and how this work would affect the activities of standards development organisations.

25) Several delegations proposed to suspend further development of the guidelines pending peer review by the scientific community of the proposed papers. Other delegations highlighted the importance of this work especially to countries that needed guidance on how to evaluate acceptable methods and were of the opinion that the two processes could run concurrently.

26) After considerable discussion, the Committee agreed that further development of the guidelines would be suspended pending publication in scientific journals and peer review and that the next session of the Committee would consider how to proceed with the development of the guidelines. The Committee expressed its gratitude to the Delegation of New Zealand for the work done.

Status of the Draft Guidelines for Evaluating Acceptable Methods of Analysis

27) The Committee agreed to suspend further development of the Guidelines and to retain them at Step 7 until publication of papers in scientific journals.

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[3] CX/MAS 07/28/3; CRD 4 (comments of Japan), CRD 17 (comments of Kenya)

DRAFT GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS (Agenda Item 3b)[4]

28) The Committee recalled that the 29th Session of the Commission had adopted the Draft Guidelines at Step 5 with the understanding that the comments submitted to the Commission would be considered by the next session of the Committee, and that they had been circulated for comments at Step 6.

General Discussion

29) The Delegation of Germany, speaking on behalf of the member states of the European Community present at the session, informed the Committee that they had proposed a revised, simplified, and more focused document, as presented in CRD 19.

30) The Delegation of the United Kingdom indicated that the revised text was based on measurement uncertainty and not on the precision characteristics of the method, since laboratories should be accredited to ISO/IEC 17025:2005. The revised text also took into account the more recent Codex texts, especially the Guidelines on Measurement Uncertainty, and the fact that measurement uncertainty should be reported with the results. The Delegation stressed that the main issue was the uncertainty in the results and not the validation of the method itself, and on that basis the guidelines had been simplified to address the main causes of disputes.

31) The Delegation of Argentina, supported by several other delegations, expressed the view that the guidelines should not apply to microbiological methods as there were frequent discrepancies between the initial and subsequent results of the tests carried out for confirmation when samples were re-analysed due to the specific characteristics of microbiological contamination. The Committee therefore agreed to exclude microbiological analysis from the scope of the guidelines and noted that in the future consideration could be given to the development of additional annexes that could cover specific areas of food analysis.

32) The Delegation of New Zealand stressed the need to facilitate rapid resolution of disputes and for this purpose proposed to recommend a three way split of the samples in order to allow confirmatory analysis, to add a new Step 3 on the analysis of reserve samples, and to include in the Annex a calculation of the reproducibility limit to allow for comparison of sample means.

33) The Delegation of Japan proposed to replace the reference to official accreditation of laboratories with “compliance with the general criteria for the testing laboratories laid down in ISO/IEC 17025:2005” to make the text consistent with that of the Guidelines GL 27-1997.

34) Some delegations expressed the view that the document was very useful, that they had considered its application at the national level, and that in particular the flow chart should be further developed to facilitate its application. Some delegations stressed the importance of the practical application of the guidelines in the area of contaminants where disputes were more likely to occur at the import stage. The Delegation of Algeria noted that analysis of a lot at the import stage could result in non conformity of products that were in conformity at the export stage, due to deterioration during transport or to chemical treatment at the point of import, and stressed the importance of taking into account practical experience in the development of the guidelines.

35) Some delegations proposed to refer the guidelines to CCFICS as it was related to import and export inspection. The Committee recalled that the document had already been submitted for advice to the CCFICS in its initial stage and that it had been developed in the light of the recommendation of CCFICS that it should not be too prescriptive.[5]

36) The Committee noted the offer of the Inter Agency Meeting to host a workshop on measurement uncertainty in conjunction with the next session of the CCMAS.

37) Following the general discussion, the Committee considered the first two sections and made the following amendments and comments.

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4 CL 2006/47-MAS, CX/MAS 07/28/4 (comments of Argentina, Australia, Brazil, Cuba, Iran, Malaysia, New Zealand, Norway), CX/MAS 07/28/4-Add.1 (comments of Japan), CRD 7 (comments of Indonesia), CRD 8 (comments of United States), CRD 13 (comments of Thailand), CRD 17 (comments of Kenya) CRD 19 (comments of the EC)

5 ALINORM 03/23, para. 29 and ALINORM 01/30, para. 101

Title

38) The Delegation of the European Community proposed that the title would read "Draft Guidelines for Settling Disputes over Analytical Disputes (Test) Results with respect to the compliance of a lot to a legal specification" in order to clarify the nature of the dispute. Several delegations however objected to this change as the term "legal specification" would create some confusion, and the purpose of the guidelines was described clearly in the text. The Committee agreed to retain the current title and to add any additional clarification that would be required in the text.

Scope

39) The Committee agreed with the proposal of the Delegation of Hungary to clarify that the tests were carried out on the lot, not the consignment, and amended the first sentence accordingly. A footnote referring to the definition of the lot in the General Guidelines on Sampling was also inserted. A similar change was made in the Prerequisites Section, second paragraph in order to ensure consistency.

40) In the third paragraph, the Committee agreed to amend the text and Footnote 3 to clarify the possible reasons for disputes which were not covered in the guidelines and should be investigated. The last sentence on guidance on measurement uncertainty was deleted as this would be covered under the prerequisites section.

41) The Delegation of India proposed to delete the second paragraph as it was a duplication of the first and to replace it with the text: "These Guidelines should be limited to chemical, physical and physico-chemical analytical tests only and will not cover microbiological tests".

42) Following its general decision to exclude microbiological analysis, the Committee agreed to insert a new sentence to that effect at the end of the section. Some delegations supported a text describing the areas that were covered (chemical and physical analysis), however the Committee agreed that it was preferable to specify only the area that was excluded from the scope, as this meant that all other types of methods were covered by the guidelines.

43) The Committee considered the inclusion of the additional sentence proposed in the comments from the EC that "the settlement of the dispute without new analysis or sampling operations should be the preferred option". Some delegations, while not objecting to the text itself, noted that it would be more appropriate to include it either in the prerequisites or the section on the procedures for settlement of disputes. The Committee could not come to a conclusion on this proposal.

Prerequisites

44) The Committee discussed the proposal from Japan to indicate a first prerequisite, to the effect that "the importing country and the exporting country reach agreement on using these Guidelines to settle the dispute over analytical (test) results". The Delegation of New Zealand proposed to add at the end of this prerequisite that the parties to the disputes "agree that the only question at issue is the validity of the analytical test results"

45) The Delegation of France expressed the view that this important provision would be more adequately included in the section on procedures as it related to the dispute settlement, whereas the prerequisites section referred to the material conditions necessary to apply the procedure. The Committee did not come to a conclusion on the addition of this requirement and agreed that it would require further discussion at the next session.

46) The Committee agreed to clarify that the laboratories "have been designated by their respective competent authorities in both the importing and exporting countries", as proposed in the comments of the EC, and a similar amendment was made in the second paragraph.

47) The Delegation of Malaysia questioned the requirement for a sample to be taken by each competent authority as it was not common practice to take samples when it was not known whether a dispute would occur. The Committee noted that in some countries, the procedure could not be carried out if samples had not been taken at the export stage, while in other countries, common practice at the import stage in case of disputes was to give a sample to the importer who would forward it to the exporting country authority.

48) The Delegation of New Zealand proposed to insert the words "<u>or samples have</u> been split" and to recommend a three way splitting of the samples in order to obtain two duplicates of the contentious sample for dispute resolution. Several delegations indicated that they were required to use triplicate samples at the national level and did not support the splitting of the initial samples in cases of disputes. Other delegations

supported the use of a single sample that could be split if further analysis was required. The Committee could not come to a consensus on this question and agreed to consider it further at its next session.

49) The Delegation of India proposed that the time frame for each step might be laid down as most of the foodstuffs exported are perishable in nature.

50) The Committee recognized that it would not be possible to consider the entire document at the present session in view of the extensive comments and changes proposed to all sections, and discussed how to proceed further.

51) Several delegations supported the approach based on measurement uncertainty as it took into account the current situation in laboratory analysis and the Codex guidelines in this area and therefore proposed to take the revised version in CRD 19 as a basis for further development of the guidelines.

52) Other delegations, while not objecting to the revised approach, stated that the revised text required further consideration and that they could not take a position at this stage since it had been presented at the session. These delegations proposed to retain the document included in the Circular Letter for further consideration.

53) After some discussion, the Committee agreed to circulate the following text for further comments: sections 1 and 2, as amended at the current session, section 3 of the original document in CL 2006/47-MAS, and section 3 and the remaining part of CRD 19 as an alternative text in square brackets.

Status of the Draft Guidelines for Settling Disputes over Analytical (Test) Results

54) The Committee agreed to return the Draft Guidelines, as amended at the present session, to Step 6 for further comments and consideration at the next session (see Appendix IV).

55) The Committee agreed that its objective would be to finalise the Draft Guidelines at its next session for adoption by the Commission in 2008.

REVIEW OF THE ANALYTICAL TERMINOLOGY FOR CODEX USE (Agenda Item 4)[6]

56) The Committee recalled that its last session had agreed that the Delegation of the United States, with assistance of an electronic working group would prepare a first draft of the Guideline for comments at Step 3 following approval by the Commission to transfer the terminology section in the Procedural Manual to a separate Guideline and proceed with its revision.

57) The Delegation of the United States introduced the document and explained that CRD 17 as presented at the last session of the Committee was used as a basis for its development. The Delegation also noted that several definitions were still under development by ISO and VIM and that the current list would be updated once these had been finalized. Since the document had not been circulated for comments prior to this session, the Delegation proposed that it be attached to the report of the current session with an invitation by Circular Letter for comments from interested parties upon which revisions could be made. The Delegation also acknowledged the contribution of the late Dr. Horwitz in providing guidance during the development of the document.

58) The Delegation further referring to its comments in CRD 5 proposed that editorial corrections be made to the current definition for linearity as it appeared in the Procedural Manual. The Committee agreed to this proposal and the secretariat indicated that it would be corrected in the next edition of the Procedural Manual.

59) The Committee agreed to hold a general discussion on the document and noted the following contributions.

60) The Observer from AOCS speaking as the secretariat of the IAM noted that several definitions in the document were taken from original sources such as ISO, NMKL and others and reproduced without modification but that although a hierarchy existed between VIM and ISO that the document had chosen to use the most appropriate definitions for Codex purposes and that this could cause confusion for analysts. In acknowledging that Codex should use the most appropriate definitions for its purposes, it was proposed that a practical guide be developed as an adjunct to this guideline to provide countries with a practical approach for the use of these definitions. The Committee agreed to this proposal and requested IAM to consider its development.

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6 CX/MAS 07/28/5; CRD 5 (comments of United States)

61) Several delegations proposed the introduction of some additional definitions of terms already in use in several adopted Codex texts such as fitness-for-purpose', 'between laboratory standard deviation' and alpha and beta-error', amongst others; the inclusion of the IUPAC definition for 'selectivity' and amendments to the 'HorRat' definition.

62) The Delegation of Chile questioned the proposed definition for Limit of Quantification (LOQ) noting that LOQ was not equivalent to limit of determination as stated in the proposed definition.

