

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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ALINORM 08/31/23

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-first Session
Geneva, Switzerland, 30 June - 4 July 2008

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

Budapest, Hungary
10 - 14 March 2008

Note: This document incorporates Codex Circular Letter CL 2008/7-MAS

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CX 4/50.2

CL 2008/7-MAS
March 2008

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 29th Session of the Codex Committee on Methods of Analysis and Sampling (ALINORM 08/31/23)

A. MATTERS FOR ADOPTION BY THE 31st SESSION OF THE CODEX ALIMENTARIUS COMMISSION

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

1. Proposed Amendment to the *Working Instructions for the Implementation of the Criteria Approach in Codex* (para. 86, Appendix II).

METHODS OF ANALYSIS AND SAMPLING

2. Methods of Analysis in Codex Standards at different steps (paras. 52-61, 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 15 May 2008.**

PROPOSED DRAFT GUIDELINES AT STEP 5

3. Proposed Draft Guidelines on Analytical Terminology (para. 51, Appendix V)

Governments wishing to submit comments on the implications which the Proposed Draft Guidelines may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of World-wide Standards at Step 5 to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme at the above address **before 15 May 2008.**

B. REQUEST FOR COMMENTS AND INFORMATION

DRAFT GUIDELINES AT STEP 6

3. Draft Guidelines for Settling Disputes on Analytical (Test) Results (para. 34, 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, codex@cfri.hu), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, at the above address **before 15 September 2008.**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 29th Session of the Codex Committee on Methods of Analysis and Sampling are as follows:

Matters for adoption by the 31st Session of the Commission:

The Committee:

- agreed to propose an amendment to the *Working Instructions for the Implementation of the Criteria Approach in Codex* in the Procedural Manual (para. 86, Appendix II);
- endorsed or updated the status of several methods of analysis in Codex standards (paras. 52-61, Appendix III);
- agreed to advance to Step 5 the Proposed Draft Guidelines on Analytical Terminology (para. 51, Appendix V);
- agreed to undertake new work on Guidelines for Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology (para. 93) and on the revision of the *Guidelines on Measurement Uncertainty* (CAC/GL 54-2004) (para. 101).

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. 19);
- agreed to return to Step 6 the Draft Guidelines for Settling Disputes on Analytical (Test) Results (para. 34, Appendix IV);
- agreed to consider further at its next session the development of guidelines for establishing methods criteria for identification of relevant analytical methods (para. 86); guidance on sampling uncertainty (para. 108); the question from the Committee on Milk and Milk Products concerning conformity assessment in the presence of significant measurement error (para. 109); and methods of analysis for dioxins and dioxin-like PCBs (para. 128).

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INTRODUCTION

1) The Codex Committee on Methods of Analysis and Sampling held its Twenty-ninth Session in Budapest, Hungary, from 10 to 14 March 2008, by courtesy of the Government of Hungary. The Session was chaired by Professor Péter 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 159 delegates and observers representing 59 Member Countries, one Member Organisation (EC) and 8 international organizations.

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 and recalled the active involvement of Hungary in Codex work throughout the years. She noted the importance of the work of Codex in order to ensure consumer protection in view of its recognition in terms of the WTO Agreements. 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 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.5 of the Rules of Procedure of the Codex Alimentarius Commission.

4) The Committee agreed with the proposal of the Delegation of Sweden to delete Agenda Item 10, the Discussion paper on the reliability of published analytical data, noting that the discussion paper had not been prepared and that work was continuing in this regard in other fora and with this amendment adopted the Provisional Agenda as the Agenda for the Session.

5) The Committee agreed with the proposal of the Delegation of the European Community to convene an in-session working group working in English, French and Spanish under the chairmanship of the Netherlands, open to all interested members and observers, to consider Agenda Item 3(b), the Draft Guidelines for Settling Disputes over Analytical (Test) Results, in order to consider all comments received and to make proposals to facilitate discussion in the plenary session.

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

6) The Committee noted that some matters would be discussed under the relevant agenda items and made the following observations as follows:

Strategic Plan 2008-2013

7) The Committee noted that Activities 1.4, 2.5, 3.3, 4.1, 5.5 and 5.6 of the Strategic Plan 2008-2013 were of specific relevance to the Committee.

8) The Committee further noted the observations of the Delegation of the European Community as expressed in CRD 16, in particular that:

- in relation to activity 1.4, it supported the development and maintenance of Codex standards listing available methods of analysis and sampling under the responsibility of a dedicated committee;
- in relation to activity 2.5, it noted the concerns raised as regards the financial resources devoted by FAO and WHO to the provision for scientific advice, and that the process for the provision of

¹ CX/MAS 08/29/1

² CX/MAS 08/29/2, CRD 5 (comments of CFS), CRD 14 (comments of Thailand) CRD 16 (Comments of European Community)

scientific advice was to be rationalized and in this regard welcomed the Global Initiative for Food-related Scientific Advice (GIFSA);

- in relation to activity 3.3, it was in favour of the development of priority-setting criteria and the recourse to an efficient mechanism to prioritise the list of proposals for new work while recognizing that part of the activities of CCMAS was dependant on the work of other committees.

Draft Guidelines for the Inspection and Certification of Fresh Fruits and Vegetables for Conformity to Quality Standards

9) The Committee considered the sections on sampling in the draft guidelines and noted that procedures were written for inspection of complete lots at the border of the importing country and proposed that procedures should provide for flexibility especially to allow for, amongst others, inspection in the exporting country; in-line inspections and inspections after distribution in the importing country after lots had been broken down. The Committee also recommended that flexibility should be provided for sampling rates taking into account that homogeneity of sampling lots or consistent performance required fewer samples to be inspected.

10) The Committee further recommended that the Committee on Fresh Fruit and Vegetables should take into account the OECD Scheme for the Application of International Standards for Fruits and Vegetables in order to avoid contradictions and duplication of work.

Standard for Sugars: Method for Determination of Colour in Plantation and Mill White Sugar

11) The Committee considered the recommendations of the Committee on Sugars for the methods for determination of colour in plantation and mill white sugar as requested by the Commission.

12) The Delegation of Brazil proposed that Method GS2/3-9 should be included as an alternative method for determination of colour since the principle of the method was similar to Method GS9/1/2/3-8, was equivalent and was widely used. The Delegation of the EC was of the opinion that the recommendations of the CCS should be supported. The Delegation of the United Kingdom informed the Committee that the International Commission for Uniform Methods of Sugar Analysis (ICUMSA) under the chairmanship of a representative of British Sugar, UK, would be discussing this matter at its next meeting in October 2008 and proposed that the Committee should request an information paper from ICUMSA on its decisions regarding the methods for sugar before further consideration of the methods. In addition, the Delegation of the United Kingdom proposed that the Committee should request that ICUMSA should reconsider the numbering of its methods since the current numbering system was confusing to those not familiar with the analysis of sugar.

13) In view of the discussion, the Committee agreed to postpone consideration and endorsement of the methods for determination of colour in sugar to its next session pending inputs from ICUMSA.

Methods of Analysis for Dioxins

14) The Committee noted the reply from the Committee on Contaminants in Foods with regard to the questions posed by the 27th session of the Committee as presented in Annex 2 of CX/MAS 08/29/2 and considered whether the Committee should proceed with the development of methods for dioxins and dioxin-like PCBs or to apply the criteria approach for the determination of dioxins and dioxin-like PCBs. The Committee agreed to discuss the approach to the methods for dioxins and dioxin-like PCBs under Agenda Item 11 "Other Business and Future Work".

Discussion Paper on Sampling Plans for Milk Products in Presence of Significant Measurement Error

15) The Committee noted the request from the Committee on Milk and Milk Products to consider whether assessment of conformity to specifications for milk and milk products and possibly other products in the presence of significant measurement error could be dealt with in a horizontal manner by this Committee. The Delegation of the EC, supported by the Delegation of New Zealand, was in favour of taking a horizontal approach and noted that this matter could be addressed by the ongoing work on measurement uncertainty and uncertainty of sampling. The Committee therefore agreed to consider this matter further under Agenda Item 7.

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS

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

16) The Committee recalled that its last session had agreed to suspend further development of the draft Guidelines and to retain them at Step 7 until publication of papers in scientific journals.

17) The Delegation of New Zealand introduced the item and informed the Committee on the progress of the three papers for publication.

18) The Committee noted that the first paper entitled “Allowing for imprecision in experimental estimates of measurement uncertainty” had been completed and submitted to the Journal of Quality Technology for publication. The Committee further noted that the other two papers, “Allowing for imprecision in experimental estimates of measurement uncertainty” and “Calculating upper confidence limits for the between-laboratories standard deviation and associated measures of precision” required revision before submission for publication. The Committee agreed that matter should be reconsidered by the next session of the Committee pending the publication of the papers and that the Delegation of New Zealand could do a presentation on the possible technical material for inclusion in the Draft Guidelines.

Status of the Draft Guidelines for Evaluating Acceptable Methods of Analysis

19) The Committee agreed to retain the draft Guidelines at Step 7 until publication of the three papers in scientific journals.

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

20) The Committee recalled the decision of its last session to circulate the draft Guidelines for comments at Step 6 and consideration by this session. The Committee further recalled the decision to establish an in-session working group to consider all comments and prepare a revised draft for discussion by the plenary (see Agenda Item 1).

21) The Delegation of the Netherlands as lead of the in-session working group introduced the revised Draft Guidelines as presented in CRD 19 and informed the Committee that the draft had been considerably amended to accommodate the comments received and to reflect discussion in the in-session working group. The Delegation encouraged the Committee to consider the document with the view of forwarding it for adoption by the 31st Session of the Commission.

General Discussion

22) Several delegations noted that the document had been considerably changed from the previous version and that in view of the short time to thoroughly consider the revised version it could not be sent for final adoption, but should be re-circulated for comments at Step 6. The Delegation of Germany speaking on behalf of the EC member states present at the meeting was of the view that the document was a much simpler, clearer and understandable document and should be considered and finalized at the Session.

23) Some delegations highlighted the need to stipulate a time-line for settling of disputes since consignments incorrectly stored could lose their integrity and pose a risk to consumers and would no longer reflect the same conditions as the reserve sample on which a dispute could be settled.

24) Following the general discussion, the Committee considered the document as presented in CRD 19 section by section and made the following amendments and comments.

Scope

25) The Delegation of Kenya, supported by some other delegations, proposed to amend the second sentence in the third paragraph to indicate that the procedure examines the validity of results not only in the

³ CX/MAS 08/29/3, CRD 8 (comments of Kenya), CRD 16 (comments of EC)

⁴ ALINORM 07/30/23, Appendix IV, CX/MAS 08/29/4 (comments of Argentina, Australia, Brazil, EC, New Zealand), CRD 8 (comments of Kenya), CRD 9 (comments of Cuba), CRD 15 (comments of Chile), CRD 19 (report of in-session working group), CRD 23 (report of in-session working group),

importing country since results of the exporting country could also be used. It was clarified that compliance was at the point of entry in the importing country and that it was at this point that non-compliance could be disputed. The Committee therefore agreed to retain the sentence unchanged. In view of this decision, the Delegation of Japan expressed the view that more explanation was needed particularly when it was alleged that non-compliance had occurred.

26) The Committee did not agree to a proposal to indicate that the procedures to resolve disputes were voluntary, recognising that all Codex texts were voluntary in nature and that it was up to governments to apply the guidelines and that the document clearly indicated that the procedures should be followed if there were agreement between the importing and exporting countries.

Prerequisites

27) The Delegation of the Netherlands explained that the previous session of the Committee had agreed upon two prerequisites, but that three additional prerequisites had been added by the in-session working group.

28) To the request from the Delegation of Cuba that the pre-requisites should include the reproducibility limit since it was included in Section 3 Analysing Reserve Samples, it was clarified that the section on pre-requisites gave conditions under which the procedures should be followed and that the inclusion of the reproducibility limit was not applicable in this section.

29) The Committee agreed to include as a pre-requisite the need for both countries to agree on using the guideline to clarify that these guidelines would only apply if both countries agreed to their use.

New Section

30) The Committee agreed to re-insert section 4 of the original document⁵ as section 3 to allow for flexibility in the settlement of disputes, recognising that disputes could be settled without further analysis, but also through the revision of results and procedures between the laboratories of the importing and exporting countries.

Analysing Reserve Samples

31) The Committee agreed to amend the first paragraph to indicate that agreement should be between competent authorities on analysis of reserve samples and to insert a footnote regarding the timeline to indicate that disputes should be resolved within the shortest possible time so as to avoid adversely affecting the quality of the commodity during storage.

