codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 06/29/23

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-ninth Session
Geneva, Switzerland, 3 – 7 July 2006

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

Budapest, Hungary
15 - 19 May 2006

Note: This document incorporates Codex Circular Letter CL 2006/18-MAS

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CX 4/50.2 **CL 2006/18-MAS**
May 2006

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 27th Session of the Codex Committee on Methods of Analysis and Sampling (ALINORM 06/29/23)**

MATTERS FOR ADOPTION BY THE 29th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

METHODS OF ANALYSIS AND SAMPLING

1. Methods of Analysis in Codex Standards at different steps (paras. 57-75, Appendix II)

Governments wishing to propose amendments or comments on the above documents 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 Secretary, Joint FAO/WHO Food Standards Programme at the above address **before 15 June 2006.**

PROPOSED DRAFT GUIDELINES AT STEP 5

2. Proposed Draft Guidelines for Settling Disputes on Analytical (Test) Results (para. 43, Appendix III)

Governments wishing to submit comments on the implications which the Proposed Draft Amendment 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 June 2006.**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 27th Session of the Codex Committee on Methods of Analysis and Sampling are as follows:

Matters for consideration by the 29th Session of the Commission:

The Committee:

- endorsed several methods of analysis in Codex standards at different steps of the Procedure (paras. 57-75, Appendix II);
- agreed to advance to Step 5 the Proposed Draft Guidelines for Settling Disputes on Analytical (Test) Results (para. 43, Appendix III);
- agreed to seek the approval of the Commission to continue its work on the review of *Analytical Terminology for Codex Use* by transferring the relevant section in the Procedural Manual to a separate Proposed Draft Guideline on Analytical Terminology (para. 55);
- agreed to initiate new work on the revision of the Principles for the Establishment of Codex Sampling Procedures in the Procedural Manual (paras. 113-114).
- agreed to update the reference to the Revised IUPAC/ISO/AOAC Protocol for Proficiency Testing (para. 102).

Other Matters of Interest to the Commission

The Committee:

- agreed to return to Step 6 the Draft Guidelines for Evaluating Acceptable Methods of Analysis (para. 22);
- agreed to consider further at its next session the conversion of methods for trace elements into criteria (para. 83); the criteria for methods of analysis for foods derived from biotechnology (para. 91); and the need to revise the terms of reference of the Committee (para. 123);
- agreed to consider at its next session the update of the work of EURACHEM on uncertainty of sampling (para. 110) and of IUPAC on the International Guidelines for Validation of Qualitative Methods through Collaborative Trials (para. 121).

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LIST OF APPENDICES

INTRODUCTION

1) The Codex Committee on Methods of Analysis and Sampling held its Twenty-seventh Session in Budapest, Hungary, from 15 to 19 May 2006, by courtesy of the Government of Hungary. The Session was chaired by Professor Peter Biacs, professor of microbiology and biotechnology 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 132 delegates and observers representing 44 Member Countries, one Member Organisation (EC) and 12 international organizations. A complete list of participants is given in Appendix I of this report.

OPENING OF THE SESSION

2) The Session was welcomed by Dr Zsuzsa Folláth, Deputy State Secretary of the Ministry of Agriculture and Regional Development. Dr Folláth welcomed the participants and expressed the view that it was a great honour for Hungary to host the Codex Committee on Methods of Analysis and Sampling as it had been doing for many years. She emphasised the increasing participation of members to this Committee whose work is of great importance in protecting the health of consumers and to other Codex Committees. Dr Folláth pointed out that Hungary had completed the privatization of its food sector and modernization of its food processing industry. Emphasizing the role of the CCMAS in establishing methods of analysis and the importance of the Codex Alimentarius standards in harmonization and international food trade, Dr Folláth wished the delegates all success in their work.

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

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

4) The Committee agreed to the proposal of the European Community to consider Agenda Item 5 (b) after Item 3 (a) as these items were interrelated and with this amendment adopted the Provisional Agenda as presented in CX/MAS 06/27/1.

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

5) The Committee noted that a number of matters referred by the 28th Session of the Codex Alimentarius Commission (CAC), and other Codex Committees were presented for information purposes or would be discussed under Agenda Item 5 (a) ”Endorsement of Methods of Analysis Provisions in Codex Standards”. In addition the Committee noted other Matters as follows.