63) To the concern raised by a delegation on how Codex would keep in step with definitions being developed by several other international organisations especially in the field of metrology, statistics, quality management and analytical chemistry, it was clarified that it was the function of the CCMAS to coordinate the update of definitions.

64) In noting the proposals and comments made, the Committee agreed that the Delegation of the United States, with assistance of an electronic working group, would redraft the draft Guidelines taking into account discussions at the present session and written comments submitted.

Status of the Proposed Draft Guideline on Analytical Terminology

65) The Committee agreed to return the Proposed Draft Guideline to Step 3 for comments, redrafting by an electronic working group led by the Delegation of the United States and consideration at the next session (see Appendix V).

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS (Agenda Item 5a)[7]

66) The report of the ad hoc Working Group on Endorsement of Methods of Analysis (CRD 1) was presented by its Chair, Dr Roger Wood (United Kingdom). The Committee considered the methods proposed for endorsement and in addition to editorial changes made the following amendments and comments.

Committee on Processed Fruits and Vegetables

Draft Standard for Pickled Fruits and Vegetables

Determination of arsenic

67) The Committee noted that the methods for determination of arsenic could be converted to criteria, but that due to time constraints the working group could not make any recommendations on this for consideration by the Committee.

68) To the question raised by the Observer of NMKL on the appropriateness to endorse the AOAC 952.13 as Type II method, it was explained that although the method was a surplus method, that it had not been withdrawn, but might simply not be that readily available and that this issue should be further discussed. Some delegations were of the opinion that clear guidance needed to be given on how to proceed with this matter in future. It was agreed that the paper on the conversion of methods into criteria using trace elements as an example could provide further guidance and basis for discussion at the next session (see also Agenda Item 5b).

Determination of benzoic acid and sorbates

69) The Committee agreed with the proposal to include the more recent NMKL method by liquid chromatography as Type II. In addition, it recognised that the AOAC 983.16 was the same as NMKL 103 and endorsed these methods as Type III.

Determination of lead

70) It was clarified that the method for the determination of lead was a flame atomic absorption method in view of the level to be detected. The Delegation of Algeria pointed out that the flame atomic absorption method was not appropriate for trace analysis, and in that case the graphite furnace atomic absorption method was entirely adequate.

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[7] CX/MAS 07/28/6, CX/MAS 07/28/6-Add.1, CRD 1, CRD 11 (comments of Republic of Korea), CRD 12 (comments of AOCS), CRD 16 (methods submitted for endorsement by FAO/WHO Committee for the Near East)

Determination of pH

71) The Committee noted that the working group had had extensive discussion on whether the methods proposed for the measurement of pH should be classified as either Type I or II, accepted that the methods proposed were rational methods, equivalent and used as alternative procedures and thus endorsed the AOAC and NMKL methods as Type III and II, respectively.

Draft Standard for Processed Tomato Concentrates

72) The Committee agreed that the method for tomato soluble solids, AOAC 970.59, was the more appropriate of the two methods proposed by the Committee on Processed Fruits and Vegetables, endorsed it together with all other methods proposed and corrected the reference of the method for lactic acid.

Draft Standard for Preserved Tomatoes

73) The Committee endorsed all methods proposed with the exception of the method for the determination of drained weight for crushed style tomatoes which was temporarily endorsed pending confirmation of the correct ISO reference.

74) The Committee endorsed the NMKL method as Type II and the AOAC method as Type III for the determination of calcium, although it was noted that the AOAC method had been endorsed as Type II as a general method for processed fruit and vegetables. The Committee agreed that the general method for the determination of calcium for processed fruits and vegetables might need updating as this could cause confusion to analysts.

FAO/WHO Coordinating Committee for Asia

Proposed Draft Standard for Gochujang

Determination of Capsaicin

75) The Committee agreed with the proposal to endorse the AOAC method as Type II and to temporarily endorse the methods proposed in Annexes A and B as Type IV since these were not yet fully validated and noted the on-going work in this regard and encouraged the Delegation of the Republic of Korea to consider further validation of these methods.

Other Considerations

76) The Committee temporarily endorsed the methods for determination of crude protein as Type I since the scope of this method had not been extended to this matrix (Gochujang), but was satisfactorily used in the industry and the method for moisture as Type I as further clarification should be provided on the range of temperatures for drying.

Committee on Fish and Fishery Products

Proposed Draft Standard for Live and Bivalve Molluscs

Determination of Biotoxins

77) The Committee agreed to endorse the method for determination of the saxitoxin group in shellfish as Type II. It did not agree with the recommendation to endorse the method for determination of domoic acid but agreed to inform the Committee on Fish and Fishery Products that the recently published AOAC 2006:02 for the determination of domoic acid by ELISA was available for their consideration.

Codex Committee on Fats and Oils

Draft Standard for Fat Spreads and Blended Spreads

78) The Committee noted that the methods put forward by CCFO were to determine fat content by calculation, but since no provisions existed in the Standard for moisture or solids non-fat as such and since a direct method for the determination of fat was available, endorsed the direct method for determination of fat as a replacement for the three methods put forward by CCFO.

Draft Amendment to the Standard for named vegetable oils: rice bran oil

79) The Committee endorsed the method for gamma oryzanols in rice bran oil as Type IV since the method had not yet been fully validated and agreed to encourage countries involved in the work on the development of the method to complete validation studies.

Update of existing methods for fats and oils

80) The Committee noted and agreed with the updates as presented in CRD 1, however in view of the proposals made in the paper on conversion of methods to criteria on the appropriateness of the methods for determination of arsenic (as also mentioned in previous discussions), agreed that in future this question would need to be carefully considered and that perhaps the IUPAC method previously used for determination of arsenic could be reconsidered if appropriate.

Codex Committee on Nutrition and Foods for Special Dietary Uses

Draft Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

81) The Committee agreed that the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) needed to further consider the proposed methods since many required updating and agreed to refer all methods back to CCNFSDU. In particular the Committee made the following comments:

82) The list included two methods for total dietary fibre and clarification was needed on which of these methods should be used and for what purpose.

83) In general, methods using microbioassay as a principle should be reviewed, as well as the methods for determination of PER, carbohydrates and fat in order to replace them with more modern methods.

84) Clarification was required as to how Vitamin C was expressed and on the differences between the methods proposed for Vitamin K, B12 and B6.

85) It was recommended that the method for sodium and potassium be replaced with the ISO 8070|IDF 119.2007 method (atomic absorption).

86) As regards crude protein, the Committee agreed that the conversion factors included in the method proposed corresponded to the earlier standard and recommended that the CCNFSDU correct the conversion factor for soy protein to 5.71 in the description of the method in order to be consistent with the provision in the revised standard.

Update of other Methods

87) The Committee agreed to update the references to some methods as consequential or related amendments to the update of the methods for fats and oils It noted that the method for determination of free fatty acids in the Standard for Cocoa Butter (CODEX STAN 86-1981) measured free acidity and allowed for conversion to fatty acids and thus agreed to update the method as Type I.

88) In updating the methods in the Guidelines for Nutrition Labelling, it was noted that AOCS Ce 1h-05 was also available as a validated method for the determination of trans unsaturated fatty acids and agreed to inform the CCNFSDU of this.

FAO/WHO Coordinating Committee for Near East

89) The Committee considered the methods proposed for endorsement by the CCNEA in CRD 16 and noted that these methods had not been presented to the Working Group due to their late submission. Although it was noted that the methods were mainly AOAC methods and collaboratively tested, the Committee did not agree to endorse them since several of the methods proposed were relatively old and could be replaced by more recent methods, limited background information was available and a short time was allowed for their consideration. The Committee therefore agreed that the methods should be resubmitted to the Committee in a more suitable format for consideration at its next session.

Other issues

90) The Committee, taking into account discussions by the Working Group on how to introduce the Dumas method for determination of protein in soy protein products in addition to the Kjeldahl method, and its earlier discussion on methods for pH, agreed that in future it would need to have discussions on how to clearly differentiate between Type I and Type II methods. The Committee was informed that the United Kingdom had commissioned work on this aspect which would be completed shortly and requested the Delegation of the United Kingdom to provide an update on this work to the Committee at its next session to facilitate discussion in this regard.

91) The Committee expressed its appreciation to Dr Wood and to the Working Group for their excellent work, which had facilitated discussion in the Plenary Session, and agreed that it would be reconvened prior to the next Session. The Status of the endorsement of methods of analysis is presented in Appendix III.

CONVERSION OF THE METHODS FOR TRACE ELEMENTS INTO CRITERIA (Agenda Item 5b)[8]

92) The Delegation of Sweden recalled that the last session had considered a discussion paper on the conversion of methods for trace elements into criteria and had agreed that Sweden, in cooperation with NMKL, would further develop the document for consideration at the next session.

93) The Observer of NMKL highlighted the main technical aspects of the document, as follows: the methods criteria and characteristics for use in trace element analysis presented in Table 1, the explanation as to how the values of the criteria were selected, with specific examples of the application of the criteria and the problems to be addressed. For example, the LOD was set at one tenth of the maximum level for a specific heavy metal but when the maximum level was at low levels such as 0.1 mg/kg, the LOD was set at one fifth of the maximum level. It was also noted that for some commodities such as fats and oils or foods with a high fat content, separate methods validated for the appropriate matrices would be necessary.

94) Taking into account the data on the characteristics of methods, as available in the reports of collaborative trials, the values of the criteria had been specified for all Codex methods currently used for the determination of heavy metals. On that basis, Codex methods for heavy metals were listed in Table 4 according to the selected method performance characteristics and criteria, and according to compliance or non compliance with basic validation requirements, depending on their method performance characteristics. The Observer pointed out that a number of current methods did not meet the criteria, as in some cases the LOD was greater than the maximum level specified in the standard, or the performance of the method close to the ML could not be assessed.

95) The Committee expressed its appreciation to the Delegations of Sweden and the Observer from NMKL for their excellent work on the complex issues related to the criteria approach. Several delegations indicated that the document was an excellent basis to develop recommendations on the conversion of methods into criteria, and made the following suggestions for further work. The Delegation of the United States proposed hat the document should be rewritten more descriptively and in a format which could provide stepwise instructions for developing criteria from existing methods, and explanations of how the criteria were established. The Committee also noted the written comments of Japan intended to provide clarification in the document.

96) The Delegation of New Zealand commented that, to be consistent with the principles proposed for the evaluation of acceptable methods, allowance should be made, if necessary, for measurement error and the imprecision of its estimates. The relative bias should be justified in terms of fitness for purpose, and the criteria should be met with a stated level of confidence.

97) The Observer from NMKL indicated that the criteria were intended to evaluate the characteristics of the methods and therefore the measurement uncertainty related to measurement itself was not considered.

98) The Delegation of the United Kingdom supported further work on the development of guidance in a simple form that could be used by Codex Committees, in addition to the current provisions on criteria in the Procedural Manual. The Delegation informed the Committee of the approach followed at the national level and in the EU in addressing measurement uncertainty, and that in certain sectors a limit was specified for uncertainty. The Delegation pointed out that the information on the characteristics of the methods would allow the Committee to reconsider the endorsement of the methods that did not meet the criteria and were not adequate for the analysis of heavy metals at the maximum level specified in the standards.