Annex

32) Some delegations were of the opinion that the Annex should be deleted, noting that measurement uncertainty of the results was of relevance and that reproducibility and repeatability were not applicable and their inclusion could be confusing to users of the guidelines. The Delegation of New Zealand indicated that the current equations had been taken from ISO 5725-3, but that the Annex could be rewritten in terms of measurement uncertainty. The Delegation of the United Kingdom, supported by the Observer from BIPM, also noted that an ISO guideline was available and that there was no need to reproduce these guidelines in the document. The Committee however agreed to request the Delegation of New Zealand to revise the Annex in terms of measurement uncertainty and to remove references to reproducibility and repeatability and as a consequence deleted the reference to reproducibility in section 3 (new section 4) Analysing Reserve Samples.

33) The Committee considered the revised Annex as presented in CRD 23. The Delegation of Germany expressed the view that only the first formula should be included in the Annex. The Delegation of New Zealand clarified that the Annex needed to cover also the situation where more than one test was done using several reserve samples. The Committee agreed to retain the Annex as proposed for future discussion.

⁵ ALINORM 07/30/23, Appendix IV

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

34) 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) with a view to its finalization by that session.

PROPOSED DRAFT GUIDELINES ON ANALYTICAL TERMINOLOGY FOR CODEX USE⁶

(Agenda Item 4)

35) The Committee recalled that its last session had agreed to return the Proposed Draft Guidelines to Step 3 for comments and redrafting by an electronic working group led by the United States in the light of the comments received. The Delegation of the United States informed the Committee that all definitions from international standard development organizations (SDO) under revision were harmonizable, as ISO/IEC Guide 99, International Vocabulary of Metrology-Basic and General Terms (VIM) had reached the final publication stage. The list of definitions, as presented in Appendix I of the working document, had been redrafted taking into account international harmonization work and the comments received. The Delegation indicated that some additional definitions suggested for Codex use were added to the list in Appendix II for further consideration by the Committee because they either were not included in CL 2007/10-MAS, could not be found in other international sources or represented substantial modifications of current Procedural Manual definitions. Throughout this item reference is made to Appendix I or II of the working document.

36) The Committee expressed its thanks to the Delegation of the United States and to the working group for their excellent work on the revision of the definitions. It was agreed to consider first the definitions in Appendix II in order to decide whether they should be integrated into Appendix I with a view to their finalisation, deleted or retained for further consideration.

37) The Delegation of the United States proposed to replace the definitions in Appendix I for Limit of Detection and Limit of Quantification and consider replacing them with the terms Critical Value, Detection Limit and Quantification Limit in Appendix II as the current definitions in the Procedural Manual were not updated or harmonized internationally and as the current definition of Limit of Detection represents an incorrectly stated definition of the term “critical value”.

38) Some delegations expressed the view that it might be premature to amend definitions that were widely used by analysts, such as limit of detection and limit of quantification, and it was also proposed to retain the current and new terms as alternatives. After some discussion, the Committee agreed to replace the current definitions of Limit of Detection and Limit of Quantification with the new definitions of Critical Value, Detection Limit (Limit of Detection) and Quantification Limit (Limit of Quantification) proposed in Appendix II, and made a number of corrections to the relevant definitions as proposed in CRD 12.

39) The Committee also deleted the definitions of Alpha Error, Beta Error, Decision Limit and Decision Capability as no internationally harmonised definitions existed for these terms. The Committee noted that there was no separate definition of Expectation as it was covered under Bias. The definition of Bias in Appendix II was deleted as it was agreed to use the ISO definition included in Appendix II. The Committee transferred the other definitions in Appendix II to Appendix I.

40) As regards accuracy, some delegations pointed out that the link between accuracy, precision and trueness should be clarified and proposed that “accuracy” should be defined in terms of precision and trueness, as related to a reference value. Other delegations noted that the three current definitions were clear and should be retained. The Committee considered whether to amend the current Note, but agreed that the ISO definition should not be changed and therefore agreed to insert a footnote to clarify that “when applied to a test method, the term accuracy refers to a combination of trueness and precision”.

41) The Committee agreed to use the definition of “applicability” in Appendix II and to delete the term “practicability” as it could not be used as an alternative term.

⁶ CX/MS 08/29/5, CX/MS 08/29/5-Add.1 (comments of Australia, Brazil, New Zealand, Argentina, Japan), CRD 8 (comments of Kenya), CRD 11 (comments of ISO), CRD 12 (comments of the United States), CRD 16 (comments of the EC)

42) The Delegation of Argentina proposed to amend Note 2 to Limit of Detection (LOD) to delete the specific reference to PCR methods and to refer generally to all cases where the blank value is not normally distributed, and did not consider it appropriate to include examples of specific methods in the final version. The Committee noted that the definition including specific provisions on the PCR method had been deleted and that in the new version (from Appendix II) these methods were mentioned only as an example.

43) The Delegation of the Czech Republic proposed to delete the definition of Empirical Method as it was not currently defined in the Procedural Manual or used in Codex and could create confusion as it was very similar to the Type I (defining method). The Committee recognized that two different terms existed to describe the same type of methods and agreed to include Empirical Method in brackets after Defining Method.

44) The note to the definition of the HorRat was amended to clarify the application of the Predicted Relative Standard Deviation (PRSD) calculated by Thompson for very low values of the concentration.

45) As regards measurement uncertainty, the Committee noted a proposal to delete the last part of the definition (“based on the information used”) but agreed to retain it as the estimation of measurement uncertainty for each component depended on the information used.

46) The definition of Quality Assurance was amended to make it clear that it applied to analytical results rather than to “a product or service”.

47) The Committee discussed the reference to a system of units in the definition of Reference Material and agreed to delete the last sentence in the second paragraph of the Notes as it was only an example, although it was noted that this was part of the VIM definition.

48) As regards Relative Uncertainty, the Delegation of Japan proposed either to define "uncertainty" or to refer to "*relative measurement uncertainty*". The Delegation of Finland pointed out that this definition was outdated as current terminology referred to measurement uncertainty and the Committee agreed to delete the definition.

49) The Delegation of Egypt proposed to separate the definitions of reproducibility and repeatability and to specify the difference between intra-laboratory and inter-laboratory conditions, and referred to the relevant EURACHEM definition. The Committee also considered the proposal to include a definition of intermediate reproducibility as defined by ISO.

50) The Delegation of the United States proposed to add a new note to the definition of precision to clarify the intermediate conditions between repeatability and reproducibility when one or more factors within a laboratory are allowed to vary under specified circumstances and to indicate that precision is normally expressed in terms of standard deviation, with the relevant reference to ISO Standard 5725-3. The Committee agreed with this proposal.

Status of the Proposed Draft Guidelines for Analytical Terminology

51) The Committee, recognizing that substantial progress had been made on the revision of the definitions, agreed to advance the Proposed Draft Guidelines for adoption at Step 5 by the 31st Session of the Codex Alimentarius Commission (see Appendix V).

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS

(Agenda Item 5a)⁷

52) 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.

⁷ CX/MAS08/29/6, CRD 1 (Report of the Working Group on Endorsement of Methods of Analysis and Sampling); CRD 6 (comments of IDF); CRD 10 (comments of Republic of Korea)

FAO/WHO Coordinating Committee for the Near East

Standard for Humus with Tehena and Standard for Tehena

Determination of fat content

53) The Committee considered the proposal to use Soxhlet extraction followed by gas chromatography to determine the teheana origin of the fat content in humus with teheana, and similarly to determine the sesame oil origin of the fat content in teheana. It noted that this would not be technically feasible as a mixture of oils might have the same fatty acid profile as sesame seed oil, when analysed with the methods for the determination of fatty acid ranges, ISO 5508: 1995 and ISO 5509: 2000. The Committee therefore agreed to request clarification from the Coordinating Committee for the Near East (CCNEA) on the method to be used for the determination of teheana and sesame seed oil origin, respectively. The Committee also recommended that CCNEA consider the relevant ISO methods used for fat determination in fat or cereal products noting that the proposed method, ISO 6983:1997, was incorrect.

Sampling plans

54) The Committee agreed with the recommendation to delete reference to the General Guidelines on Sampling and recommended that CCNEA consider development of specific sampling plans for the products covered by the Standards for Humus with Tehena, Tehena and Foul Medames.

Codex Committee on Nutrition and Foods for Special Dietary Uses

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

55) The Committee noted the replies by the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and agreed to delete methods for dietary fibre and PER. While agreeing to the request from CCNFSDU to delete the methods for dietary fibre, the Committee noted that a method for dietary fibre was necessary to calculate total energy and agreed to request the CCNFSDU to reconsider inclusion of methods for dietary fibre.

56) The Committee endorsed the ISO and IDF method for sodium and potassium as Type II and the AOAC 984.27 method as Type III and agreed to replace the current method for crude protein with AOAC 991.20 or ISO 8968-1/2:2001|IDF 20-1/2:2001 with a footnote on the use of the appropriate conversion factors as proposed by the CCNFSDU.

FAO/WHO Coordinating Committee for Asia

Draft Standard for Ginseng Product

57) The Committee agreed with the recommendation to endorse all methods for ginseng products as Type IV in view of the need for further method performance studies. The Committee acknowledged the work carried out by the Republic of Korea and encouraged the Republic of Korea to publish the methods currently being validated.

Codex Committee on Milk and Milk Products

Determination of sucrose

58) To the request for clarification on whether the proposed method for the determination of sucrose in blends of sweetened condensed skimmed milk and vegetable fat was appropriate for this product, the Observer from IDF confirmed that the method was applicable to sweetened condensed milk of normal composition prepared from whole, partially skimmed or skimmed milk and sucrose only and containing no altered sucrose, but was of the view that the method was applicable although the scope of the method did not include the type of product under consideration. The Committee therefore agreed to endorse the method as proposed.

Determination of natamycin

59) The Committee noted that two methods had been proposed for the determination of natamycin and agreed to request the CCMMP to clarify which of the two methods should be used as the reference method.

Determination of milk fat in cottage cheese

60) Noting that the methods used for the determination of milk fat in cottage cheese depended on the lactose concentration of the cottage cheese, the Observer from IDF clarified that the Weibull-Berntrop method could be used for all cottage cheese regardless of the composition of the cheese, but that the Schmid-Bondzynski-Ratzlaff method was used for determination of milk fat in cottage cheese with less than 5% lactose.

Peroxide value

61) The Committee noting that the method for determination of peroxide value in milk fat was an empirical method, agreed to endorse this method as a Type I method rather than Type III as proposed.

General Issues – safety concerns of methods

62) The Committee had a brief discussion on the approach to be taken with regard to health and safety concerns of methods. The Chairperson of the Working Group on Endorsement of Methods pointed out that laboratory workers should work in an accredited environment and that regard should be given to use of methods by laboratories. The Delegation of the Netherlands, while supporting the view of the chairperson, further emphasized that Codex committees should also take into account safety and sustainability when proposing methods for inclusion in standards. The Committee agreed that, although safety should be taken into account when considering methods for endorsement, it should not affect endorsement of methods and that if there was a choice between different methods, the safer option should be given preference. The Committee further noted that concerns of health and safety should be addressed through good laboratory practice and that standards development bodies should continue to take into account these factors when developing new methods.

63) The Committee expressed its appreciation to Dr Wood and to the Working Group for their excellent work and agreed that the Working Group would be reconvened prior to the next Session. The status of endorsement of methods of analysis is presented in Appendix III.

CONVERSION OF METHODS FOR TRACE ELEMENTS INTO CRITERIA⁸

(Agenda Item 5b)

64) The Committee recalled that its last session had considered a discussion paper on the conversion of methods for trace elements into criteria and had agreed that it would be redrafted by the Delegation of Sweden, with the assistance of Norway and NMKL and interested members and observers. The Delegation of Sweden pointed out that the title of the document was changed to “Guidelines on Establishing Methods Criteria for the Identification of Relevant Analytical Methods” as the focus was not on the conversion of methods but on the development of criteria on the basis of the specification for the commodity concerned.

65) The Observer from NMKL presented the document and pointed out that the criteria approach would allow analysts to select adequate methods of analysis, and would also be useful to the Committee when considering the methods submitted for endorsement. In Section 1, it was proposed to amend the section in the Procedural Manual on the working instructions for the implementation of the criteria approach, including a table of numerical values for the minimum applicable range, LOD, LOQ, precision, recovery and trueness, according to the value of the maximum level. Section 2 included more detailed guidelines for establishing methods criteria for the identification of relevant analytical methods, with a step by step procedure to decide on the applicability of the method. Section 3 suggested appropriate criteria for heavy metals and complying methods, including a review of current methods for heavy metals according to the criteria.