Sampling Procedures

6) The Committee noted the comments made by the Delegation of Japan at the 28th Session of the CAC and the CCMAS that the Section dealing with Sampling Procedure in the Procedural Manual should be revised in view of the fact that the Commission adopted the Codex General Guidelines for Sampling (CAC/GL 50-2004). The Committee accepted the proposal of the Delegation of the United Kingdom to consider this issue under Agenda Item 9 dealing with uncertainty of sampling.

Use of Analytical Results: Sampling Plans

7) The Committee noted the concern expressed by the Delegation of Thailand at the 23rd Session of the Committee on General Principles that the document on the *Use of Analytical Results: Sampling Plans, Relations between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards* might be difficult to implement using different concepts in each Commodity Committee. The Delegation requested to develop additional guidelines to facilitate the implementation of this document.

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1 CX/MAS 06/27/1.

2 CX/MAS 06/27/2; CX/MAS 06/27/2-Add.1; CRD 10 (Extract from the CCFAC report on the Proposed Draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-Like PCB Contamination in Foods and Feeds (ALINORM 06/29/12)).

The Committee noted that the text in CRD 11 provided additional information and guidance to help practitioners to address measurement uncertainty.

Estimation of Uncertainty of Results

8) The Delegation of Australia proposed that the Guidelines on Estimation of Uncertainty of Results elaborated by the Codex Committee on Pesticide Residues (CCPR) and advanced to the 29th Session of the Commission for final adoption should be examined at the CCMAS as there were issues addressed there from a general point of view. The Committee noted that the Guidelines were prepared taking into account the Codex Guidelines on Measurement Uncertainty (CAC/GL 54) elaborated by the CCMAS and covered the area specifically related to residues and that this area fell outside the terms of reference of the CCMAS.

9) The Committee agreed to make the Draft Guidelines available as a reference document under Agenda Item 9.

Determination of Dioxins and PCBs

10) The Secretariat recalled that the CCMAS at its 26th Session, while considering the methods for determination of dioxins and PCBs, had asked the Committee on Food Additives and Contaminants (CCFAC) to clarify what it intended to do with this work as methods are selected only when there were specific numerical provisions corresponding to these methods. The last Session of the CCFAC had been considering the Proposed Draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-Like PCB Contamination in Foods and Feed and had replied to questions raised by the CCMAS (CRD 10).

11) The Committee agreed to consider this matter under Agenda Item 7 "Methods of Analysis for the Determination of Dioxins and PCBs".

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

12) The Committee recalled that its last session had discussed extensively the general approach, scope and requirements of the Draft Guidelines and had agreed to return them to Step 6 for redrafting by an electronic Working Group led by the Delegation of New Zealand.

13) The Delegation of New Zealand indicated that the revised draft took into account the comments made as indicated in the "explanation of changes" column, and reflected the complexity of the subject that should be addressed on a scientific basis. In particular, the statistical approach allowed to control the risks involved in accepting a new method.

14) The Delegation of New Zealand outlined the basis of the conditions for acceptance of methods in Annex B:

- the limit of a 14% increase in σ_L (standard deviation of laboratory /run bias) comes from the undesirability of increasing a producer's risk of 5% to more that 7.5%.
- the requirement for 80% confidence on σ_L is a compromise: higher levels of confidence would require very large validation trials
- the requirement for a specific correction for bias arises from the difficulty of adequately limiting the uncertainty of estimation of the bias in a realistically sized validation trial

15) The Delegation also illustrated the range of biases and repeatabilities obtained by different laboratories, which would not be reflected by single laboratory validation. The Delegation noted that following the discussion at the last session, the section including relevant definitions had been placed in square brackets for further consideration as to whether they should be retained in the document, or included in another Codex document. It was also noted that Annex C included examples illustrating how to apply the Draft Guidelines step by step to evaluate the acceptability of a specific method.

16) The Committee had a general discussion on the approach taken in the revised Draft Guidelines. Several delegations, while expressing their appreciation of the revised document and recognising its

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[3] CL 2005/44-MAS, CX/MAS 06/27/3 (comments of Argentina, Australia, Brazil, Cuba, Hungary, Japan, Switzerland), CX/MAS 06/27/3-Add.1 (comments of EC), CX/MAS 06/27/3-Add.2 (comments of Chile, Venezuela)

scientific basis, noted that it was too complex and proposed to make it simpler and more practical to allow governments to evaluate the acceptability of methods.

17) Several delegations generally supported the revised document and pointed out that the estimation of performance characteristics of candidate methods should be considered as suggestions rather than prescriptions.