99) The Observer from IDF cautioned that the criteria approach would increase the workload of laboratories and that the Committee needed to consider carefully the implications of the conversion of methods into criteria.

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8 CX/MAS 07/28/7, CRD 4 (comments of Japan), CRD 9 (comments of United States)

100) Several delegations supported the development of guidance intended for governments on the conversion of methods to criteria in order to facilitate comparisons of the methods between laboratories and to determine equivalence, especially for the purpose of export and import control.

101) The Committee agreed that the Delegation of Sweden, with the assistance of Norway and NMKL, and interested members and observers, would revise the document in order to develop guidance on the conversion of methods into criteria for Codex committees and for governments, as appropriate. The Committee would decide at its next session whether to undertake new work on recommendations for Codex purposes and on guidelines for governments. It was further agreed that the characteristics of current methods for heavy metals according to the criteria (Table 4) should be retained in the document as an example and as a basis for further review of current methods. The Committee agreed that this review would be carried out as part of its work on the endorsement of methods of analysis.

102) The Committee also agreed that the revision of the paper would take into account the proposal from the Delegation of Thailand to consider criteria for the methods for dioxins and dioxin-like PCBs, as mentioned under Agenda Item 2.

CRITERIA FOR THE METHODS FOR THE DETECTION AND IDENTIFICATION OF FOODS DERIVED FROM BIOTECHNOLOGY (Agenda item 6)[9]

103) The Committee recalled that its last session had agreed that an electronic working group led by Germany and the United Kingdom would revise the discussion paper for consideration by this session.

104) The Delegation of Germany informed the Committee that a new revised document (CRD 18) had been prepared during the current session with assistance of the delegations of the United States, France, European Community and United Kingdom, taking into account all comments made at previous sessions of the Committee, and proposed that this document be considered by the Committee.

105) It was indicated that an effort had been made to incorporate these comments into the revised document and particularly to address the concerns expressed previously to include protein-based methods in addition to PCR–based methods. The Committee was informed that the document comprised a general section and six annexes providing information that needed to be provided when a method is to be considered for endorsement by the Committee; applicable definitions; validation of PCR-based and protein-based methods and proficiency testing of foods derived from biotechnology. The Delegation proposed that the Committee consider the document further and that it be brought forward as a new work item.

106) The Delegation of the European Community, supported by the Delegation of Norway, stressed the importance of this work in the light of increasing introduction of foods derived from biotechnology and the need for identification of methods using the criteria approach and thus supported its development as a new work item.

107) The Delegation of the United States, supported by several delegations, while acknowledging the importance of the revised document, noted that it had been available only at the session, proposed that the document be circulated to members of the electronic working group and revised as necessary for consideration by the next session.

108) Several delegations also indicated that in addition to the revision of the document which seemed to focus on guidance within Codex, that there was a need for guidance to member countries and proposed that the electronic working group consider the development of such guidance.

109) To the question of the Delegation of Cuba on whether the document should be submitted to the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology for review, it was clarified that the work under discussion originated from that Task Force[10] as well as the Committee on Food Labelling, that the Task Force was mainly responsible for the development of guidance on risk assessments for foods derived from biotechnology and that the work of this Committee was notified to other Codex Committees where necessary through the standard item of matters referred.

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9 CX/MAS 07/28/8, CRD 10 (comments of the United States), CRD 15 (comments of AOCS), CRD 18 (comments of the EC)

10 ALINORM 01/23, paras 10-12; ALINORM 03/23, paras 71-81

110) The Committee held considerable discussion on whether the revision of the document should also be considered by a physical working group either prior to the next session or between sessions as a means of facilitating discussion at the next session. Many delegations preferred the establishment an inter-session physical working group as this would allow sufficient time for the circulation of the revised document for consideration by members, which would not be the case if the group met prior to the session.

111) Following this discussion, it was agreed that the electronic working led by the Delegations of Germany and the United Kingdom would revise the current document and in addition would give consideration to the development of guidelines for governments and prepare a project document as a proposal for new work. It was further agreed to establish a physical working group to be hosted by Germany that would meet inter-session, if necessary, in accordance with the guidelines for physical working groups in the Procedural Manual. The Committee emphasized that the revised document would need to be circulated to members well in advance of the next session to allow for its thorough consideration.

REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT OF CODEX SAMPLING PROCEDURES (Agenda Item 7)[11]

112) The Committee recalled that at its last session, the Delegation of Japan had drawn the attention of the Committee to the fact that the Principles for the Establishment or Selection of Codex Sampling Procedures in the Procedural Manual referred to the Sampling Plans for Prepackaged Foods, that had been superseded by the General Guidelines on Sampling adopted by the Commission and its decision that the Delegation of Japan would update the section of the Procedural Manual dealing with this matter, taking into account the adoption of the Guidelines, for consideration by the current session.

113) The Delegation of Japan informed the Committee that it had prepared two draft revisions for its consideration. It explained that option one included minimum changes necessary to reflect the adoption of the General Guidelines on Sampling, whereas option two included changes as in option one, other editorial modifications and references to the General Guidelines as well as to Table 1 of these guidelines for ease of use.

114) Delegations generally agreed to propose option 2 for endorsement by the Committee on General Principles since this option provided better coherence with other adopted Codex texts.

115) The Delegation of New Zealand while supporting option 2 suggested it would be useful to consider whether Codex should prescribe sampling plans, or perhaps preferably specify criteria that sampling plans should meet. With regard to the section on sampling plans for compositional criteria, the Delegation noted that the General Guidelines do not cover sampling in the presence of significant measurement uncertainty and informed the Committee that the Committee on Milk and Milk Products were in the process of developing a discussion paper on the subject.

116) The Delegation of the United Kingdom also expressed support for option 2, but reminded the Committee that principles for sampling and methods of analysis on which guidance in Codex were based were dated and that in future these would need to be revisited to take into account new work such as sampling uncertainty.

Status of Revision of the Principles for the Establishment of Codex Sampling Procedures

117) The Committee agreed to submit option 2 to the Committee on General Principles for endorsement as an amendment to the Principles for the Establishment or Selection of Codex Sampling Procedures (see Appendix II).

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS AND SAMPLING (Agenda Item 8)[12]

118) The Secretary of the Inter-Agency Meeting, Dr Richard Cantrill (AOCS), introduced the report of the 19th IAM presented in CRD 2. In noting that several outputs of this report (harmonisation of analytical terminology; the paper on Guidelines for Evaluating Acceptable Methods of Analysis; the paper on measurement uncertainty and editorial corrections to method references) had been considered under earlier

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11 CX/MAS 07/28/9

12 CRD 2 (Report of the 19th Meeting of the International Organisations Working in the Field of Methods of Analysis and Sampling (Interagency Meeting))

items on the agenda or at the Working Group on Endorsement of Methods and Analysis and Sampling, he highlighted the following important issues discussed at the IAM.

119) It was indicated that with the adoption of the criteria approach, there was an increased need among analytical chemists for fully validated official methods of analysis and that little progress had been made on the request to Members to consider collection and collation of validation data to meet criteria for inputs into the Revision of Codex methods that do not meet criteria, since members were not necessarily holders of data, but of the final methods developed.

120) It was reported that the IAM had considered a presentation of results on work carried out at the Joint Research Centre (JRC) (Geel) on the evaluation of collaborative trial results where results corrected and uncorrected for recovery were reported and where both sets of results were used to calculate performance parameters of the methods. It was indicated the presentation would be available through the IAM website.

121) The Committee was informed that the IAM website would continue to include information on work programmes of IAM members, links to publicly available newsletters and news items of IAM individual members and lists of published standards and links to newly published standards.

122) He further informed the Committee of work by NMKL on approaches to international guidelines for the validation of qualitative methods through collaborative trials, the launch of the EU-funded MoniQA project and that the IAM was awaiting the outcome of discussions on the work on criteria for detection and identification of foods derived from biotechnology.

123) Finally, he informed the Committee of the retirement of Mr. Fred van Luin of the IDF, that the AOCS would continue as the Secretariat of the meeting and that Dr Wood would continue to chair this meeting for another year.

124) The Committee expressed its appreciation to the international organizations participating in the meeting of the IAM for their contribution to the work of the Committee and to the Hungarian Food Safety Office for hosting the IAM. It also noted that the next IAM would be held on the Friday prior to the next Session of the Committee.

125) In response to a question posed by the Delegation of Brazil as to the status of IAM within Codex, it was clarified that all members of IAM had observer status within Codex and that IAM was not a formal organisation but a meeting that takes place prior to Sessions of CCMAS.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)[13]

The Role of CCMAS with Respect to Methods without Detailed Provisions in Codex-Standards

126) The Delegation of the Netherlands informed the Committee that in view of the difficulties experienced in developing or endorsing methods of analysis when no provisions existed in Codex standards, it had prepared a discussion paper in this regard as requested by the last session of the Committee. The discussion paper highlighted several of the instances where difficulties arose, for example in the endorsement of methods of analysis for the Standard for Fruit Juices and Nectars for which no numerical values existed. It was proposed that the Committee discuss the limitations of its terms of reference and that it consider new work to identify unwanted restrictions in its terms of reference and to propose changes where necessary.

127) Several delegations supported the proposal for new work and emphasized that in future, the Committee may increasingly need to look at methods for which no standards existed.

128) Several other delegations were of the view that no amendment was necessary since the Committee had been able to provide advice on methods within its current terms of reference.

129) Taking into account the divergent views, the Committee agreed to request the Delegation of the Netherlands to further develop the discussion paper and to provide further evidence of restrictions with respect to the Committee's terms of reference for consideration by the next session.

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13 CX/MAS 07/28/10, CX/MAS 07/28/11, CRD 6

Uncertainty of Sampling

130) The Delegation of the United Kingdom informed the Committee that the EURACHEM/EUROLAB/CITAC/Nordtest *Guide on the Estimation of Measurement Uncertainty Arising from Sampling* would be published soon and that comments on this Guide were welcome.

131) The Delegation recommended that the Committee recognise the existence of the Guide and that it was critical that the Committee recognise that a decision should be taken on whether sampling uncertainty should be taken into account when assessing compliance or whether it wished to take the non-scientific or simplistic route of defining sampling uncertainty as being zero.

132) The Committee was further informed that the European Union had commissioned a project in this area which further illustrates recognition of this issue.

133) The Delegation of Australia agreed that sampling uncertainty was important and needed attention and was certainly applicable in the appropriate circumstances. However Australia felt that assessing compliance against an MRL was not one of those circumstances as the MRL does not reflect the average concentration of a lot but rather a maximum value for a sample taken in accordance with a defined sampling plan. The Delegation of Hungary indicated that uncertainty of sampling should be taken into account in all cases, including testing for compliance with MRLs for the purpose of export.

134) The Delegation of New Zealand noted that this was an important subject, but expressed its serious reservations with regard to the soundness of the work on the above *Guide* and indicated that it would provide comments on the *Guide*. As regards the development of guidelines the Delegation stressed the need to clarify whether Codex limits applied to the average concentration of the lot or of the sample.