66) The Committee expressed its appreciation to Sweden and NMKL for the preparation of this comprehensive and excellent document on complex questions. The Committee had a general discussion on the application of the criteria approach and its possible implications for the work of the Committee and the use of methods for the purpose of food control at the national level.

⁸ CX/MS 08/29/7, CRD 7 (comments of Japan), CRD 16 (comments of the EC), CRD 20 (revised version of Section 1)

67) The Delegation of New Zealand stressed the need for a scientific approach to the evaluation of methods of analysis and recalled that the scientific papers currently under development took a different approach to that proposed in the document. The Delegation indicated that further consideration should be given to the proximity of the result to the maximum limit, the high levels of measurement uncertainty in the estimated characteristics of the method, and the risk of excluding methods that were applicable for the provision concerned. The Delegation also expressed the view that the scope of the criteria should not be expanded beyond the determination of trace elements.

68) The Delegation of the United Kingdom recalled that the criteria approach had already been adopted and that the purpose of the document was to provide instructions on its practical applications and to quantify acceptable ranges for particular criteria, which would allow the Committee to assess individual methods against a set of specific criteria, which had not been possible so far. The Delegation noted that this approach was also taken by standard developing organizations and that alternative approaches were not likely to be available in the near future.

69) The Delegation of Australia proposed to consider the application of the criteria to methods which were not collaboratively tested, and especially for pesticide and veterinary drugs residue analysis.

70) The Observer from IDF pointed out that the criteria approach should take into account the risk to the producer and to the consumer, the implications of the use of alternative methods and the fitness for purpose of the method.

71) Several delegations supported the general approach of the document and the revised working instructions as they provided clear instructions to develop criteria for the methods for trace elements and facilitate the selection of appropriate methods.

Section 1: Working Instructions for the Implementation of the Criteria Approach

72) Several delegations supported in principle the inclusion of Section 1 in the Procedural Manual as it would provide useful instructions to the CCMAS and other Codex Committees. The Committee discussed the text in detail and made the following amendments and comments.

73) The Committee agreed that the criteria would not replace the relevant methods of analysis for trace elements but would be specified in conjunction with the method where appropriate, as it would facilitate the use of the criteria by analysts, and amended the second paragraph in Section 1 accordingly. It was clarified at the beginning of the paragraph that these provisions applied when a committee decides that a set of criteria should be developed.

74) The Committee recognized that methods were not submitted only by commodity committees and therefore agreed to refer to “Codex committees” or “responsible committees” throughout the document, and to “standard” instead of “commodity standard.”

75) As regards the Table, the Committee agreed that the minimum applicable range of the method depends on the specified level and can be expressed either in terms of the reproducibility standards deviation or in terms of the LOD and LOQ.

76) The Delegation of Egypt, supported by other delegations, expressed the view that the precision value for $ML < 0.1$ mg/kg RSD_R of 44% was too high. The Observer from NMKL indicated that this was based on the application of the Thompson calculation whereby for concentration below 0.12 ppm the theoretical relative standard deviation (RSD_{TR}) was 22% and that the RSD_R was twice that value. After some discussion, the Committee agreed to refer to the RSD_{TR} of 22% in the Table.

77) The Delegation of Japan proposed to delete the figures on recovery in the Table as other calculations could result in different values. After some discussion, the Committee agreed to retain the current figures and to indicate that other guidelines are available for expected recovery ranges.

78) The Committee agreed that for the evaluation of trueness preferably certified reference material should be used and the sentence relating to z score was deleted.

79) The Committee agreed to forward the proposed amendment to the *Working Instructions for the Implementation of the Criteria Approach in Codex* in Section I, to the 31st Session of the Codex Alimentarius Commission for adoption and inclusion in the Procedural Manual (see Appendix II).

Section II

80) The Committee did not consider the section in detail at this stage and agreed that an electronic working group coordinated by Sweden, with the assistance of NMKL, would redraft Section II in the light of the decisions of the current session on Section I in order to provide guidelines for establishing method criteria for inclusion in the Procedural Manual, for consideration at the next session.

Section III

81) In Table 1 on the review of methods for trace elements, the Committee noted the comments of the Delegation of Belgium that the method for mercury in fish should be deleted as it was not validated for fish and the comments of the Delegation of Algeria that the method for tin in canned food should be updated. The Committee however could not consider the Table in detail at this stage and agreed that further consideration should be given to these methods in the framework of the endorsement process.

82) The Committee agreed to amend the endorsement status of some methods that did not meet the current criteria for endorsement and were not applicable to the commodities concerned, as follows.

83) The Committee agreed that the methods for the determination of lead, arsenic, cadmium and mercury in salt (ESPA/CN E/108-1994 105 to 108) should be classified as Type IV instead of the current Type II as the collaborative studies for these methods were tested on levels below the LOD and demonstrated poor precision.

84) The Committee agreed that the endorsement of AOAC 986.15 as Type III should be withdrawn in the following cases: cadmium in mineral water as the detection limit (0.05 mg/kg) is higher than the specified Codex ML (0.003 mg/kg); lead in milk as the RSDr= 106% for the lowest assessed level of 0.03 mg/kg, which is above the ML for milk (0.02 mg/kg); and lead in fruit juices as the method shows poor precision around the ML. It was noted that this change applied only to these specific commodities as the method was endorsed as a Codex General Method.

85) The Committee confirmed the applicability of the ISO method for mercury in natural mineral waters as Type II and updated the reference to ISO 5666-3:1999.

Status of the Guidelines on Establishing Methods Criteria for the Identification of Relevant Analytical Methods

86) The Committee agreed to forward the proposed amendment to the Procedural Manual in Section I, as amended at the session, to the 31st Session of the Codex Alimentarius Commission for adoption and inclusion in the Procedural Manual (see Appendix II); to consider further the proposed Guidelines in Section II at its next session with a view to their inclusion in the Procedural Manual; to consider Section III in the framework of the endorsement of methods of analysis; and to forward the changes in endorsement status of several methods for adoption by the Commission (see Appendix III).

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

87) The Committee recalled that its last session had agreed that an electronic working group led by the Delegations of Germany and the United Kingdom would revise the document discussed at that session and in addition would give consideration to the development of guidelines for governments and would prepare a project document as a proposal for new work.

88) The Delegation of Germany, also speaking on behalf of the Delegation of the United Kingdom, as the lead of the electronic working group, introduced the document and informed the committee that the document had been revised taking into consideration comments received, that changes made were not too substantial and that the structure had been maintained. The Delegation also reminded the committee that the *ad hoc* Task Force on Foods Derived from Biotechnology had encouraged the Committee to proceed with work in this regard. The Delegation, referring to the *Principles for the Risk Analysis of Foods Derived from*

⁹ CX/MAS 08/29/8, CRD 4 (comments of Argentina), CRD 13 (comments of United States), CRD 17 (comments of Republic of Korea), CRD 21 (Project document)

Modern Biotechnology (CAC/CL 44-2003), further indicated that for post market monitoring of foodstuffs derived from biotechnology specific risk management tools such as analytical methods were needed and recommended that the Committee consider new work on guidelines as presented in the project document in CRD 21.

89) The Delegation of Argentina, referring to its comments in CRD 4, indicated the need to proceed with caution when developing criteria for methods since reference materials and proficiency testing were necessary for this approach but were not always available.

90) The Delegation of the United States, supported by the Delegation of Australia, referring to its comments in CRD 13, expressed the view that there was no clearly defined need in Codex for methods as no provisions existed and that development of methods were not in line with Codex strategic objectives, in particular as ISO had active work in this area and such work in the Committee could lead to duplication. The Delegation proposed to forward the paper to FAO who could convene an expert consultation to use the paper as a basis for a guidance document for Governments. The Delegation further stated that only once specific provisions requiring detection and identification of foods derived from biotechnology had been established in Codex, development of guidelines should be considered.

91) The Delegation of the EC expressed support for new work as presented in CRD 21 emphasizing that the development of guidelines was essential for future work of Codex, that it would be useful to have methods to assess the foodstuffs entering the market to ensure fair practices in the food trade, and that this was important work particularly for developing countries.

92) In noting the clarification by the Secretariat that since the proposal for new work was guidance for governments, reference to Codex committees in the section on *assessment against the criteria for the establishment of work priorities* should be deleted, the Committee agreed to revise the project document accordingly.

93) In view of the discussion, the Committee agreed to the proposal for new work and agreed to submit the revised project document, as amended in paragraph 92, to the 31st Session of the Commission for approval as new work, as part of the working document including all proposals for new work. Subject to the decision of the Commission, the Proposed Draft Guidelines as presented in the working document (CX/MAS 08/29/8) would be circulated at Step 3 for comments and consideration by the next session of the Committee. The Delegations of the United States, Australia and New Zealand expressed their opposition to this decision to undertake new work.

GUIDANCE ON MEASUREMENT UNCERTAINTY AND UNCERTAINTY OF SAMPLING (Agenda Item 7)¹⁰

MEASUREMENT UNCERTAINTY

94) The Committee recalled that, when adopting the text 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 CCMAS the request made by some delegations for further guidance in order to address measurement uncertainty. The Committee had considered at its 28th Session a discussion paper prepared by the Delegation of the United Kingdom on this subject and had agreed that the paper would be revised by an electronic working group for further consideration by the 29th Session.

95) The Delegation of the United Kingdom indicated that the paper had been revised in the light of the comments received in order to provide explanatory notes to the current Guidelines on Measurement Uncertainty (CAC/GL 54-2004), which addressed the relationship between measurement uncertainty (MU), the analytical result and the method used to obtain the result; the use of measurement uncertainty and definition of a dispute situation; the procedures for estimating measurement uncertainty; and relevant considerations to be taken into account in the process. The Delegation pointed out that the values of measurement uncertainty estimations were intended to give an indication to laboratories of the uncertainty that could be expected for a range of acceptable concentrations.

¹⁰ CX/MAS 08/29/9, CX/MAS 08/29/9-Add.1, CRD 18 (examples of uncertainty of sampling to be read in conjunction with CX/MAS 08/29/9-Add.1), CRD 15 (comments of Chile), CRD 22 (project document)

96) Several delegations supported further work on the development of the document as an amendment to the current Guidelines and the Committee had a general discussion on the type of guidance that should be provided.

97) The Delegation of Australia, supported by other delegations, expressed the view that under section 6. Use of Measurement Uncertainty and Definition of a Dispute Situation, the last paragraph was too prescriptive as it required that for the purpose of export the “certificated value” obtained by the producer/exporter must have the uncertainty of the result added to it, and for that value to be below the specification. The Delegation proposed that this should be left to the exporter to decide and that the decision should be based on risk. The Delegation of the United Kingdom clarified that producers or exporters should be aware that this was an objective requirement in order to avoid disputes but that they could always decide to apply it or not in view of the circumstances.

98) The Delegation of Chile indicated that its written comments in CRD 15 provided additional definitions and explanations of the different components of uncertainty and suggested how to consider these aspects for a better understanding of the document.

99) The Delegation of New Zealand expressed the view that the Committee should proceed with caution before establishing new guidance or procedures on measurement uncertainty in order to avoid conflicting requirements, as relevant provisions already existed in the *General Guidelines on Sampling* (CAC/GL 50-2004) and the *Guidelines on Estimation of Uncertainty of Results* (CAC/GL 59-2006) in the area of pesticide residue analysis.

100) The Observer from BIPM, referring to its written comments, proposed several amendments and in particular updating the definitions according to the latest version of the ISO Guides 98 and 99; clarifying that the use of reproducibility obtained from collaborative studies is insufficient to assess measurement uncertainty; and that metrological traceability should be considered as an additional factor along with bias, matrix effect and competence of laboratory under Section 3 of Annex IIa.

101) The Committee noted that, although the initial intention of the working document was to provide additional guidance to the current *Guidelines on Measurement Uncertainty* (CAC/GL 54-2004), the main body of the Guidelines may also need to be updated as appropriate. The Committee therefore agreed to propose new work on the development of guidance on measurement uncertainty, through the addition of explanatory notes to the Guidelines, and updating of the current Guidelines as necessary. The Committee considered the project document presented in CRD 22, deleted the second sentence under Assessment against the Criteria (page 2) as it was not clear, and agreed that it provided all the information required to justify the proposal for new work and would be forwarded to the Commission as part of the working document including all proposals for new work. The Committee also recalled that the revision of the Guidelines would address the direct request of the 26th Session of the Commission to the Committee concerning the development of further guidance on measurement uncertainty (ALINORM 06/29/41, para.34).