135) Several delegations expressed the importance of this work and indicated the need for guidelines on the interpretation of sampling uncertainty and noted that the focus should be on sampling of food whereas the scope of the draft *Guide* was more general. The Delegation of India proposed that simple guidelines for uncertainly of sampling might also be prepared as an Annex for better implementation by customs or competent authorities. The Delegation of the United Kingdom noted the need for guidelines and offered to incorporate as an appendix such guidelines in the work currently under development on guidelines for measurement uncertainty (see Agenda Item 2).

136) The Committee noted the information provided by the Delegation of Norway of the Nordtest workshop on sampling uncertainty to take place on 12-13 April 2007.

The Role of CCMAS Regarding Reliability of Published Analytical Data

137) The Delegation of Sweden drew the attention of the Committee to the reliability of published data and stated that increasing amounts of data were being published in international journals for example for trace elements of which the quality was questionable, which means that decisions were based on false data. The Delegation proposed that Codex consider the development of guidelines to ensure the analytical quality of data and informed the Committee that it was prepared to develop a discussion paper on where in the Codex system such a guideline would fit. The Committee welcomed the offer of Sweden.

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

138) The Committee was informed that the 29th Session of the Committee would be held in Budapest in March 2008. The exact date and venue would be determined by the host country and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	**Step**	**Action by**	**Document Reference in ALINORM 07/30/23**
Proposed Amendment to the Principles for the Establishment of Codex Sampling Procedures	(*)	24th CCGP Governments 30th CAC	para. 117 Appendix II
Endorsement of methods of analysis in Draft Standards and existing Standards		Governments 30th CAC	paras. 67-91 Appendix III
Reference to IUPAC/ISO/AOAC Protocols (amendment to references)		30th CAC	para. 17
Draft Guidelines for Evaluating Acceptable Methods of Analysis	7	29th CCMAS	para. 27
Draft Guidelines for Settling Disputes on Analytical (Test) Results	6	Governments 29th CCMAS	para. 54 Appendix IV
Proposed Draft Guideline on *Analytical Terminology*	3	Governments 29th CCMAS	para. 65 Appendix V
Conversion of methods for trace elements into criteria		Sweden/Norway/ NMKL 29th CCMAS	para. 101-102
Criteria for methods of analysis for foods derived from biotechnology		United Kingdom/ Germany 29th CMAS	para. 111
Guidance on measurement uncertainty and uncertainty of sampling		United Kingdom 29th CCMAS	paras. 10 and 134
Discussion paper on role and terms of reference of CCMAS		Netherlands 29th CCMAS	para. 129
Discussion paper on the reliability of analytical data		Sweden 29th CCMAS	para. 137

(*) Procedural Manual

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PROPOSED AMENDMENT TO THE PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION OF CODEX SAMPLING PROCEDURES

PURPOSE OF CODEX METHODS OF SAMPLING

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

METHODS OF SAMPLING

Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

Such plans~~These~~ are normally applied to visual defects (e.g. loss of colour, ~~mis-graded for~~ misgrading of size, etc.) and extraneous matter. They are~~will~~ normally ~~be~~ attributes plans, and plans such as those included in Section 3.1 and 4.2 of the ~~FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL 6.5)~~ *General Guidelines on Sampling (CAC/GL 50-2004)* (hereinafter referred to as "General Guidelines") may be applied.

(b) Sampling Plans for Net Contents:

~~These~~ Such plans are ~~sampling plans~~those which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents. Plans such as those included in Section 3.3 and 4.4 of the General Guidelines may be applied.

(c) Sampling Plans for Compositional Criteria:

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation. Plans such as those included in Section 4.3 of the General Guidelines may be applied.

(d) Specific Sampling Plans for Health-related Properties:

Such plans are ~~generally~~ normally applied to heterogeneous conditions, e.g., in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants.

General Instructions for the Selection of Methods of Sampling

~~(a) Official methods of sampling as elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such methods, when attracted to Codex standards, may be revised using Codex recommended sampling terms (to be elaborated).~~

(a) Sampling methods described in the General Guidelines or official methods of sampling elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such official methods may be written using the General Guidelines when attracted to Codex standards.

(b) When selecting appropriate sampling plans, Table 1 in the General Guidelines may be utilized.

(~~b~~c) The appropriate Codex Commodity Committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by the Codex Committee on Methods of Analysis and Sampling, the following:

(i) the basis on which the criteria in the Codex Commodity standards have been drawn up (e.g. whether on the basis that every item in a lot, or a specified high proportion, shall comply with the provision in the standard or whether the average of a set of samples extracted from a lot must comply and, if so, whether a minimum or maximum tolerance, as appropriate, is to be given);

(ii) whether there is to be any differentiation in the relative importance of the criteria in the standards and, if so, what is the appropriate statistical parameter each criterion should attract, and hence, the basis for judgement when a lot is in conformity with a standard.

(~~c~~d) Instructions on the procedure for the taking of samples should indicate the following:

(i) the measures necessary in order to ensure that the sample taken is representative of the consignment or of the lot;

(ii) the size and the number of individual items forming the sample taken from the lot or consignment;

(iii) the administrative measures for taking and handling the sample.

(~~d~~e) The sampling protocol may include the following information:

(i) the statistical criteria to be used for acceptance or rejection of the lot on the basis of the sample;

(ii) the procedures to be adopted in cases of dispute.

GENERAL CONSIDERATIONS

(a) The Codex Committee on Methods of Analysis and Sampling should maintain closest possible relations with all interested organizations working on methods of analysis and sampling.

(b) The Codex Committee on Methods of Analysis and Sampling should organize its work in such a manner as to keep under constant review all methods of analysis and sampling published in the Codex Alimentarius.

(c) In the Codex methods of analysis, provision should be made for variations in reagent concentrations and specifications from country to country.

(d) Codex methods of analysis which have been derived from scientific journals, theses, or publications, either not readily available or available in languages other than the official languages of FAO and WHO, or which for other reasons should be printed in the Codex Alimentarius *in extenso*, should follow the standard layout for methods of analysis as adopted by the Codex Committee on Methods of Analysis and Sampling.

(e) Methods of analysis which have already been printed as official methods of analysis in other available publications and which are adopted as Codex methods need only be quoted by reference in the Codex Alimentarius.

STATUS OF ENDORSEMENT OF METHODS OF ANALYSIS

All methods are endorsed unless otherwise specified.

A. Codex Committee on Processed Fruits and Vegetables

B. FAO/WHO Coordinating Committee for Asia

C. Codex Committee on Fish and Fishery Products

D. Codex Committee on Fats and Oils

E. Update of methods previously endorsed

A. CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES[1]

1. Draft Standard for Pickled Fruits and Vegetables (At Step 8)

PROVISION	METHOD	PRINCIPLE	TYPE
Arsenic	AOAC 952.13 (Codex General Method)	Colorimetry, diethyldithiocarbamate	II
	ISO 6634:1982	Spectrophotometry, silver diethyldithiocarbamate	III
Benzoic acid	NMKL 103 (1984); or AOAC 983.16	Gas Chromatography	III

[1] ALINORM 07/30/27, Appendices II to V

PROVISION	METHOD	PRINCIPLE	TYPE
	NMKL 124 (1997)	Liquid Chromatography	II
Drained weight	AOAC 968.30 (Codex General Method for processed fruits and vegetables)	Sieving Gravimetry	I
Fill of containers	CAC/RM 46-1972[2] (Codex General Method for processed fruits and vegetables)	Weighing	I
Lead	AOAC 972.25 (Codex General Method)	Atomic absorption spectrophotometry (Flame absorption)	III
pH	AOAC 981.12	Potentiometry	III
	NMKL 179:2005		II
Sorbate	NMKL 103 (1984); or AOAC 983.16	Gas Chromatography	III
	NMKL 124 (1997)	Liquid Chromatography	II
Tin	AOAC 980.19 (Codex General Method)	Atomic absorption spectrophotometry	II

2. Draft Standard for Processed Tomato Concentrates (At Step 8)

PROVISION	METHOD	PRINCIPLE	TYPE
Fill of containers	CAC/RM 46-1972 (Codex General Method for processed fruits and vegetables)	Weighing	I

[2] As previously amended (ALINORM 03/23, Appendix VI-H)

PROVISION	METHOD	PRINCIPLE	TYPE
Lactic Acid	EN 2631:1999	Enzymatic determination	II
Mould count	AOAC 965.41	Howard mould count	I
pH	AOAC 981.12	Potentiometry	III
	NMKL 179:2005		II
Tomato soluble solids	AOAC 970.59	Refractometry	I

3. Draft Standard for Preserved Tomatoes (At Step 8)

PROVISION	METHOD	PRINCIPLE	TYPE
Calcium	NMKL 153:1996	Atomic Absorption Spectrophotometry	II
	AOAC 968.31 (Codex General Method for processed fruits and vegetables)	Complexometry Titrimetry	III
Drained weight	AOAC 968.30 (Codex General Method for processed fruits and vegetables)	Sieving Gravimetry	I
	ISO UNIUN SERIES 2331*	Sieving Gravimetry	I (TE)

PROVISION	METHOD	PRINCIPLE	TYPE
Fill of containers	CAC/RM 46-1972 (Codex General Method for processed fruits and vegetables)	Weighing	I
Mould count	AOAC 965.41	Howard mould count	I
pH	AOAC 981.12	Potentiometry	III
	NMKL 179:2005		II
Solids (Soluble)	AOAC 932.12 ISO 2173:2003 (Codex General Method for processed fruits and vegetables)	Refractometry	I

***** for crushed style tomatoes only

4. Draft Standard for Certain Canned Citrus Fruits (At Step 8)

PROVISION	METHOD	PRINCIPLE	TYPE
Calcium	NMKL 153:1996	Atomic Absorption Spectrophotometry	II
	AOAC 968.31 (Codex General Method for processed fruits and vegetables)	Complexometry Titrimetry	III
Drained weight	AOAC 968.30 (Codex General Method for processed fruits and vegetables)	Sieving Gravimetry	I
Fill of containers	CAC/RM 46-1972 (Codex General Method for processed fruits and vegetables)	Weighing	I

PROVISION	METHOD	PRINCIPLE	TYPE
Solids (Soluble)	AOAC 932.12 ISO 2173:1978	Refractometry	I

B. FAO/WHO COORDINATING COMMITTEE FOR ASIA[3]

Proposed Draft Standard for Gochujang (At Step 5)

PROVISION	METHOD	PRINCIPLE	TYPE	STATUS OF ENDORSEMENT
Capsaicin	AOAC 995.03	HPLC	II	E
	According to the method described in the Annex A or B[4].	Gas chromatography / HPLC	IV	TE
Crude Protein	AOAC 984.13 (Nitrogen conversion factor: 6.25).	Kjeldahl	I	TE
Moisture	AOAC 934.01.	Gravimetry	I	TE

C. CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS[5]

Proposed Draft Standard for Live and Raw Bivalve Molluscs (At Step 5)

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
Raw Bivalve Molluscs	Net weight of products covered by glaze	AOAC 963.18	weighing	I
	Net weight of products covered by glaze with water added inside a "block-frozen" product	AOAC 963.26	weighing	I

[3] ALINORM 07/30/15, Appendix II

[4] CX/MAS 07/28/6

[5] ALINORM 07/30/18, Appendix V

	Drained weight of shucked molluscs	AOAC 953.11	weighing	I

Determination of Biotoxins

PROVISION	METHOD	PRINCIPLE	TYPE
Saxitoxin Group	AOAC 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish) NMKL 182: 2005	LC-FL	II

D. CODEX COMMITTEE ON FATS AND OILS[6]

1. Draft Standard for Fat Spreads and Blended Spreads (At Step 8)

PROVISION	METHOD	PRINCIPLE	TYPE
fat content	ISO 17189 | IDF 194: 2003	Gravimetry	I

2. Draft Amendment to the Standard for Named Vegetable Oils: Rice Bran Oil (at Step 6)

PROVISION	METHOD	PRINCIPLE	TYPE
gamma oryzanols	see description below	spectrophotometry	IV

Method of Analysis for Gamma Oryzanols

[6] ALINORM 07/30/17, Appendices II, V and VIII

1. Definition

This method is used to determine gamma oryzanol content (%) in oils from spectrophotometer absorption measurements at the wavelength of maximum absorption near 315nm.