102) The Committee agreed that, subject to the approval of the Commission, the Delegation of the United Kingdom, with the assistance of an electronic working group open to all members and observers and working in English, would prepare a Proposed Draft Revision of the Guidelines for comments at Step 3 and consideration by the next session.

GUIDANCE ON UNCERTAINTY FROM SAMPLING

103) The Committee recalled that its last session had been informed of the latest developments concerning uncertainty from sampling at the international level and, recognizing the importance of addressing this subject in the framework of Codex, had agreed that the Delegation of the United Kingdom would prepare a document addressing this question in conjunction with sampling uncertainty.

104) The Delegation of the United Kingdom indicated that the following guides had been published since the last session: EURACHEM/EUROLAB/CITAC/Nordtest *Guide on the Estimation of Measurement Uncertainty Arising from Sampling*; and Nordtest handbook for sampling planners on sampling quality assurance and uncertainty estimation *Uncertainty from sampling* (Based upon the EURACHEM international guide *estimation of measurement uncertainty arising from sampling*). It was

noted that The Nordtest Guide is intended to be rather more practical than the procedures outlined in the EURACHEM Guide.

105) The Delegation stressed the importance of addressing sampling uncertainty in Codex in view of the publication of these guides, and indicated that the document considered methods of estimating uncertainty, using real case studies as examples (CRD 18), addressed the role of measurement uncertainty in the decision making process and the assessment of fitness for purpose. The second part of the document examined whether global fitness for purpose criteria could be set for sampling uncertainty.

106) The Delegation of Hungary pointed out that the estimation of sampling uncertainty depended on the portion of the sample on which the analysis applied, for example in the case of MRLs, and that the establishment of fitness for purpose criteria should be further clarified.

107) The Delegation of Australia supported further work in this area and pointed out that the estimation of sampling uncertainty would depend on how compliance was defined, either on the average concentration of the lot or against a maximum value in a sample.

108) The Committee recognized that at this stage it was premature to undertake new work but that this question should be kept under consideration and therefore agreed that the Delegation of the United Kingdom, with the assistance of an electronic working group, would revise the discussion paper for consideration by the next session.

Committee on Milk and Milk Products

109) The Committee considered the question from the Committee on Milk and Milk Products concerning conformity assessment in the presence of significant measurement error (see Agenda Item 2). The Committee agreed that this could be considered in conjunction with the general approach to uncertainty of sampling. The Delegation of New Zealand pointed out that the General Guidelines on Sampling did not address this issue and recalled that the document presented to the CCMMP made specific proposals. The Committee welcomed the offer of the Delegation of New Zealand to prepare a discussion paper clearly outlining the problem and indicating how it could be addressed in a horizontal manner.

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS AND SAMPLING (Agenda Item 8)¹¹

110) The Secretary of the Inter-Agency Meeting, Dr Richard Cantrill (AOCS), introduced the report of the 20th IAM presented in CRD 2. In noting that several outputs of this report (criteria approach; harmonization of analytical terminology; measurement uncertainty and editorial corrections to method references) had been considered under earlier agenda items or at the Working Group on Endorsement of Methods and Analysis and Sampling, he highlighted the following important issues discussed at the IAM.

111) Dr Cantrill informed the Committee that the IAM was willing to develop position papers for CCMAS on the implementation of a hierarchical method selection process and on how Standards Development Organisations' view and use the criteria if such guidance was needed by the Committee on the use of the criteria approach.

112) It was reported that IAM would encourage its members to use the revised guidelines on Analytical Terminology for Codex Use once finalized.

113) It was reported that ISO had started a new initiative on the determination of baseline practices used in sampling bulk commodities and that IAM proposed to have a workshop on bulk commodity grain sampling.

114) It was reported that little progress had been made since the last meeting of IAM on the recovery correction in collaborative trials and indicated that the previous results would be made available through the IAM website (www.aocs.org/meeting/iam).

115) It was reported that the IAM website would continue to include information on the current work programmes of IAM members and members of the Committee were encouraged to use the website which served as a useful resource for published standards and other information.

¹¹ CRD 2 (Report of the 20th Meeting of the International Organizations Working in the Field of Methods of Analysis and Sampling (Inter-Agency Meeting))

116) The Committee was updated on the European Framework 6 Project MoniQA which in the long term will form the basis of a global network of food safety and quality experts.

117) The Committee was also informed of the development of guidelines for the validation of qualitative methods through collaborative trials which was a joint IUPAC/MoniQA cooperation using professional statisticians; that the EURACHEM and Nordtest Guides on the estimation of sampling uncertainty have been published and that workshops have or will be held to aid in interpretation and implementation of the guides; that a recent publication on measurement uncertainty had been reviewed and that it was acknowledged that the Horwitz equation may not always be an accurate predictor of the performance of a method.

118) The Committee was further informed that upon its request, the workshop on measurement uncertainty to assist CCMAS delegates with the application of method performance and analytical uncertainty had been held on 9 March, hosted by IAM and its sponsoring organizations. The workshop was attended by 75 delegates from 29 countries, included many presentations from experts in the field, allowed for ample audience participation and had been a great success. The Chair of the IAM also reported that should the Committee require similar workshops in future, the IAM and its sponsoring organizations would be willing to assist in organizing and hosting such workshops. The Committee expressed its appreciation to the IAM and its sponsors for a successful informative workshop.

119) Finally, the Chair of the IAM informed the Committee that the AOCS would continue as the Secretariat of the meeting and that Dr Wood would continue to chair this meeting for another year.

120) In conclusion, 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 noted that the next IAM would be held on the Friday prior to the next session of the Committee.

DISCUSSION PAPER ON THE ROLE OF CCMAS WITH RESPECT TO METHODS WITHOUT SPECIFIC PROVISIONS IN CODEX STANDARDS (Agenda Item 9)¹²

121) The Committee recalled that its last session had discussed the difficulties experienced in developing or endorsing methods of analysis when no provisions existed in Codex standards and that it had agreed that the Delegation of the Netherlands should further develop a discussion paper and to provide evidence of restrictions with respect to the Committee's terms of reference for consideration by the next session.

122) The Delegation of the Netherlands introduced the paper and informed the Committee that it had identified three existing phrases that put limitations on the work of the Committee, i.e. the terms of reference; the General Criteria for the Selection of Methods of Analysis paragraph (d); and the Recommendations for a Checklist of Information Required to Evaluate Methods of Analysis Submitted to the CCMAS for Endorsement, points 1.1.3 and 1.1.4.

123) The Delegation therefore proposed that these sections be amended to allow for methods from task forces also to be considered by the Committee and to allow for the endorsement of methods for which no specific provisions existed in Codex standards.

124) The Delegation of Brazil supported the proposal to amend the terms of reference to reflect that the Committee should also consider methods of analysis and sampling proposed by task forces and to allow more flexibility for the Committee to endorse or develop methods for which no provisions existed in standards. The Delegation of France cautioned that the amendments proposed were not necessarily consistent with the provisions in other sections of the Procedural Manual such as on "normal practice" for methods of analysis in the Relations between Commodity Committees and General Committees which referred specifically to provisions. Other delegations that spoke did not support the proposed amendments and were of the opinion that the terms of reference should not be too open-ended and that the current terms of reference were sufficient to allow the Committee to conduct its work.

125) In view of the discussion the Committee agreed not to make any amendments as proposed and thanked the Delegation of Netherlands for its efforts.

DISCUSSION PAPER ON THE RELIABILITY OF PUBLISHED ANALYTICAL DATA**(Agenda Item 10)**

Deleted (see Agenda Item 2)

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)**Methods of Analysis for Dioxins and Dioxin-like PCBs**

126) The Committee recalled that it had received a detailed reply from the Committee on Contaminants in Foods (CCCF) to the questions put forward by the 27th Session concerning methods of analysis for dioxins and dioxin-like PCBs (see Agenda Item 2).

127) The Committee noted that the establishment of criteria for dioxins was under consideration in the framework of the criteria approach, as discussed under Agenda 5a). The Delegation of Germany proposed to consider this issue under a separate agenda item in order to update the document prepared at the 27th Session in the light of the replies and comments provided by the CCCF, and therefore to discontinue consideration of methods for dioxins under Agenda Item 5b). The Committee agreed with this proposal.

128) The Committee agreed that the Delegation of Germany would lead an electronic working group open to all members and observers, in order to update document CX/MAS 06/27/8 in the light of the remarks made by CCCF; answer the questions on the applicability of the methods for the indicated ranges and commodities concerned; review the validation data for the methods; and set criteria for dioxin analysis. This discussion paper would be considered as a separate Agenda Item at the next session.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 12)

129) The Committee was informed that the 30th Session of the Committee would be held in Budapest from 9 to 13 March 2009. The exact date and venue would be determined by the host country and the Codex Secretariat. The Committee confirmed that the current interval between meetings should be maintained.

130) The Committee expressed its warm thanks and appreciation to Professor Péter Biacs, Chair of the Committee, and to Vice-Chair Professor Pál Molnar, on the occasion of their last session as Chair and Vice-Chair respectively, as the excellent chairmanship of the Committee throughout the years had contributed significantly to the progress made by the Committee on many complex issues of great importance for the work of Codex in the area of analysis and sampling, and wished them all success in their future activities.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 08/31/23
Proposed Amendment to the <i>Working Instructions for the Implementation of the Criteria Approach in Codex</i>	(*)	Governments 31 st CAC	para. 86 Appendix II
Endorsement of methods of analysis in Draft Standards and existing Standards		Governments 31 st CAC	paras. 52-61 Appendix III
Proposed Draft Guidelines on Analytical Terminology	5	Governments 31 st CAC 30 th CCMAS	para. 51 Appendix V
Draft Guidelines for Evaluating Acceptable Methods of Analysis	7	30 th CCMAS	para. 19
Draft Guidelines for Settling Disputes on Analytical (Test) Results	6	Governments 30 th CCMAS	para. 34 Appendix IV
Proposed Draft Guidelines for Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology	1/2/3	Governments 31 st CAC 30 th CCMAS	para. 93
Guidance on measurement uncertainty and uncertainty of sampling (Proposed Draft Revision of the <i>Guidelines on Measurement Uncertainty</i>)	1/2/3	Governments 31 st CAC 30 th CCMAS	para. 101
Other issues (discussion papers)			
Guidelines for establishing methods criteria for identification of relevant analytical methods	(*)	Sweden/NMKL 30 th CCMAS	para. 86
Guidance on Uncertainty from Sampling		United Kingdom 30 th CCMAS	para. 108
Consideration of Methods of Analysis for Dioxins and Dioxin-like PCBs		Germany 30 th CCMAS	para. 128
Question from the Committee on Milk and Milk Products		New Zealand 30 th CCMAS	para. 109

(*) Procedural Manual

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ALINORM 08/31/23
APPENDIX II

PROPOSED AMENDMENT TO THE PROCEDURAL MANUAL
WORKING INSTRUCTIONS FOR THE IMPLEMENTATION OF
THE CRITERIA APPROACH IN CODEX

(This replaces the *Working Instructions for the Implementation of the Criteria Approach in Codex* in the *Principles for the Establishment of Codex Methods of Analysis*)

Any Codex Committee may continue to propose an appropriate method of analysis for determining the chemical entity and/or develop a set of criteria to which a method used for the determination must comply. In either case the specified maximum level, minimum level, any other normative level or the concentration range of interest has to be stated.

When a Codex Committee decides that a set of criteria should be developed, in some cases the Committee may find it easier to recommend a specific method and request the Codex Committee on Methods of Analysis and Sampling (CCMAS) to “convert” that method into appropriate criteria. The Criteria will then be considered by the CCMAS for endorsement and will, after the endorsement, form part of the standard. If a Codex Committee wishes to develop the criteria, it should follow instructions given for the development of specific criteria as outlined in table 1.

Table 1: Guidelines for establishing numeric values for the criteria:

Applicability:	The method has to be applicable for the specified provision, specified commodity and the specified level(s) (maximum and/or minimum) (ML). The minimum applicable range of the method depends on the specified level (ML) to be assessed, and can either be expressed in terms of the reproducibility standard deviation (s_R) or in terms of LOD and LOQ.
Minimum applicable range:	For $ML \geq 0.1$ mg/kg, $[ML - 3 s_R, ML + 3 s_R]$ For $ML < 0.1$ mg/kg, $[ML - 2 s_R, ML + 2 s_R]$ s_R^1 = standard deviation of reproducibility
Limit of Detection (LOD):	For $ML \geq 0.1$ mg/kg, $LOD \leq ML \cdot 1/10$ For $ML < 0.1$ mg/kg, $LOD \leq ML \cdot 1/5$
Limit of Quantification (LOQ):	For $ML \geq 0.1$ mg/kg, $LOQ \leq ML \cdot 1/5$ For $ML < 0.1$ mg/kg, $LOQ \leq ML \cdot 2/5$

¹ The s_R should be calculated from the Horwitz / Thompson equation. When the Horwitz / Thompson equation is not applicable (for an analytical purpose or according to a regulation) or when “converting” methods into criteria then it should be based on the s_R from an appropriate method performance study.

Precision:	For ML \geq 0.1 mg/kg, HorRat value \leq 2 For ML $<$ 0.1 mg/kg, the $RSD_{TR} < 22\%$. RSD_R^2 = relative standard deviation of reproducibility			
Recovery (R):	Concentration	Ratio	Unit	Recovery (%)
	100	1	100% (100 g/100g)	98 – 102
	≥ 10	10^{-1}	$\geq 10\%$ (10 g/100g)	98 – 102
	≥ 1	10^{-2}	$\geq 1\%$ (1 g/100g)	97 – 103
	≥ 0.1	10^{-3}	$\geq 0.1\%$ (1 mg/g)	95 – 105
	0.01	10^{-4}	100 mg/kg	90 – 107
	0.001	10^{-5}	10 mg/kg	80 – 110
	0.0001	10^{-6}	1 mg/kg	80 – 110
	0.00001	10^{-7}	100 μ g/kg	80 – 110
	0.000001	10^{-8}	10 μ g/kg	60 – 115
	0.0000001	10^{-9}	1 μ g/kg	40 – 120
	Other guidelines are available for expected recovery ranges in specific areas of analysis. In cases where recoveries have been shown to be a function of the matrix other specified requirements may be applied.			
Trueness:	For the evaluation of trueness preferably certified reference material should be used.			

The criteria in Table 1 must be approved for the determination in question.

However, the primary responsibility for supplying information about the specified CODEX level(s), methods of analysis and criteria resides with the referring Committee. If the Committee fails to provide a method of analysis or criteria despite numerous requests, then the CCMAS may establish appropriate criteria as above.

CONVERSION OF SPECIFIC METHODS OF ANALYSIS TO METHOD CRITERIA BY THE CCMAS

When a Codex Committee submits a Type II or Type III method to CCMAS for endorsement, it should also submit information on the specified Codex level(s) along with the provision to enable the CCMAS to convert it into suitable generalized analytical characteristics:

- trueness
- applicability (matrix, concentration range and preference given to 'general' methods)
- limit of detection
- limit of quantification

² The RSD_R should be calculated from the Horwitz / Thompson equation. When the Horwitz / Thompson equation is not applicable (for an analytical purpose or according to a regulation) or when “converting” methods into criteria then it should be based on the $RSDs_R$ from an appropriate method performance study.

- precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories), but generated from method performance study data rather than measurement uncertainty considerations
- recovery
- selectivity
- sensitivity
- linearity

These terms are defined in the Analytical Terminology for Codex Use, as are other terms of importance.

The CCMAS will assess the actual analytical performance of the method which has been determined in its validation. This will take account of the appropriate precision characteristics obtained in method performance studies which may have been carried out on the method together with results from other development work carried out during the course of the method development. The set of criteria that are developed will form part of the report of the CCMAS and will be inserted in the appropriate Codex Standard.

In addition, the CCMAS will identify numeric values for the criteria for which it would wish such methods to comply.

ASSESSMENT OF THE ACCEPTABILITY OF THE PRECISION CHARACTERISTICS OF A METHOD OF ANALYSIS

The calculated repeatability and reproducibility values can be compared with existing methods and a comparison made. If these are satisfactory then the method can be used as a validated method. If there is no method with which to compare the precision parameters then theoretical repeatability and reproducibility values can be calculated from the Horwitz equation. (M. Thompson, *Analyst*, 2000, 125, 385-386).

STATUS OF ENDORSED METHODS OF ANALYSIS

- A. FAO/WHO Coordinating Committee for the Near East
- B. Codex Committee on Nutrition and Foods for Special Dietary Uses
- C. FAO/WHO Coordinating Committee for Asia
- D. Codex Committee on Milk and Milk Products - Update of methods previously endorsed
- E. Change in status of methods for contaminants

A. FAO/WHO COORDINATING COMMITTEE FOR THE NEAR EAST¹

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE	STATUS
Humus with tehena	Sample Preparation	AOAC 945.68		–	E
Humus with tehena	Salt content	AOAC 971.27 NMKL 178:2004	Potentiometry	II	E
Humus with tehena	Total acidity	AOAC 925.53	Titrimetry	I	E
Humus with tehena	Fat content	AOAC 945.16 ²	Gravimetry (Soxhlet extraction)		NE
Tehena	Moisture Content	ISO 934:1980	Gravimetry	I	E
Tehena	Protein content	ISO 1871:1975	Titrimetry, Kjeldahl	I	E
Tehena	Fat Content	ISO 8292:1991 or ISO 7302:1982 Gas Chromatography method to verify the sesame oil origin of the fat content ²	Gas Chromatography		NE
Tehena	Total Ash	ISO 6884:1980	Gravimetry	I	E
Tehena	Acid Insoluble Ash	ISO 735:1977	Gravimetry	I	E
Tehena	Total Acidity	ISO 729:1988	Titrimetry	I	E
Tehena	Sesame oil	AOCS Cb 2-40 (97) (Baudouin Test)	Colour reaction	I	E

¹ ALINORM 07/30/40, Appendices II, III and IV

² CCNEA to provide clarification on how to determine the tehena origin of fat content

Foul medames	Sample Preparation	AOAC 945.68		–	E
Foul medames	Salt content	AOAC 971,27 NMKL 178:2004	Potentiometry	II	E
Foul medames	Drained weight	AOAC 968.30	Sieving	I	E

B. COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES³

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

Provision	Method	Principle	TYPE
Sodium and potassium	ISO 8070 IDF 119:2007	Flame atomic absorption spectrophotometry	II
Sodium and potassium	AOAC 984.27	ICP emission spectrometry	III
Crude protein	AOAC 991.20 ISO 8968-1/2 IDF 20-1/2: 2001	Titrimetry (Kjeldahl)	I

Determination of Crude Protein

The calculation of the protein content of infant formulas prepared ready for consumption may be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

³ ALINORM 07/30/26, Appendix II

C. FAO/WHO COORDINATING COMMITTEE FOR ASIA⁴

Draft Standard for Ginseng Product

PROVISION	METHOD	PRINCIPLE	TYPE
Moisture	AOAC 925.45	Gravimetry, drying at atmospheric pressure	IV
Solids	AOAC 925.45 and calculated by subtracting the content of water from 100%.	calculation	IV
Ash	AOAC 923.03	Gravimetry, after ashing at 550°C	IV
Water-insoluble Solids	described in Annex A	Gravimetry	IV
Water-saturated 1-butanol extracts	described in Annex B	Gravimetry	IV
Identification of ginsenosides Rb1 and Rf	described in Annex C	TLC or HPLC	IV

⁴ ALINORM 07/30/15, Appendix III

Determination of Water-insoluble Solid Content

Place ca 1 g sample in 25 ml centrifugal tube with constant weight. Add 15 ml of distilled water and dissolve the sample. Centrifuge for 15 min at 3000 rpm and discard supernatant. Repeat twice this centrifugation. Dry centrifugal tube and residue to constant weight at 105°C. Report results in percent.

$$\text{water-insoluble solid content (\%)} = (W1-W0)/ S \times 100$$

S: weight of sample (g)

W1: weight of centrifugal tube and residue after drying (g)

W0: weight of centrifugal tube (g)

* The method mentioned in Annex A is stipulated in the Korean Food Standards Law and modifies the "AOAC Official Method 950.66."

Determination of water-saturated 1-butanol extracts

1. Preparation of water-saturated 1-butanol

Mix 1-butanol with water in separatory funnel in the ratio of 70:30 and shake it vigorously. Let stand until the upper and lower phases are separated. Discard lower layer (water layer).

2. Analysis method

2.1 Dried Ginseng

Weigh ca 5 g test portion, ground to pass 80 mesh or finer sieve, into 250 ml erlenmeyer flask and reflux with 50 ml water saturated 1-butanol on a water bath at 80°C for 1 hour. Decant 1-butanol into another 250 ml erlenmeyer flask. Repeat twice the above extraction. Combine the solvent and filter into a 250 ml separatory funnel. Add 50 ml of distilled water. Shake and stand until the upper and lower layer are separated completely into two layers. Collect 1-butanol layer (upper layer) in an evaporation flask, vacuum-evaporate to dryness. Add 50 ml of diethyl ether, re-flux it on a water bath approximately at 46°C for 30 minutes, and decant the diethyl ether. Dry flask and contents to constant weight at 105°C. Report increase in weight flask as "1-butanol extracts in ginseng". Express the result as mg per gram on dried ginseng.

$\text{water-saturated 1-butanol extracts(mg/g)} = (A-B)/ S$
--

S: weight of sample (g)

A: weight of flask after concentrating and drying extracts (mg)

B: weight of flask (mg)

2.2 Ginseng Extract (including a powered type)

Place 1~2 g sample in 250 ml erlenmeyer flask, dissolve in 60ml water and transfer into separating funnel. Add 60ml of diethyl ether. Shake and stand until the upper and lower layer are separated. Collect lower layer and extract with 60 ml water saturated 1-butanol for three times. Combine the solvent into a 250 ml separatory funnel. Add 50 ml of distilled water. Shake and stand until the upper and lower layer are separated completely into two layers. Collect 1-butanol layer (upper layer) in an evaporation flask with constant weight, vacuum-evaporate to dryness. Dry flask and contents to constant weight at 105°C. Report increase in weight flask as "1-butanol extracts in ginseng extract". Express the result as mg per gram on ginseng extract.

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Annex C

Identification of ginsenosides Rb1 and Rf

Ginsenosides in ginseng products can be identified either by Thin Layer Chromatography(TLC) or High Performance Liquid Chromatography(HPLC).

1. Preparation of sample solution

Dilute the dried 1-butanol extract of Annex B with ten-fold volume of methanol, dissolve completely, and filter through 0.45 µm membrane filter.

2. Preparation of standard solution

Dissolve standard ginsenosides, such as ginsenoside-Rb1 and -Rf, in methanol to make a 1% solution and filter through 0.45 µm membrane filter.

3. Identification

3.1 Thin Layer Chromatography

Spot 2-5 µl of the standard and sample solutions, as indicated in the above, on TLC plate (silica gel), previously dried at 110°C for 15 minutes in dry oven. Develop with an upper solution of 1-butanol:ethylacetate:water (5:1:4, v/v/v) or a lower solution of chloroform:methanol:water (65:35:10, v/v/v). Spray 10% sulfuric acid or 30% sulfuric acid-ethanol solution over TLC plate and oven dry it at 110°C for 5-10 minutes to reveal its color. Identify the ginsenosides of Ginseng products by comparing the Rf values and colors with those of standard ginsenosides.

3.2 High Performance Liquid Chromatography

Prepare standard and sample solutions, as indicated in the above. Analyze ginsenoside with HPLC depending upon the operating condition. Identify ginsenosides of sample by comparing retention times of peaks with those of the standard.