2. Scope

Applicable to crude rice bran oil.

3. Apparatus

3.1. Spectrophotometer - for measuring extinction in the ultraviolet between 310 and 320 nm.

3.2. Rectangular quartz cuvettes - having an optical light path of 1 cm.

3.3. Volumetric flask - 25mL.

3.4. Filter paper - Whatman no.2, or equivalent.

4. Reagents

4.1. n-Heptane - Spectrophotometrically pure.

5. Procedure

5.1. Before using, the spectrophotometer should be properly adjusted to a zero reading filling both the sample cuvette and the reference cuvette with n-Heptane.

5.2. Filter the oil sample through filter paper at ambient temperature.

5.3. Weigh accurately approximately 0.02g of the sample so prepared into a 25mL volumetric flask, make up to the mark with n-Heptane.

5.4. Fill a cuvette with the solution obtained and measure the extinction at the wavelength of maximum absorption near 315nm, using the same solvent as a reference.

5.5. The extinction values recorded must lie within the range 0.3-0.6. If not, the measurements must be repeated using more concentrated or more diluted solutions as appropriate.

6. Calculation

Calculate gamma oryzanol content as follows:

$$\text{Gamma oryzanol content, \%} = 25 \times (1 / W) \times A \times (1 / E)$$

Where -

W = mass of sample, g

A = maximum extinction (absorbance) of the solution

E = specific extinction $E^{1\%}_{1cm} = 359$

3. Update of existing methods for fats and oils

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
Fats and Oils (all)	Arsenic	AOAC 952.13 (Codex general method)	Colorimetry (diethyldithiocarbamate)	II
Fats and oils	Butylhydroxyanisole, butylhydroxytoluene, tert-butylhydroquinone, & propyl gallate	AOAC 983.15; or AOCS Ce-6-86	Liquid chromatography	II
Fats and Oils (all)	Insoluble impurities	ISO 663:2007	Gravimetry	I
Fats and Oils (all)	Lead	AOAC 994.02 ISO 12193:2004 (Codex general method) or AOCS Ca 18c-91 (03)	Atomic absorption spectrophotometry (direct graphite furnace)	II
Fats and Oils (all)	Matter volatile at 105°C	ISO 662:1998	Gravimetry (open-drying)	I
Fats and Oils (all)	Soap content	BS 684 Section 2.5; or AOCS Cc 17-95 (97)	Gravimetry	I
Fats and oils not covered by individual standards	Acid Value	ISO 660:1996; or AOCS Cd 3d-63 (03)	Titrimetry	I
Fats and oils not covered by individual standards	Copper and Iron	AOAC 990.05 ISO 8294:1994; or AOCS Ca 18b-91 (03) (Codex general method)	Atomic absorption Spectrophotometry (direct graphite furnace)	II
Fats and oils not covered by individual standards	Peroxide value	AOCS Cd 8b-90 ISO 3961:1996	Titrimetry using *iso*-octane	I

Named Animal Fats	Acidity	ISO 660:1996 amended 2003; or AOCS Cd 3d-63 (03)	Titrimetry	I
Named Animal Fats	GLC ranges of fatty acid composition	ISO 5508: 1990 and ISO 5509: 2000 or AOCS Ce 2-66 (97) and Ce 1e-91 (01) or Ce 1f-96 (02)	Gas chromatography of methyl esters	II
Named Animal Fats	Copper and Iron	AOAC 990.05 ISO 8294:1994; or AOCS Ca 18b-91 (03) (Codex general method)	Atomic absorption Spectrophotometry (direct graphite furnace)	II
Named Animal Fats	Iodine value (IV)	ISO 3961:1996; or AOAC 993.20; or AOCS Cd 1d-1992 (97)	Wijs-Titrimetry	I
Named Animal Fats	Peroxide value	AOCS Cd 8b-90 (97) ISO 3961:1996	Titrimetry using *iso*-octane	I
Named Animal Fats	Relative density	**Note**: Needs to be replaced with ISO/AOCS method for apparent density	Pycnometry	II
Named Animal Fats	Refractive index	ISO 6320:2000; or AOCS Cc 7-25 (02)	Refractometry	II
Named Animal Fats	Saponification value	ISO 3657:2002; or AOCS Cd 3-25 (03)	Titrimetry	I
Named Animal Fats	Unsaponifiable matter	ISO 3596:2000 or ISO 18609: 2000; or AOCS Ca 6b-53 (01)	Titrimetry after extraction with diethyl ether	I
Named Animal Fats	Titre	ISO 935:1988; or AOCS Cc 12-59 (97)	Thermometry	I

E. UPDATE OF METHODS IN EXISTING STANDARDS

1. Codex Standard for Cocoa Butter (CODEX STAN 86-1981)

PROVISION	METHOD	PRINCIPLE	TYPE
Free fatty acids	ISO660:1996 amended 2003; or AOCS Cd 3d-63 (03)	Titrimetry	I
Unsaponifiable matter	ISO 3596:2000 or ISO 18609: 2000; or AOCS Ca 6b-53 (01)	Titrimetry after extraction with diethyl ether	I

2. Guidelines for Nutrition Labelling (CAC/GL2-1985)

PROVISION	METHOD	PRINCIPLE	TYPE
Polyunsaturated fatty acids	AOCS Ce 1h-05[7]	Gas Liquid chromatography	II
Saturated fat	AOAC 996.06; or AOCS Ce 1h-05	Gas liquid chromatography	II
Saturated fatty acids	AOCS Ce 1h-05	Gas liquid chromatography	II

[7] Can also be used to measure *trans* unsaturated fatty acids

DRAFT GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS

(At Step 6 of the Procedure)

1. SCOPE:

These guidelines provide guidance to governments on the procedures to resolve disputes which arise between food control authorities about the status of a food consignment[8], when the test results by the laboratory[9] in the importing country disagree with test results by the laboratory in the exporting country over the same lot[10].

The basic assumption is that when the assessment based on test results made in the importing country disagrees with the assessment made by the exporting country.

These guidelines only address disputes related to methods of analysis or laboratory performance and do not address questions of sampling. It is recognised that disputes may arise from other cause(s), which should also be investigated[11].

These guidelines do not cover microbiological test results.

2. PREREQUISITES:

The procedure described in these Guidelines may only be used when:

- laboratories comply with quality assurance provisions and with the Codex *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and the Export of Food (CAC-GL 27)*; and the laboratories have been designated by their respective Competent Authories in both the importing and exporting countries;
- at least, one representative analytical laboratory sample from the same food lot has been taken by each Competent Authority in accordance with established sampling plans and/or good sampling practices, where applicable; the laboratory sample has been split for the purposes of analysis and for confirmatory analysis (reserve sample); the reserve sample has been kept in a satisfactory condition for the appropriate length of time.

3. PROCEDURE:

(see FLOWCHART)

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8 Status of the food consignment depends on the "interpretation" of the test result(s), in the light of measurement uncertainty, sampling error and the closeness of those test results to the limit. It could still be that the results do not differ by an amount which is significant, but nevertheless one result indicates conformity, but the other result does not.

9 For the purpose of these guidelines, the word "laboratory" applies to both official and officially recognised laboratories. An official laboratory would be a laboratory administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both. An officially recognised laboratory would be a laboratory that has been formally approved or recognised by a government agency having jurisdiction.

10 As defined in the General Guidelines for Sampling (CAC/GL 54 -2004)

4 Possible reasons for disagreement may include one or several causes such as : the existence, appropriateness and statistical validity of the sampling plan used to assess the product; the allowances made for normal measurement error and within-lot product variation; differences in physical sampling procedures; differences in composition of the samples tested due to product inhomogeneity or changes occurring during storage and/or transport of the product;

The settlement of the dispute without new analysis or sampling operations should be the preferred option as far as possible.

3.1. – STEP 1: THE ANALYTICAL RESULTS ARE COMPARED USING THE REPRODUCIBILITY LIMIT

When the difference between the test results are within the existing reproducibility limit, the mean value of the test results of the 2 laboratories should be used to assess conformity, taking into account measurement uncertainty of the mean (see ANNEX for definition).

When both laboratories have used the same method of analysis and published reproducibility limits exist for the method, these limits should be used.

In other cases, the ANNEX suggests a simple procedure, based on the Horwitz's model, to implement this criterion and resolve the dispute. When available or recognised, other models than Horwitz's could be used.

If results are outside the reproducibility limit, the attempt to resolve the dispute should proceed to step 2.

In case these models cannot be applied, the attempt to resolve the dispute should proceed directly to step 2.

3.2. – STEP 2: THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED

In accordance with relevant Codex Guidelines[12], the following information should be shared between competent authorities of the importing and exporting country to allow comparison of the results and procedures of the laboratory of the exporting country and its counterpart in the importing country. The relevant information covers:

- validation status of the methods of analysis used (including method specific sampling and preparation procedures),
- raw data (including spectral data, calculations, chemical standards used are assessed and are in order),
- results of repeat analysis,
- internal quality assurance/control (assessment of control charts, sequence of analysis, blank data, recovery data, uncertainty data, use of appropriate reference standards and materials),
- performance in relevant proficiency testing or collaborative studies.
- official accreditation status of the laboratories and

Each competent authority reviews its initial assessment on the basis of the additional information received from the other in order to recognise the validity of the results of one of the two laboratories (agreement on conformity or agreement on non conformity).

In this way, the dispute is resolved without further analysis or sampling.

If no agreement is reached, resolution of the dispute may be sought using the next step (where reserve samples are available).