Operating condition

Column: NH2 column, µ-Bondapak C18 column, carbohydrate analyzing column or equivalent

Detector: UV (203 nm) or ELSD

Eluent: UV: acetonitrile: water (30:70, v/v)

ELSD: acetonitrile: water: isopropanol (94.9:5.0:0.1, v/v/v)

Flow rate: 1.0 ml/min ~ 2.0 ml/min

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3. *Journal of Chromatography*, Volume 356, 1986, Pages 212-219
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D. COMMITTEE ON MILK AND MILK PRODUCTS⁵**UPDATED LIST OF METHODS OF ANALYSIS AND SAMPLING FOR CODEX STANDARDS FOR MILK AND MILK PRODUCTS**

Milk and Milk Products				
Commodity	Provision	Method	Principle	Type
Milk products	Iron	IDF 103A:1986 / ISO 6732:1985	Photometry (bathophenanthroline)	IV
Milk products (products not completely soluble in ammonia)	Milk fat	ISO 8262-3 IDF 124-3:2005	Gravimetry (Weibull-Berntrop)	I
Blend of evaporated skimmed milk and vegetable fat	Milk solids-not-fat (MSNF) ⁶	IDF 21B:1987 / ISO 6731:1989 and IDF 13C:1987 / ISO 1737:1999	Calculation from total solids and fat contents Gravimetry (Röse-Gottlieb)	IV
Blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF ⁶	ISO 8968-1/2 IDF 20-1/2:2001	Titrimetry (Kjeldahl)	IV
Reduced fat blend of skimmed milk and vegetable fat	Milk protein in MSNF ⁶	ISO 8968-1/2 IDF 20-1/2:2001	Titrimetry (Kjeldahl)	IV
Blend of skimmed milk and vegetable fat in powdered form	Water ⁷	ISO 5537 IDF 26:2004	Gravimetry, drying at 87°C	IV
Blend of skimmed milk and vegetable fat in powdered form	Milk protein in MSNF ⁶	ISO 8968-1/2 IDF 20-1/2:2001	Titrimetry (Kjeldahl)	IV
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Water ⁷	ISO 5537 IDF 26:2004	Gravimetry, drying at 87°C	IV
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Milk protein in MSNF ⁶	ISO 8968-1/2 IDF 20-1/2:2001	Titrimetry (Kjeldahl)	IV

⁵ ALINORM 08/31/11, Appendix VII⁶ Milk total solids and MSNF content include water of crystallization of lactose⁷ Water content excluding the crystallized water bound to lactose (in fact to read moisture content)

Blend of sweetened condensed skimmed milk and vegetable fat	Sucrose	ISO 2911 IDF 35:2004	Polarimetry	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Milk solids-not-fat (MSNF) ⁶	IDF 15B:1991 / ISO 6734:1989 and IDF 13C:1987 / ISO 1737:1999	Calculation from total solids and fat contents Gravimetry (Röse-Gottlieb)	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF ⁶	ISO 8968-1/2 IDF 20-1/2:2001	Titrimetry (Kjeldahl)	IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF ⁶	ISO 8968-1/2 IDF 20-1/2:2001	Titrimetry (Kjeldahl)	IV
Butter	Copper	ISO 5738 IDF 76:2004 AOAC 960.40	Photometry, diethyldithiocarbamate	II
Butter	MSNF ⁶	ISO 3727-2 IDF 80-2:2001	Gravimetry	I
Butter	Milk fat	ISO 17189 IDF 194:2003	Gravimetry Direct determination of fat using solvent extraction	I
Butter	Salt	ISO 15648 IDF 179:2004	Potentiometry (determination of chloride, expressed as sodium chloride)	II
Butter	Salt	ISO 1738 IDF 12:2004	Titrimetry (Mohr: determination of chloride, expressed as sodium chloride)	III
Butter	Vegetable fat (sterols)	ISO 12078 IDF 159:2006	Gas chromatography	II
		ISO 18252 IDF 200:2006	Gas chromatography	III
Butter	Water ⁷	ISO 3727-1 IDF 80-1:2001	Gravimetry	I
Cheese	Citric acid	ISO/TS 2963 IDF/RM 34:2006	Enzymatic method	IV
Cheese	Citric acid	AOAC 976.15	Photometry	II
Cheese	Milk fat	ISO 1735 IDF 5:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff)	I

Cheese	Moisture	ISO 5534 IDF 4:2004	Gravimetry, drying at 102 °C	I
Cheese (and cheese rind)	Natamycin	ISO 9233-1 IDF 140-1: 2007 ⁸	Molecular absorption spectrophotometry	
		ISO 9233-2 IDF 140-2:2007 ⁸	HPLC	
Cheeses, individual	Milk fat in dry matter	ISO 1735 IDF 5:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Cheeses in brine	Milk fat in dry matter (FDM)	ISO 1735 IDF 5:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Cottage cheese	Fat-free dry matter	ISO 5534 IDF 4:2004	Gravimetry, drying at 102°C	IV
		ISO 1735 IDF 5:2004	Calculation from dry matter and fat contents	IV
Cottage cheese	Milk fat	ISO 8262-3 IDF 124-3:2005	Gravimetry (Weibull-Berntrop)	IV
Cottage cheese	Milk fat in dry matter	ISO 8262-3 IDF 124-3:2005	Gravimetry (Weibull-Berntrop)	I
Cheese, unripened including fresh cheese	Protein	ISO 8968-1 IDF 20-1:2001 AOAC 991.20-23	Titrimetry, Kjeldahl	I
Cream	Milk fat	IDF 16C:1987 / ISO 2450:1999	Gravimetry (Röse-Gottlieb)	I
Cream	Solids	IDF 21B:1987 / ISO 6731:1989	Gravimetry (drying at 102°C)	I
Creams lowered in milk fat content	Milk fat	IDF 16C:1987 / ISO 2450:1999 AOAC 995.19	Gravimetry	I
Creams, whipped creams and fermented creams	MSNF ⁶	ISO 3727-2 IDF 80-2:2001 AOAC 920.116	Gravimetry	I
Cream cheese	Dry matter	ISO 5534 IDF 4:2004	Gravimetry drying at 102°C	IV

⁸ CCMMP is requested to clarify which is the reference method

Cream cheese	Moisture on fat free basis	ISO 5534 IDF 4:2004 and	Gravimetry, drying at 102°C	IV
		ISO 1735 IDF 5:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff)	IV
			Calculation of moisture on fat free basis from fat content and moisture content	IV
Dairy fat spreads	Total fat	ISO 17189 IDF 194:2003	Gravimetry Direct determination of fat using solvent extraction	I
Dairy fat spreads	Vegetable fat (sterols)	ISO 12078 IDF 159:2006	Gas chromatography	II
Dairy fat spreads		ISO 18252 IDF 200:2006	Gas chromatography	III
Edible casein products	Acids, free	ISO 5547 IDF 91:2007	Titrimetry (aqueous extract)	IV
Edible casein products	Ash (including P ₂ O ₅)	ISO 5545 IDF 90:2007	Gravimetry, ashing at 825°C	IV
Edible Casein Products	Casein in protein	ISO 17997-1 IDF 29-1:2004	Titrimetry, Kjeldahl	I
Edible casein products	Copper	ISO 5738 IDF 76:2004	Colorimetry (diethyldithiocarbamate)	III
Edible casein products	Lactose	ISO 5548 IDF 106:2004	Photometry (phenol and H ₂ SO ₄)	IV
Edible casein products	Lead	ISO/TS 6733 IDF/RM 133:2006	Spectrophotometry (1,5-diphenylthiocarbazone)	IV
Edible casein products	Milk fat	ISO 5543 IDF 127:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Edible casein products	Moisture	ISO 5550 IDF 78:2006	Gravimetry (drying at 102°C)	I
Edible casein products	pH	IDF-115A:1989 / ISO 5546:1979	Electrometry	IV
Edible casein products	Protein (total N x 6.38 in dry matter)	IDF 92:1979 / ISO 5549:1978	Titrimetry, Kjeldahl digestion	IV

Edible casein products	Sediment (scorched particles)	ISO 5739 IDF 107:2003	Visual comparison with standard disks, after filtration	IV
Emmental	Calcium ≥ 800 mg/100g	ISO 8070 IDF 119:2007 ⁹	Flame atomic absorption	IV
Evaporated milks	Milk fat	IDF 13C: 1987 / ISO 1737:1999	Gravimetry (Röse-Gottlieb)	I
Evaporated milks	Protein	ISO 8968-1 IDF 20-1:2001 AOAC 945.48H / AOAC 991.20	Kjeldahl, titrimetry	I
Evaporated milks	Solids, total	IDF 21B:1987 / ISO 6731:1989	Gravimetry (drying at 102°C)	I
Fermented milks	Milk fat	IDF 1D:1996 / ISO 1211:1999 AOAC 905.02	Gravimetry	I
Fermented milks - Yoghurt and yoghurt products	<i>Lactobacillus delbrueckii</i> subsp <i>bulgaricus</i> & <i>Streptococcus thermophilus</i>	ISO 7889 IDF 117:2003	Colony count at 37°C	I
Fermented milks - Yoghurt and yoghurt products	<i>Lactobacillus delbrueckii</i> subsp <i>bulgaricus</i> & <i>Streptococcus thermophilus</i>	ISO 9232 IDF 146:2003	Test for strain identification	I
Fermented milks	Dry matter (total solids)	ISO 13580 IDF 151:2005	Gravimetry (drying at 102 °C)	I
Milk powders and cream powders	Milk fat	IDF 9C:1987 / ISO 1736:2000	Gravimetry (Röse-Gottlieb)	I
Milk powders and cream powders	Protein (in MSNF) ⁶	ISO 8968-1 IDF 20-1:2001	Titrimetry, Kjeldahl digestion	I
Milk powders and cream powders	Scorched particles	ISO 5739 IDF 107:2003	Visual comparison with standard disks, after filtration	IV
Milk powders and cream powders	Solubility	ISO 8156 IDF 129:2005	Centrifugation	I
Milk powders and cream powders	Acidity, titratable	IDF 86:1981/ ISO 6091:1980	Titrimetry, titration to pH 8.4	I
Milk powders and cream powders	Water ⁷	ISO 5537 IDF 26:2004 ¹⁰	Gravimetry (drying at 102°C)	IV
Milk fat products	Antioxidants (phenolic)	IDF-165:1993	Reversed phase gradient liquid chromatography	II
Milk fat Products	Copper	ISO 5738 IDF 76:2004 AOAC 960.40	Photometry, diethyldithiocarbamate	II
Milk fat products	Fatty acids, free (expressed as oleic acid)	ISO 1740 IDF 6:2004	Titrimetry	I

¹⁰ The method has only been validated for milk powders, not for cream powders

Milk fat products	Milk fat	IDF 24:1964	Gravimetry (calculation from solids-not-fat and water content)	IV
Milk fat Products	Peroxide value (expressed as meq. of oxygen/kg fat)	ISO 3976 IDF 74:2006	Photometry	I
Milk fat products	Vegetable fat (sterols)	ISO 12078 IDF 159:2006	Gas chromatography	II
		ISO 18252 IDF 200:2006	Gas chromatography	III
Milk fat products	Water	ISO 5536 IDF 23:2002	Titrimetry (Karl Fischer)	II
Milk fat products (anhydrous milk fat)	Peroxide value	ISO 3976 IDF 74:2006	Photometry	I
Milk products obtained from fermented milks heat-treated after fermentation	Protein	ISO 8968-1 IDF 20-1:2001 AOAC 991.20-23	Titrimetry (Kjeldahl)	I
Mozzarella	Milk fat in dry matter – with high moisture	ISO 1735 IDF 5:2004	Gravimetry after solvent extraction	IV
Mozzarella	Milk fat in dry matter – with low moisture	ISO 1735 IDF 5:2004	Gravimetry after solvent extraction	IV
Processed cheese products	Citric acid	ISO/TS 2963 IDF/RM 34:2006	Enzymatic method	IV
Processed cheese products	Milk fat	ISO 1735 IDF 5:2004	Gravimetry (Schmid- Bondzynski- Ratzlaff)	I
Processed cheese products	Phosphate, added (expressed as phosphorus)	IDF 51B:1991	Calculation from phosphorous and nitrogen content	IV
Processed cheese products	Phosphorus	IDF 33C:1987 / ISO 2962:1984	Spectrophotometry (molybdate-ascorbic acid)	II
Processed cheese products	Salt	ISO 5943 IDF 88:2004	Potentiometry (determination of chloride, expressed as sodium chloride)	II
Sweetened condensed milk	Milk fat	IDF 13C: 1987 / ISO 1737:1999	Gravimetry (Röse-Gottlieb)	I
Sweetened and Condensed Milks	Protein	ISO 8968-1 IDF 20-1:2001 AOAC 945.48H AOAC 991.20	Kjeldahl, titrimetry	I
Sweetened Condensed Milks	Solids	IDF 15B:1991 / ISO 6734:1989	Gravimetry, drying at 102 °C	I

Whey cheeses by coagulation	Milk fat	ISO 1735 IDF 5:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Whey cheeses by coagulation	Milk fat in dry matter	ISO 1735 IDF 5: 2004 and ISO 5534 IDF 4:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff) Gravimetry, drying at 102°C	I IV
			Calculation from fat content and dry matter content	IV
Whey cheeses by concentration	Milk fat	IDF 59A:1986 / ISO 1854:1999	Gravimetry (Röse Gottlieb)	I
Whey cheeses by concentration	Milk fat in dry matter	IDF 59A:1986 / ISO 1854:1999 and ISO 2920 IDF 58:2004	Gravimetry (Röse Gottlieb) Gravimetry, drying at 88°C	I I
			Calculation from fat content and dry matter content	I
Whey powders	Ash	ISO 5545 IDF 90:2007	Gravimetry, ashing at 825°C	IV
Whey powders	Copper	ISO 5738 IDF 76:2004	Photometry (diethyldithiocarbamate)	III
Whey Powders	Lactose	ISO 5765-1/2 IDF 79-1/2:2002	Enzymatic method: Part 1 - Glucose moiety or Part 2 - Galactose moiety	II
Whey powders	Milk fat	IDF 9C:1987 / ISO 1736:2000	Gravimetry (Röse-Gottlieb)	I
Whey powders	Moisture, "Free"	ISO 2920 IDF 58:2004	Gravimetry (drying at 88 °C ±2°C)	IV
Whey powders	Protein (total N x 6.38)	IDF 92:1979 / ISO 5549:1978	Titrimetry, Kjeldahl digestion	IV
Whey powders	Water (not including water of crystallization of lactose)	ISO 5537 IDF 26:2004 AOAC 927.05	Gravimetry	I

CHANGES TO CODEX STAN 234 PART 1-B, P. 47-48

METHODS OF SAMPLING BY ALPHABETICAL ORDER OF COMMODITY CATEGORIES AND NAMES

Milk and Milk Products	Methods of Sampling	Notes
Butter	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Cheese	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Cheeses in brine	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Edible casein products	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Creams, Whipped creams and Fermented Creams	IDF Standard 50C:1995	General instructions
Fermented Milks	ISO 707:1997 AOAC 968.12	
Evaporated milks	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Milk powders and cream powders	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Milkfat products	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Sweetened condensed milks	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Whey cheese	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk
Whey powders	IDF 113 ISO 5538:2004	Inspection by attributes
Whey powders	ISO 707 IDF 50	General Instructions for obtaining a sample from a bulk

E. CHANGE OF STATUS IN ENDORSEMENT OF METHODS FOR CONTAMINANTS

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
Natural mineral waters	Mercury	ISO 5666-3:1999	Flameless atomic absorption spectrophotometry	II
Food grade salt	Arsenic	ESPA/CN-E/105-1996	Photometry	IV
Food grade salt	Mercury	ESPA/CN-E/106-1994	Cold vapour atomic absorption spectrophotometry	IV
Food grade salt	Cadmium	ESPA/CN-E/107-1997	Atomic absorption spectrophotometry	IV
Food grade salt	Lead	ESPA/CN-E/108-1994	Atomic absorption spectrophotometry	IV
All foods (except for cadmium in mineral water, lead in milk, and lead in fruit juices) ¹¹	Cadmium and Lead	AOAC 986.15	Anodic stripping voltametry	III

¹¹ For amendment to CODEX STAN 228-2001 General Codex Methods for Contaminants and to CODEX STAN 234-1999 Recommended Methods of Analysis and Sampling

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 consignment¹, when the test results by the laboratory² in the importing country disagree with test results by the laboratory in the exporting country over the same lot³.

The basic assumption is that 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. The procedure examines only the validity of the importing country's results on which non-compliance is alleged. It is recognised that disputes may arise from other cause(s), which should also be investigated⁴.

These guidelines do not cover microbiological test results.

2. PREREQUISITES/ASSUMPTIONS:

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

- Both countries agree on using this guideline;
- 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 Authorities in both the importing and exporting countries;
- at least one representative analytical laboratory sample from the same food lot has been taken by the Competent Authority at import in accordance with established sampling plans and/or good sampling practices, where applicable; the laboratory sample has been split into three essentially identical parts for the purposes of primary analysis and for confirmatory analysis (reserve samples); the split reserve samples should be kept in a satisfactory condition for the appropriate length of time;
- [laboratories report quantitative analytical results in the form of " $a \pm 2u$ or $a \pm U$ " where " a " is the best estimate of the true value of the concentration of the measurand (the analytical result) and " u " is the standard uncertainty and " U " (equal to $2u$) is the expanded uncertainty. The range " $a \pm 2u$ "

¹ 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.

² 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, designated or recognised by a government agency having jurisdiction.

³ As defined in the General Guidelines for Sampling (CAC/GL 50 -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;

represents a 95% level of confidence where the true value would be found. The value of “U” or “2u” is the value which is normally used and reported by analysts and is referred to as the “measurement uncertainty”; it may be estimated in a number of different ways (*see Codex Guidelines on Measurement Uncertainty, CAC/GL 54-2004*);

- laboratories report results according to the recommendations given in the Codex Paper “Use of Analytical Results: Sampling Plans, Relations between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards” (*reference required – recently accepted by CAC for the Procedural Manual*).
- laboratories use specific methods of analysis, which have been endorsed by the Codex Alimentarius Commission (CAC) or use methods of analysis which comply with performance parameters which have been endorsed by the CAC when they are available. Otherwise, methods must have been validated according to the requirements of the CAC.]

3. THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED

The competent authorities have the option to agree on comparison of the background information of the analysis of the sample. In accordance with relevant Codex Guidelines⁵, 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

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.

4. ANALYSING RESERVE SAMPLES:

If it is established that sample integrity and its chain of custody have not been compromised and there is an agreement between the respective competent authorities on the following:

1. the analysis of any reserve samples,
2. the timeline, and the time of availability of the sample⁶
3. The analysis of the reserve sample by either

⁵ 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."

⁶ The dispute shall be solved within the shortest possible time, which should not adversely affect the quality of the commodity during storage, where appropriate.

The importing country's laboratory in the presence of an expert from the exporting country

OR

A laboratory chosen by the exporting country

4. The methods of analysis to be used by the laboratory,

the test results are compared. If the test results from the two laboratories differ by less than would be expected from measurement uncertainty of the results (see Annex), the importing country's original assessment of the lot shall stand, and the dispute is thus resolved.

If the dispute still exists, the measures outlined in Step 5 of this procedure, using arbitration by a third laboratory, should be applied.

5. ANALYSIS OF REMAINING RESERVE SAMPLES

Where third reserves of the samples on which the finding of non-conformity was based are available, these should be analysed by a suitably qualified laboratory agreed on by the two countries, and a final assessment of conformity is based on the results from this laboratory. Failing agreement on the choice of laboratory the competent authority of the importing country can select a laboratory. The original results and the results from the second duplicate tested under Step 4 are discarded. If possible this laboratory should be independent of the two laboratories whose results were compared in step 4.

ANNEX

When each laboratory tests only a single reserve sample giving one result the limit Δ is

$$\Delta = \sqrt{U_1^2 + U_2^2}$$

Where U_1 and U_2 are the expanded measurement uncertainties of the two laboratories.

When each laboratory tests n samples, the limit for the difference between the two averages is

$$\Delta = 2\sqrt{\left(\frac{3}{4} + \frac{1}{4n}\right)u_1^2 + \left(\frac{3}{4} + \frac{1}{4n}\right)u_2^2}$$

Where u_1 and u_2 are the standard measurement uncertainties of the two laboratories.

This assumes that the repeatability component of the standard measurement uncertainty u is one half of the overall measurement uncertainty, as is a commonly used approximation.

**PROPOSED DRAFT GUIDELINES ON ANALYTICAL TERMS
(At Step 5 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. In most cases terms used in the Procedural Manual were adopted over time with an underlying hierarchy and can be traced verbatim to specific editions of ISO 3534, the GUM, the VIM, the IUPAC Orange Book or other international standards already adopted by Codex. Definitions of terms that have changed with newer editions of the international standards from which they were originally adopted have been updated preserving the original hierarchy found in the Procedural Manual. In cases where terms have been added in addition to those originally found in the procedural manual an effort has been made to preserve the conceptual continuity and relationship of the newer terms with extant ones. These terms, together with the terms which are included in specific International Protocols/Guidelines already adopted by Codex by reference are given below.

ANALYTICAL TERMS

The following analytical terms are defined below:

Accuracy
Applicability
Bias
Calibration
Certified reference material
Critical value
Defining (Empirical) method of analysis
Error
Expanded measurement uncertainty
Fitness for purpose
HorRat
Inter-laboratory study
Laboratory performance (Proficiency) study
Limit of detection
Limit of quantification
Linearity
Material certification study
Measurand
Measurement procedure
Measurement uncertainty
Method-performance study
Metrological Traceability
Precision
Quality assurance
Rational method of analysis
Recovery/recovery factors
Reference material
Reference value
Repeatability (Reproducibility)
Repeatability conditions
Repeatability (Reproducibility) limit
Repeatability (Reproducibility) standard deviation
Repeatability (Reproducibility) relative standard deviation
Reproducibility conditions
Result
Robustness (ruggedness)

Selectivity
Sensitivity
Surrogate
Systematic error
Trueness
True value
Validated range
Validated Test Method
Validation
Verification

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

Determination limit
Specificity

DEFINITIONS OF ANALYTICAL TERMS

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

Notes:

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 component¹.

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.

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, 17th edition, 2007

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 of 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 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

Calibration: Operation that, under specified conditions, in a first step, establishes a relation between the values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and in a second step uses this information to establish a relation for obtaining a measurement result from an indication.

Notes:

A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

¹ When applied to a test method, the term accuracy refers to a combination of trueness and precision.

Calibration should not be confused with adjustment of a measuring system often mistakenly called “self calibration”, nor with verification of calibration.

Often the first step alone in the above definition is perceived as being calibration.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd edition, 2007

Certified reference material (CRM): Reference material accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures

Notes:

Documentation is given in the form of a “certificate” (see ISO guide 30:1992).

Procedures for the production and certification of certified reference materials are given, e.g. in ISO Guide 34 and ISO Guide 35.

In this definition, “uncertainty” covers both measurement uncertainty and uncertainty associated with the value of the nominal property, such as for identity and sequence. “Traceability covers both metrological traceability of a value and traceability of a nominal property value.

Specified values of certified reference materials require metrological traceability with associated measurement uncertainty {Accred. Qual. Assur., 2006}

ISO/REMCO has an analogous definition {Accred. Qual. Assur., 2006} but uses the modifiers metrological and metrologically to refer to both quantity and nominal properties.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd edition, 2007

New definitions on reference materials, Accreditation and Quality Assurance, 10:576-578, 2006

Critical value (L_C): The value of the net concentration or amount the exceeding of which leads, for a given error probability α , to the decision that the concentration or amount of the analyte in the analyzed material is larger than that in the blank material. It is defined as:

$$\Pr(\hat{L} > L_C | L=0) \leq \alpha$$

Where \hat{L} is the estimated value, L is the expectation or true value and L_C is the critical value.

Notes:

The critical value L_C is estimated by

$$L_C = t_{1-\alpha, v} s_0$$

Where $t_{1-\alpha, v}$ is Student's-t, based on v degrees of freedom for a one-sided confidence interval of $1-\alpha$ and s_0 is the sample standard deviation.

If L is normally distributed with known variance, i.e. $v = \infty$ with the default α of 0.05, $L_C = 1.645s_0$.

A result falling below the L_C triggering the decision “not detected” should not be construed as demonstrating analyte absence. Reporting such a result as “zero” or as $< L_D$ is not recommended. The estimated value and its uncertainty should always be reported.

References:

ISO Standard 11843: Capability of Detection-1, ISO, Geneva, 1997

Nomenclature in evaluation of analytical methods, IUPAC, 1995

Defining (Empirical)(conventional) method of analysis: A method in which the quantity measured is defined by the result found on following the stated procedure.

Notes:

Empirical methods are used for purposes that cannot be covered by rational methods.

Bias in empirical methods is conventionally zero.

Reference:

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

Error: Measured value minus a reference value

Note:

The concept of measurement ‘error’ can be used both: when there is a single reference value to refer to, which occurs if a calibration is made by means of a measurement standard with a measured value having a negligible measurement uncertainty or if a conventional value is given, in which case the measurement error is not known and if a measurand is supposed to be represented by a unique true value or a set of true values of negligible range, in which case the measurement error is not known.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

Expanded measurement uncertainty: product of a combined standard measurement uncertainty and a factor larger than the number one

Notes:

The factor depends upon the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability.