3.3. – STEP 3: NEW ANALYSES ARE CARRIED OUT

Prerequisites

If it is established that sample integrity has not been compromised in transit, there is an agreement on:

1. the sharing/swapping of the reserve samples,
2. the methods of analysis,
3. the laboratories involved: each laboratory may undertake new analyses or one laboratory in the presence of a representative of the other; or a third laboratory may be selected by consensus of

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[12] See ANNEX to GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (CAC/GL 25-1997): "Where imported food has been rejected on the basis of sampling and/or analysis in the importing country, details should be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory."

exporting and importing country, or, failing that, by the competent authority of the importing country; and

4. the use of the new analytical results: either the initial results are discarded and the settlement of the dispute is determined by the comparison of the new results obtained; or the new results are used to confirm the validity of one of the two results obtained initially.

Available approaches

One (or more) may be selected.

A.– SEARCH FOR LABORATORY BIAS

It may be agreed to check for laboratory bias, by testing common samples.[13] Performances are compared by testing a common sample with a known analyte content, preferably certified reference material. The original results are then corrected according to the bias found. If the results are in agreement, within the reproducibility limit, the dispute is settled.

B.– IDENTIFICATION OF A SAMPLING PROBLEM

The two laboratories may swap their reserve samples. If both laboratories confirm the original results received by the other one, a sampling problem is identified.

C.– ANALYSES OF RESERVE SAMPLES

The new analyses are performed on shared reserve samples. Either:

1. analyses are performed in one laboratory in the presence of a representative of the other laboratory. The new results are used to assess conformity.
2. the two laboratories carry analyses separately: If the new results are in agreement, the dispute is settled. If no agreement is reached, resolution of the dispute may be sought by proceeding to step 4.

3.4 – STEP 4: New samples taken from the consignment are analysed

The consignment is located in the importing country. At this stage, the initial test results are no longer taken into account. The modalities of sampling and analysis are decided by consensus.

At the request of the competent authority of the exporting country, a new sampling of the consignment is carried out and new analyses are performed in a laboratory selected by consensus or, failing that, by the competent authority of the importing country.

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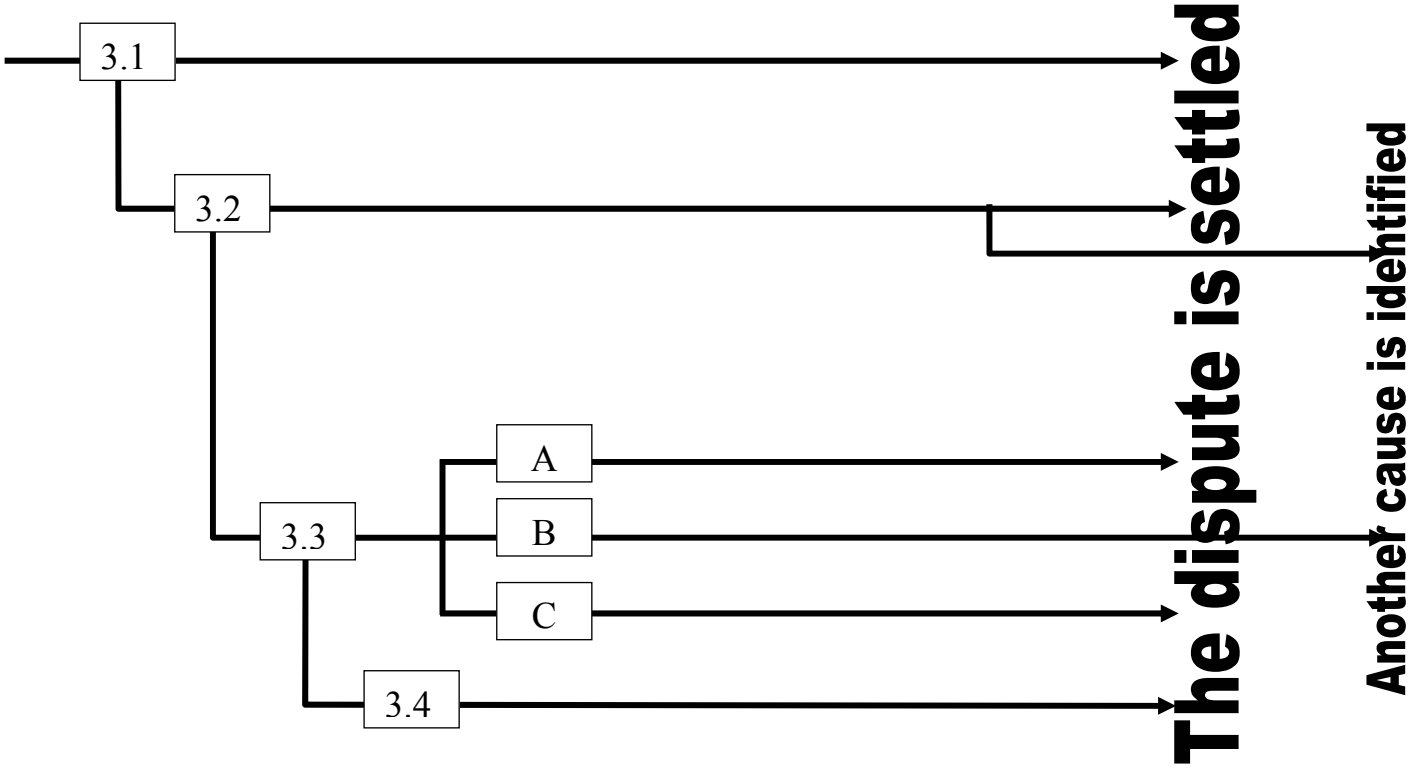
[13] To investigate analytical differences (biases) between laboratories, the laboratories need to test samples with known analyte concentrations (usually duplicate split samples). It is not necessary to test or retest samples from the original consignment of product under dispute: this would only be required if a reassessment were needed. To provide a reasonable estimate of bias, several (split) samples should be analysed, one duplicate of each sample at each laboratory. The appropriate number of samples should be used for the estimate of the bias to be reliable.

FLOWCHART


3.1
3.2
3.3
3.4
A
B
C
The dispute is settled
Another cause is identified

ANNEX

Definition of a maximum acceptable difference Δ_{max}

Let define the average contents of the sample *T* and the relative difference between results Δ% as:

$$T = \frac{Y_1 + Y_2}{2}$$

$$\Delta\% = \frac{|Y_1 - Y_2|}{T} \times 100$$

The acceptance condition is that the difference between both results is below reproducibility limit defined in ISO 5725 from the reproducibility standard deviation s_R:

$$|Y_1 - Y_2| \leq 2.83 s_R$$

If there is no published reproducibility, it is possible to use the model of Horwitz to calculate the limit of reproducibility as:

$$s_R = 0.02 \times T^{0.8495}$$

Then it comes:

$$|Y_1 - Y_2| \leq 0.0566 \times T^{0.8495}$$

Thus, the maximal acceptable difference (relative) is:

$$\Delta_{max} \leq \frac{0.0566 \times T^{0.8495}}{T} \times 100$$

Figure 1 illustrates, as an abacus, this decision criterion. When dealing with concentration around 1 ppm, the relative difference between results must be below 45%. This value seems rather high but, for instance, it is often consistent with the toxicological meaning of a contaminant. When available or recognized other models than Horwitz's could be used (see Table **1**).

Measurement uncertainty of the mean

Let define u_1 and u_2 as the measurement uncertainty of each individual test results Y_1 and Y_2 respectively, then the measurement uncertainty of the mean is:

$$u_{mean} = \sqrt{\frac{u_1^2 + u_2^2}{4}}$$

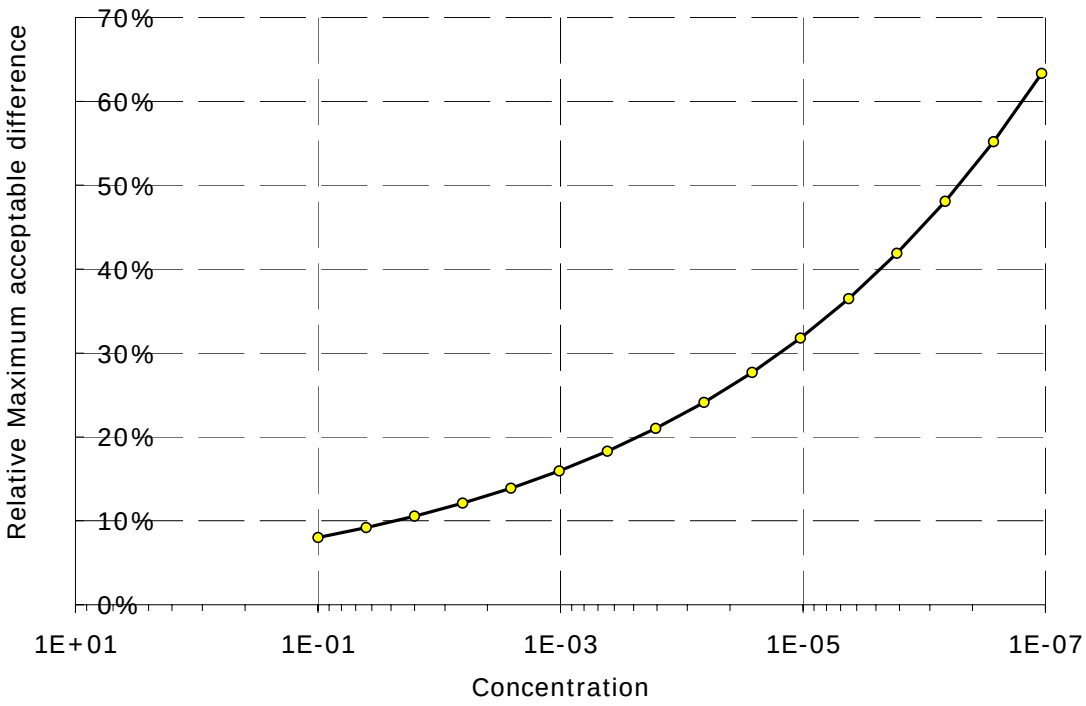


Figure 1. Relative Maximum acceptable difference based on Horwitz's model

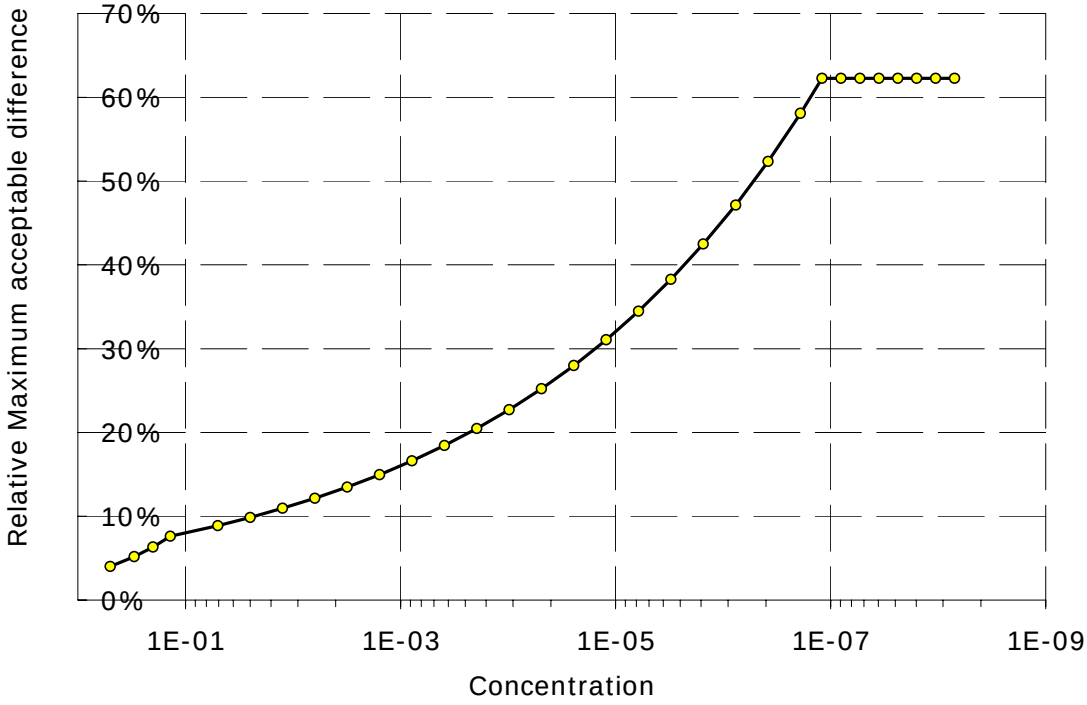


Figure 2. Relative Maximum acceptable difference based on Thompson's model

Table 1. Published recognized models

Name	Range (dimensionless)	Equation of s_R	Equation for Δ_{max} (%)	Figure
Horwitz [1]	10^{-1} to **1.2** 10^{-7}	$s_R = 0.02 \times T^{0.8495}$	$\Delta_{max} \leq \frac{5.66 \times T^{0.8495}}{T}$	**1**
Thompson [2]	> 1.38 10^{-1}	$s_R = 0.01 \times T^{0.5}$	$\Delta_{max} \leq \frac{2.83 \times T^{0.5}}{T}$	**2**
	1.38 10^{-1} to 1.2.10^{-7}	$s_R = 0.02 \times T^{0.8495}$	$\Delta_{max} \leq \frac{5.66 \times T^{0.8495}}{T}$	
	< 1.2.10^{-7}	$s_R = 0.22$ □ T	62.26%	

References

[1] Horwitz W. (1980) Quality Assurance in the Analysis of Foods for Trace Constituents, *J of the AOAC* 63:6, 1344-1354

[2] Thompson M. (2000) Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing, *Analyst* 125, 385-386

or

[3. OCCURRENCE OF A DISPUTE

A dispute within the meaning of these guidelines arises when the difference between the results obtained in the two laboratories is larger than the sum of their two expanded measurement uncertainties, and one of the two countries claims the non-compliance.

It would be expected that the expanded measurement uncertainties reported by the laboratories will not substantially exceed two times the value of the estimated reproducibility standard deviation (S_R) at the concentration of interest if the laboratory is in "analytical control".

4. The analytical results are compared taking into account measurement uncertainty

By providing the necessary documents, the laboratories involved demonstrate that they are accredited for the analyses concerned, and hence meet the prerequisites outlined above.

In accordance with relevant Codex Guidelines[14], the following information should be shared between Competent Authorities of the importing and exporting country to allow comparison of the results and procedures of the laboratory of the exporting country and its counterpart in the importing country. The relevant information covers:

- validation status of the methods of analysis used and a method description (including method specific sampling and preparation procedures),

[14] See ANNEX to GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (CAC/GL 25-1997): "Where imported food has been rejected on the basis of sampling and/or analysis in the importing country, details should be made available on request as to sampling and analytical methods and test results and the identity of the testing laboratory."

- raw data (including spectral data, calculations, chemical standards used)
- results of replicate analyses,
- internal quality assurance/control procedures (control charts, sequence of analysis, blank data, recovery data, recovery correction, uncertainty data, use of appropriate reference standards and materials),
- official accreditation status of the laboratories and
- performance in relevant proficiency testing schemes.

Each competent authority reviews its initial assessment on the basis of the additional information received from the other in order to recognise the validity of the results of each of the laboratories. If the results from each laboratory are accepted, then the importing country will use its own result to assess the compliance.

If the result from one laboratory is agreed not to be acceptable, then the result from that laboratory is discarded and the consignment is either accepted/rejected on the basis of the remaining result.

In this way, the dispute is resolved without further analysis or sampling.

If no agreement is reached, the dispute may be resolved as described below.

5. FURTHER ANALYSES ARE CARRIED OUT

Prerequisites

If it is established that sample integrity has not been compromised in transit, there is an agreement on:

1. the sharing/swapping of any reserve samples,
2. the methods of analysis to be used by each laboratory,
3. whether there is any laboratory bias (i.e. it may be agreed to check for laboratory bias by testing common samples [15].

RESOLUTION BY EVALUATION OF THE LABORATORY BIAS

Results from each laboratory are compared by testing a common sample with a known analyte content, preferably certified reference material. The original results are then corrected if a bias has been found. If the results, taking into account the measurement uncertainty, show that the same decision on compliance by both laboratories of the importing and exporting countries is found, then the dispute is resolved.

ANALYSES OF RESERVE SAMPLES

If necessary further analyses may be carried out on:

- any reserve samples taken by the exporting country but then analysed by a further designated laboratory in the importing country,
- the split sample taken on importation but analysed by a second designated laboratory in the importing country or
- the second sample taken on importation but analysed by a second designated laboratory in the importing country.

If any of the above analyses show the consignment to be unsatisfactory, the consignment is considered to be out of compliance with the Codex specification.

[15]To investigate analytical differences (biases) between laboratories, the laboratories need to test samples with known analyte concentrations (usually duplicate split samples). It is not necessary to test or retest samples from the original consignment of product under dispute: this would only be required if a reassessment were needed. To provide a reasonable estimate of bias, several (split) samples should be analysed, one duplicate of each sample at each laboratory. The appropriate number of samples should be used for the estimate of the bias to be reliable.

NEW SAMPLES TAKEN FROM THE CONSIGNMENT IF IT IS STILL AVAILABLE

The consignment is located in the importing country. At this stage, the initial test results are no longer taken into account. The modalities of sampling and analysis are decided by consensus.

It might be agreed upon to carry out sampling and analysis in the presence of representatives of both parties involved.

At the request of the competent authority of the exporting country, a new sampling of the consignment is carried out and new analyses are performed in a laboratory selected by consensus or, failing that, by the competent authority of the importing country.

The results of this analysis are used to assess conformity. The dispute is settled.**]**

<Note: rest of original paper is deleted.>

PROPOSED DRAFT GUIDELINE ON ANALYTICAL TERMINOLOGY

(At Step 3 of the Procedure)

INTRODUCTION

The Codex Committee on Methods of Analysis and Sampling has agreed on Analytical Terminology for Codex use. A number of these terms were previously included in the Codex Procedural Manual. These terms, together with the terms which are included in specific International Protocols/Guidelines already adopted by Codex by reference are given below.

These Guidelines are published as a Codex Guideline (GL xx-20xx).

SPECIFIC ANALYTICAL TERMS

The following analytical terms are used in the Procedural Manual and are defined below:

Accuracy

Applicability (and practicability)

Bias

Certified reference material

Empirical method of analysis

Error

HorRat

Interlaboratory study

Laboratory performance (Proficiency) study

Limit of detection

Limit of quantification

Linearity

Material-certification study

Measurement uncertainty

Method-performance study

Precision

Quality assurance

Rational method of analysis

Recovery/recovery factors

Reference material

Relative uncertainty

Repeatability

Reproducibility

Repeatability conditions

Repeatability (Reproducibility) limit

Repeatability (Reproducibility) standard deviation

Repeatability (Reproducibility relative standard deviation

Reproducibility conditions

Result

Robustness (ruggedness)

Selectivity

Sensitivity

Surrogate

Traceability

True value

Trueness

Validated range

The following terms are no longer to be used and so are not defined:

limit of determination

specificity

DEFINITIONS OF SPECIFIC ANALYTICAL TERMS

Accuracy: The closeness of agreement between a test result or measurement result and the true value.

Notes:

In practice the accepted reference value is substituted for the true value.

The term "accuracy", when applied to a set of test results or measurement results, involves a combination of random components and a common systematic error or bias component.

Accuracy refers to combination of trueness and precision.

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

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.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Bias: The difference between the expectation of the test result or measurement result and the true value.

Notes:

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.

The bias of a measuring instrument is normally estimated by averaging the error of indication over the appropriate number of repeated measurements. The error indication is the: "indication of a measuring instrument minus a true value of the corresponding input quantity".

In practice the accepted reference value is substituted for the true value.

Expectation is the general mean of observed values {ISO 5725-1}

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

Certified reference material (CRM): Reference material, accompanied by an authenticated certificate, having for each specified quantity a value, measurement uncertainty and stated metrological traceability chain. {VIM}

Notes:

A certificate should refer to a protocol describing the certification process.

Certified reference materials are generally prepared in batches. For a given batch, quantity values and measurement uncertainties are obtained by measurements on samples representative of the batch.

The quantity values assigned to a CRM are sometimes conveniently and reliably obtained when the material is incorporated into a specially fabricated device. The quantity value is sometimes the output of the device. Such devices may also be considered CRMs.

Some certified reference materials have quantity values that are not metrologically traceable to an International system of units.

Reference:

VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

Empirical method of analysis: A method in which the quantity estimated is simply the result found on following the stated procedure.

Note:

This differs from measurements intended to assess method-independent quantities such as the concentration of a particular analyte in a sample, in that the method bias is conventionally zero and matrix variation (i.e. within the defined class) is irrelevant

Reference:

Harmonised guidelines for single-laboratory validation of methods of analysis, 2002.

Error: Difference of quantity value obtained by measurement and true value of the measurand. {VIM}

Note:

It is often necessary to distinguish "error of measurement" from relative error of measurement.

Reference:

VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

HorRat: The relative interlaboratory standard deviation normalized with respect to concentration that is indicative of method performance for a large majority of methods in chemistry. It is the ratio of the interlaboratory relative standard deviation found to that calculated from the Horwitz equation,

$PRSD_R = 2C^{-0.15}$:

$HorRat(R) = RSD_R/PRSD_R$,

$HorRat(r) = RSD_r/PRSD_R$,

where C is concentration expressed as a mass fraction (both numerator and denominator expressed in the same units). Acceptable values lie between 0.5 and 2. (To check proper calculation of $PRSD_R$, a C of 10^{-6} should give a $PRSD_R$ of 16%.)

If applied to within-laboratory studies, the acceptable range of HorRat(r) is 0.3-1.3.

Reference:

A simple method for evaluating data from an interlaboratory study, J AOAC, 81(6):1257-1265, 1998

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.

Notes:

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.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

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:

Laboratory-performance studies can be used to support laboratory accreditation or 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. 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.

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

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Limit of Detection: The amount of an analyte corresponding to the lowest measurement signal which with a defined confidence may be interpreted as indicating that the analyte is present in the test sample, but without allowing quantitation.

The detection limit is conventionally defined as field blank + 3σ, where is the standard deviation of the field blank value signal (IUPAC definition).

However, an alternative definition which overcomes most of the objections to the above approach (i.e. the high variability at the limit of measurement can never be overcome) is to base it on the rounded value of the reproducibility relative standard deviation when it goes out of control (where $3\square_R$ = 100%; $\square_R$ = 33%, rounded to 50% because of the high variability). Such a value is directly related to the analyte and to the measurement system and is not based on the local measurement system.

Notes:

1. LOD = $3*\square_a/b$ where LOD is the limit of detection, $\square_a$ is the standard deviation of x blank results and b is the slope of the calibration curve/regression line.

2. For quantitative tests using the polymerase chain reaction (PCR), the distribution of blank values is typically truncated and thus not normally distributed (non-Gaussian) around zero. Thus, the LOD needs to be experimentally determined unless the targeted concentrations are well above the LOD and the LOD, therefore, becomes irrelevant.

References:

Nordic Committee on Food Analysis, NMKL Procedure No. 4, 2005

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Polymerase chain reaction technology as an analytical tool in agricultural biotechnology, J.AOAC, 88(1):128-135, 2005

Limit of Quantification: The limit of quantification (LOQ) (also called limit of determination) of an analytical procedure is the lowest amount of analyte in a laboratory sample which can be quantitatively determined with a defined confidence.

As for detection limit except that 6 or 10 are required rather than 3.

However, an alternative definition that corresponds to that proposed for the detection limit is to use $\square R$ = 25%. This value does not differ much from that assigned to the detection limit because the upper limit of the detection limit merges indistinguishably into the lower limit of the determination limit.

Notes:

1. LOQ = $10*\square_a/b$ where LOQ is the limit of quantification, $\square_a$ is the standard deviation of x blank results (x > 20) and b is the slope of the calibration curve/regression line. Because LOQ>LOD, fewer laboratories are required to establish a value at the same level of confidence.

2. For quantitative tests using the polymerase chain reaction (PCR), the distribution of blank values is typically truncated and thus not normally distributed (non-Gaussian) around zero. Thus, the LOQ needs to be experimentally determined unless the targeted concentrations are well above the LOQ and the LOQ, therefore, becomes irrelevant.

References:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Nordic Committee on Food Analysis, NMKL Procedure No. 4, 2005

Polymerase chain reaction technology as an analytical tool in agricultural biotechnology, J. AOAC, 88(1):128-135, 2005

Linearity: The ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quantity of analyte to be determined in the laboratory sample. This proportionality is expressed by an *a priori* defined mathematical expression. The linearity limits are the experimental limits of concentrations between which a linear calibration model can be applied with a known confidence level (generally taken to be equal to 1%).

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

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 utilises selected reference laboratories to analyse 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.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Measurement uncertainty: Parameter that characterizes the dispersion of the quantity values that are being attributed to the measurand, based on the information used. {VIM}

Notes:

Measurement uncertainty quantitatively characterizes the knowledge about the measurand, based on the information used. {VIM}

Measurement uncertainty characterizes the dispersion of a set or distribution of quantity values for the measurand, obtained by available information. The dispersion is due to definitional uncertainty of the measurand and random and systematic effects in the measurement. {VIM}

The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a given multiple of it), or the half-width of interval having a stated coverage probability. {VIM}

Measurement uncertainty comprises, in general many components. Some of these components may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from a series of measurements and can be characterized by experimental standard deviations. The other components which may be evaluated by Type B evaluation of measurement uncertainty can also be characterized by standard deviations, evaluated from assumed probability distributions based on experience or other information. {VIM}

It is understood that the result of a measurement result is the best estimate of the value of the measurand, and that all the components of measurement uncertainty, including those arising from systematic effects, such as components associated with corrections and assigned values of measurement standards, contribute to the dispersion. {VIM}

Depending upon its intended use, an expanded measurement uncertainty of a measurement result may be given with a stated coverage factor, giving a coverage interval intended to contain the value of the measurand with high probability, or encompass a stated large fraction of the dispersed quantity values that are being attributed to the measurand. {VIM}

Reference:

1. VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

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 quantitation, and applicability.

Notes

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.

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.

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

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.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Precision: The closeness of agreement between independent test/measurement results obtained under stipulated conditions.

Notes:

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

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.

Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

Quality assurance: All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Reference:

Harmonized guidelines for internal quality control in analytical chemistry laboratories, 1995

***Rational method of analysis*:** A method that determines an identifiable chemical(s) or analytes(s) for which there may be several equivalent methods of analysis available.

Reference:

Harmonized guidelines for the use of recovery information in analytical measurement, 1998

Recovery: Proportion of the amount of analyte, present in, added to or present in and added to the analytical portion of the test material, which is extracted and presented for measurement.

Notes:

Recovery is assessed by the ratio $R = c_{obs} / C_{ref}$ of the observed concentration or amount ^{c}obs obtained by the application of an analytical procedure to a material containing analyte at a reference level c_{ref}.

c_{ref} will be: (a) a reference material certified value, (b) measured by an alternative definitive method, (c) defined by a spike addition or (d) marginal recovery.

Reference:

Harmonized guidelines for the use of recovery information in analytical measurement, 1998

Use of the terms "recovery" and "apparent recovery" in analytical procedures, 2002

Reference material: Material, sufficiently homogenous and stable with respect to one or more specified quantities, used for calibration of a measuring system, or for assessment of a measurement procedure, or for assigning values and measurement uncertainties to quantities of the same kind for other materials. {VIM}

Notes:

The term reference material designates a family of materials without necessarily implying a hierarchy according to the magnitude of measurement uncertainty.

Reference material comprises both precision control material, which need not have an assigned quantity value and measurement standard functioning as trueness control material or calibrator.

The term reference material is also used for materials realizing nominal properties such as color.

Reference:

VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

Relative uncertainty: Uncertainty derived from a relative standard deviation.

Reference:

Harmonized guidelines for single-laboratory validation of methods of analysis, 2002

Repeatability [Reproducibility]: Precision under repeatability [reproducibility] conditions.

Reference:

ISO 3534-1 Statistics, vocabulary and symbols-Part 1: Probability and general statistical terms, ISO, 1993

ISO Standard 78-2: Chemistry – Layouts for Standards – Part 2: Methods of Chemical Analysis, 1999)

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

AOAC International methods committee guidelines for validation of qualitative and quantitative food microbiological official methods of analysis, 2002.

Repeatability conditions: Observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in the same test or measuring facility by the same operator using the same equipment within short intervals of time.

Note:

Repeatability conditions include: the same measurement procedure or test procedure; the same operator; the same measuring or test equipment used under the same conditions; the same location and repetition over a short period of time.

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

***Reproducibility conditions*:** Observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in different test or measurement facilities with different operators using different equipment.

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

Repeatability [Reproducibility] limit: The value less than or equal to which the absolute difference between final values, each of them representing a series of test results or measurement results obtained under repeatability [reproducibility] conditions may be expected to be with a probability of 95%.

Notes:

The symbol used is r [R]. {ISO 3534-2}

When examining two single test results obtained under repeatability [reproducibility] conditions, the comparison should be made with the repeatability [reproducibility] limit, r [R] = 2.8σr[R]. {ISO 5725-6, 4.1.4}

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.

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

ISO 5 725-6 "Accuracy (trueness and precision) of a measurement methods and results—Part 6: Use in practice of accuracy value", ISO, 1994

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

***Repeatability [reproducibility] standard deviation*:** Standard deviation of test results or measurement results obtained under repeatability [reproducibility] conditions.

Notes:

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

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

Repeatability [reproducibility] relative standard deviation: $RSD_{r[R]}$ is computed by dividing the repeatability [reproducibility] standard deviation by the mean.

Note:

Relative standard deviation (RSD) is a useful measure of precision in quantitative studies.

This is done so that one can compare variability of sets with different means. RSD values are independent of the amount of analyte over a reasonable range and facilitate comparison of variabilities at different concentrations.

The result of a collaborative test may be summarized by giving the RSD for repeatability (RSDr) and RSD for reproducibility (RSDR).

AOAC International methods committee guidelines for validation of qualitative and quantitative food microbiological official methods of analysis, 2002.

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

Notes:

The information consists of a set of quantity values reasonably being attributed to the measurand, usually summarized as a single quantity and a measurement uncertainty. The single quantity value is an estimate, often an average or the median of the set. {VIM}

If the measurand is considered to be sufficiently well described by a single quantity value (see GUM, 1993, 1,2), it is common practice to have the term 'measurement result' comprise the estimated value only. The measurement uncertainty associated with this 'measurement result' is then stated separately. {VIM}

If the measurement uncertainty is considered to be negligible for some purpose, the information may be reduced to a single quantity value. {VIM}

Reference:

IUPAC, Nomenclature for the presentation of results of chemical analysis, 1994.

VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

***Robustness (ruggedness*)**: A measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage

Reference:

ICH Topic Q2 Validation of Analytical Methods, the European Agency for the Evaluation of Medicinal Products: ICH Topic Q 2 A - Definitions and Terminology (CPMP/ICH/381/95), 1995

Selectivity: Capability of a measuring system, using a specified measurement procedure to provide measurement results for two or more quantities of the same kind involving different components in a system undergoing measurement, without interference from each other or from the quantities of the system. {VIM}

Reference:

VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

Sensitivity: Quotient of the change in the indication of a measuring system and the corresponding change in the value of the quantity being measured. {VIM}

Notes:

The sensitivity can depend on the value of the quantity being measured.

The change considered in the value of the quantity being measured must be large compared with the resolution of the measurement system.

Reference:

VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

Surrogate: Pure compound or element added to the test material, the chemical and physical behavior of which is taken to be representative of the native analyte.

Reference:

Harmonized guidelines for the use of recovery information in analytical measurement, 1998

Traceability: Property of a measurement result relating the result to a stated reference or the value of a standard whereby it can be related to stated references through an unbroken chain of comparisons, each contributing to the stated measurement uncertainty.

Notes:

A stated reference can be a definition of a measurement unit, through its practical realization, or a measurement procedure, or a national or international measurement standard.

A prerequisite to traceability is a previously established calibration hierarchy.

For measurements with more than one input quantity to the measurement function, each of the input quantities should itself be traceable.

Reference:

VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva

Harmonized guidelines for internal quality control in analytical chemistry laboratories, 1995

Trueness: The closeness of agreement between the expectation of a test result or a measurement result and a true value

Notes:

The measure of trueness is usually expressed in terms of bias.

Trueness has been referred to as “accuracy of the mean”. This usage is not recommended.

In practice the accepted reference value is substituted for the true value.

Expectation is the expected value of a random variable, e.g. assigned value or long term average {ISO 5725-1}

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

ISO Standard 5725-1: Accuracy (trueness and precision) of measurement methods and results, Part 1: General principles and definitions, ISO, Geneva, 1994.

True value: The value which characterizes a quantity or quantitative characteristic perfectly defined in the conditions which exist when the quantity or quantitative characteristic is considered.

Note:

The true value of a quantity or quantitative characteristic is a theoretical concept and, in general, cannot be known exactly

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

Validated range: That part of the concentration range of an analytical method which has been subjected to validation.

Reference

Harmonized guidelines for single-laboratory validation of methods of analysis, 2002

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