The term factor in this definition refers to a coverage factor.

Expanded measurement uncertainty is also termed expanded uncertainty.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

Fitness for purpose: Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.

Reference:

Eurachem Guide: The fitness for purpose of analytical methods: A laboratory guide to method validation and related topics, 1998

HorRat: The ratio of the reproducibility relative standard deviation to that calculated from the Horwitz equation,

Predicted relative standard deviation $(PRSD)_R = 2C^{-0.15}$:

$HorRat(R) = RSD_R / (PRSD)_R$,

$HorRat(r) = RSD_r / (PRSD)_R$,

where C is concentration expressed as a mass fraction (both numerator and denominator expressed in the same units).

Notes:

The HorRat is indicative of method performance for a large majority of methods in chemistry.

Normal 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 normal range of HorRat(r) is 0.3-1.3.

For concentrations less than 0.12 mg/kg the predictive relative standard deviation developed by Thompson (The Analyst, 2000), should be used.

Reference:

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

Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing, The Analyst, 125:385-386, 2000

Inter-laboratory 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, 16th edition, 2006

Laboratory-Performance (Proficiency) Study: An inter-laboratory 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 of laboratories or to audit performance. If a study is conducted by an organization with some type of management control over the participating laboratories—organizational, accreditation, regulatory, or contractual—the method may be specified or the selection may be limited to a list of approved or equivalent methods. In such situations, a single test sample is insufficient to judge performance.

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, 17th edition, 2007

Limit of Detection: The true net concentration or amount of the analyte in the material to be analyzed which will lead, with probability $(1-\beta)$, to the conclusion that the concentration or amount of the analyte in the analyzed material is larger than that in the blank material. It is defined as:

$$\Pr(\hat{L} \leq L_C | L = L_D) = \beta$$

Where \hat{L} is the estimated value, L is the expectation or true value and L_C is the critical value.

Notes:

The detection limit L_D is estimated by,

$$L_D \approx 2t_{1-\alpha, \nu} \sigma_0 \quad [\text{where } \alpha = \beta],$$

Where $t_{1-\alpha, \nu}$ is Student's-t, based on ν degrees of freedom for a one-sided confidence interval of $1-\alpha$ and σ_0 is the standard deviation of the true value (expectation).

$L_D = 3.29 \sigma_0$, when the uncertainty in the mean (expected) value of the blank is negligible, $\alpha = \beta = 0.05$ and L is normally distributed with known constant variance. However, L_D is not defined simply as a fixed coefficient (e.g. 3, 6, etc.) times the standard deviation of a pure solution background. To do so can be extremely misleading. The correct estimation of L_D must take into account degrees of freedom, α and β , and the distribution of L as influenced by factors such as analyte concentration, matrix effects and interference.

This definition provides a basis for taking into account exceptions to simple case that is described, i.e. involving non-normal distributions and heteroscedasticity (e.g. “counting” (Poisson) processes as those used for real time PCR).

It is essential to specify the measurement process under consideration, since distributions, σ 's and blanks can be dramatically different for different measurement processes.

At the detection limit, a positive identification can be achieved with reasonable and/or previously determined confidence in a defined matrix using a specific analytical method.

References:

ISO Standard 11843: Capability of Detection-1, ISO, Geneva, 1997

Nomenclature in evaluation of analytical methods, IUPAC, 1995

Guidance document on pesticide residue analytical methods, Organization for Economic Cooperation and Development, 2007

Limit of Quantification: A method performance characteristic generally expressed in terms of the signal or measurement (true) value that will produce estimates having a specified relative standard deviation (RSD), commonly 10% (or 6%). L_Q is estimated by:

$$L_Q = k_Q \sigma_Q, \quad k_Q = 1/\text{RSD}_Q$$

Where L_Q is the limit of quantification, σ_Q is the standard deviation at that point and k_Q is the multiplier whose reciprocal equals the selected RSD. (The approximate RSD of an estimated σ , based on v -degrees of freedom is $1/\sqrt{2v}$.)

Notes:

If σ is known and constant, then $\sigma_Q = \sigma_0$, since the standard deviation of the estimated quantity is independent of concentration. Substituting 10% in for k_Q gives:

$$L_Q = (10 * \sigma_Q) = 10 \sigma_0$$

In this case, the L_Q is just 3.04 times the detection limit, given normality and $\alpha = \beta = 0.05$

At the the L_Q , a positive identification can be achieved with reasonable and/or previously determined confidence in a defined matrix using a specific analytical method.

This definition provides a basis for taking into account exceptions to simple case that is described, i.e. involving non-normal distributions and heteroscedasticity (e.g. “counting” (Poisson) processes as those used for real time PCR).

References:

Nomenclature in evaluation of analytical methods, IUPAC, 1995

Guidance document on pesticide residue analytical methods, Organization for Economic Co-operation and Development, 2007

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 an acceptable uncertainty.

Reference:

Codex Alimentarius Commission, Procedural Manual, 17th edition, 2007

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

Note:

A material-certification study often utilizes selected reference laboratories to 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, 17th edition, 2007

Measurand: Quantity intended to be measured.

Notes:

The specification of a measurand requires knowledge of the kind of quantity, description of the state of the substance carrying the quantity, including any relevant component and the chemical entities involved.

In chemistry, ‘analyte’ or the name of a substance or compound are terms sometime used for measurand. This usage is erroneous because these terms do not refer to quantities.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

Measurement procedure: Detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a result.

Notes:

A measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement.

A measurement procedure can include a statement concerning a target measurement uncertainty.

A measurement procedure is sometimes called a standard operating procedure (SOP).

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva.

Measurement uncertainty: Non-negative parameter characterizing the dispersion of the values being attributed to a measurand, based on the information used.

Notes:

Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead associated measurement uncertainty components are incorporated.

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.

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 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.

In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quality value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

Method-Performance Study: An inter-laboratory 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 quantification, 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, 17th edition, 2007

Metrological Traceability: Property of a result of measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the stated measurement uncertainty.

Notes:

A reference can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

Metrological traceability requires an established calibration hierarchy.

Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

For measurements with more than one input quantity each of the input values should itself be traceable and the calibration hierarchy involved may form a branched structure or network. The effort involved in establishing the metrological traceability for each input value should be commensurate with its relative contribution to the measurement result.

Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and if necessary correct the value and measurement uncertainty of the measurement standards.

The ILAC considers the elements for confirming metrological to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented procedure, accredited technical competence, metrological to the SI and calibration intervals (see ILAC P-10:2002)

The abbreviated term ‘traceability’ is sometimes used to mean ‘metrological traceability’ as well as other concepts, such as sample traceability or document traceability or instrument traceability or material traceability, where history (trace) is meant. Therefore the full term of metrological traceability is preferred if there is any risk of confusion.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

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

ILAC P-10, 2002

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.

Intermediate conditions between these two extreme conditions are also conceivable, when one or more factors within a laboratory (intra-laboratory- e.g. the operator, the equipment used, the calibration of the equipment used, the environment, the batch of reagent and the elapsed time between measurements) are allowed to vary and are useful in specified circumstances.

Precision is normally expressed in terms of standard deviation.

Reference:

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

ISO Standard 5725-3: Accuracy (trueness and precision) of measurement methods and results Part 3: Intermediate measures of the precision of a standard measurement method, ISO, Geneva, 1994.

Quality assurance: All those planned and systematic actions necessary to provide adequate confidence that analytical results 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

ISO/IEC Guide 17025:2005: General requirements for the competence of calibration and testing laboratories, ISO, Geneva, 2005

Recovery / recovery factors: 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.

Recovery is primarily intended for use in methods that rely on transferring the analyte from a complex matrix into a simpler solution, during which loss of analyte can be anticipated.

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 homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.

Notes:

Examination of a nominal property provides a nominal property value and associated uncertainty. This uncertainty is not a measurement uncertainty.

Reference materials with or without assigned values can be used for measurement precision control whereas only reference materials with assigned values can be used for calibration and measurement trueness control.

Some reference materials have assigned values that are metrologically traceable to a measurement unit outside a system of units. In a given measurement, a given reference material can only be used for either calibration or quality assurance.

The specification of a reference material should include its material traceability, indicating its origin and processing. {Accred. Qual. Assur., 2006}

ISO/REMCO has an analogous definition that uses the term measurement process to mean examination which covers both measurement of a quantity and examination of a nominal property.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

New definitions on reference materials, Accred. Qual. Assur., 10:576-578, 2006

Reference value: Quantity value used as a basis of comparison with values of quantity of the same kind.

Notes:

A reference quantity value can be a true quantity value of a measurand, in which case it is unknown, or a conventional quantity value in which case it is known.

A reference quantity value with an associated measurement uncertainty is usually provided with reference to

- a) a material, e.g. a certified reference material
- b) a reference measurement procedure
- c) a comparison of measurement standards.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

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, 17th edition, 2007

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

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, $r [R] = 2.8\sigma[R]$. {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 5725-6 “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, 17th edition, 2007

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 (RSD_r) and RSD for reproducibility (RSD_R).

Reference:

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

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

Result: Set of values being attributed to a measurand together with any other available relevant information

Notes:

A result of measurement generally contains ‘relevant information’ about the set of values, such that some may be more representative of the measurand than others. This may be expressed in the form of a probability density function.

A result of measurement is generally expressed as a single measured value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured value. In many fields, this is the common way of expressing a measurement result.

In the traditional literature and in the previous edition of the VIM, result was defined as a value attributed to a measurand and explained to mean an indication or an uncorrected result or a corrected result according to the context.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, 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

Harmonized guidelines for single laboratory validation of methods of analysis, Pure and Appl. Chem., 2002.

Selectivity: Selectivity is the extent to which a method can determine particular analyte(s) in a mixture(s) or matrice(s) without interferences from other components of similar behaviour.

Note:

Selectivity is the recommended term in analytical chemistry to express the extent to which a particular method can determine analyte(s) in the presence other components. Selectivity can be graded. The use of the term specificity for the same concept is to be discouraged as this often leads to confusion.

Reference:

Selectivity in analytical chemistry, IUPAC, Pure Appl Chem, 2001

Codex Alimentarius Commission, Alinorm 04/27/23, 2004

Codex Alimentarius Commission, Procedural Manual, 17th edition, Food and Agriculture Organization of the United Nations, World Health Organization, 2007.

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

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, 3rd Edition, 2007, 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

Systematic error: Component of measurement error that in replicate measurements remains constant or varies in a predictable manner.

Notes:

A reference value for a systematic error is a true quantity value, or a measured value of a measurement standard of negligible measurement uncertainty, or a conventional value.

Systematic error and its causes can be known or unknown. A correction can be applied to compensate for a known systematic error.

Systematic error equals measurement error minus random measurement error.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd edition, 2007

Trueness: The closeness of agreement between the expectation of a test result or a measurement result and the 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: Quantity value consistent with the definition of a quantity.

Notes:

In the error approach to describing measurement, a true quantity value is considered unique and in practice unknowable. The uncertainty approach is to recognize that, owing to the inherently incomplete amount of detail in the definition of quantity, there is not a single true quantity value, but rather a set of quantity values consistent with the definition of a quantity. However, this set of values is, in principle and in practice unknowable. Other approaches dispense altogether with the concept of true quantity value and rely on the concept of metrological compatibility of measurement results for assessing their validity.

When the definitional uncertainty associated with the measurand is considered to be negligible compared to the other components of the measurement uncertainty the measurand may be considered to have an essentially “unique” true value.

Reference:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

Validation: Verification, where the specified requirements are adequate for an intended use.

References:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

Validated Test Method: An accepted test method for which validation studies have been completed to determine the accuracy and reliability of this method for a specific purpose.

Reference:

ICCVAM Guidelines for the nomination and submission of new, revised and alternative test methods, 2003

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

Verification: Provision of objective evidence that a given item fulfills specified requirements.

Notes:

When applicable method uncertainty should be taken into consideration.

The item may be e.g. a process, measuring procedure, material, compound or measuring system.

The specified requirement may be that a manufacturer’s specifications are met.

Verification in legal metrology, as defined in VIM and in conformity assessment in general pertains to the examination and marketing and/or issuing of a verification certificate for a measuring system.

Verification should not be confused with calibration. Not every verification is a validation.

In chemistry, verification of the identity of the entity involved or of the activity, requires a description of the structure and properties of that entity or activity.

References:

VIM, International vocabulary for basic and general terms in metrology, 3rd Edition, 2007, ISO, Geneva

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