18) Some delegations questioned the approach to be taken when no reference method existed. Other delegations pointed out that the issue of the method type should not arise when applying the approach outlined in the Guidelines and it was also proposed to delete the reference to method Types.

19) The Delegation of the United Kingdom noted that the document introduced new concepts and suggested that it should be considered for publication in a scientific journal prior to its consideration in the framework of Codex as the purpose of guidelines intended for governments might be different. The Delegation, referring to the example mentioned in the revised document, noted that further clarification was required as to how to address empirical methods as it would be difficult to identify alternative methods in such cases.

20) The Observer from AOCS informed the Committee that the Inter-Agency Meeting had discussed the Draft Guidelines and expressed the view that it should be simplified and made more practical for application by analysts.

21) The Committee noted some proposals for specific amendments to the text but agreed not to discuss the text in detail at this stage as further consideration should be given to the general approach and contents of the Draft Guideline before proceeding to detailed discussion. The Committee therefore agreed that the Delegation of New Zealand, with the assistance of an electronic working group, would redraft the Draft Guidelines taking into account the issues raised in written comments and at the present session.

Status of the Draft Guidelines for Evaluating Acceptable Methods of Analysis

22) The Committee agreed to return the Draft Guidelines to Step 6 for redrafting by an electronic working group led by the Delegation of New Zealand, comments and consideration at the next session.

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

23) The Committee recalled that its last session, following a detailed discussion, had agreed to return the Proposed Draft Guidelines to Step 3 for comments and redrafting by the Delegation of France with the assistance of an electronic Working Group, and consideration at the next session.

24) The Delegation of France introduced the revised version of the Guidelines and indicated that it had taken into account the written comments received and that the procedures were intended to provide practical guidance in case of disputes arising from differences in the assessment of the conformity of a food consignment on the basis of laboratory test results.

25) The Delegation pointed out that Section 3.1 was intended to identify the problems before undertaking any further step and that, on the basis of the comments received, an Annex suggesting a simple procedure based on the Horwitz model had been included, with a variant to address different concentration ranges. When available or recognized, other models could be used. The Delegation also noted that confusion should be avoided regarding the role of the laboratory since regulatory authorities are responsible for interpretation of test results to take steps towards dispute resolution, and therefore the term "competent authority" had been retained throughout the text.

26) The Committee expressed its appreciation to the Delegation of France and to the working group for their excellent work and discussed the text section by section, with the following amendments and comments.

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[4] CL 2005/28-MAS, CX/06/27/4 (comments of Argentina, Australia, EC, Japan, Malaysia, New Zealand), CX/06/27/4-Ad. 1 (revised version of the Proposed Draft Guidelines), CRD 8 (comments of Chile), CRD 9 (comments of Kenya), CRD 12 (comments of Malaysia)

1. Scope

27) The Committee discussed whether reference should be made to "members" instead of governments, as the Procedural Manual referred to members. The Committee however noted that, while the reference to "members" was used in the Procedural Manual as regards participation in the work of the Commission, Codex texts were intended for governments, as Codex was an intergovernmental organisation and there was no procedural objection to the reference to governments. The Committee therefore retained the current text of the Scope.

28) The Delegation of Argentina, supported by the Delegation of Cuba, expressed the view that the provisions in the Guidelines were not applicable to testing for microbiological disputes and proposed to exclude microbiological analysis from the Scope. Other delegations pointed out that some of the recommendations could be applicable to microbiological analysis, in the case of dried or quick frozen foods, and noted this was a general text that could be applied by governments as required. The Committee therefore retained the current text of the Scope.

29) Some delegations proposed to forward the Guidelines to the Committee on Food Hygiene for consideration and to ask its advice as to whether the Guidelines could be applied to microbiological analysis or whether specific provisions should be established in this area.

2. Prerequisites

30) Some delegations proposed to amend the first paragraph to reflect that more than one sample could be taken: in some cases, one would be taken by the exporter and one by the importer, or the sample might be split between the exporter and the competent authority. After some discussion, the Committee agreed to refer to "at least one representative sample" at the beginning of the section. The paragraph was also amended to clarify that the provisions were prerequisites that should already have been carried out.

31) The Delegation of India proposed to clarify what was intended by "an appropriate length of time" and to give more direction as to maximal length of time allowed. Other delegations however pointed out that this would depend on the nature of the food concerned and should be decided by the competent authority on a case by case basis.

3. Procedure

32) The Committee had an extensive discussion on the proposal from the Delegation of New Zealand to insert the following new text at the beginning of Section 3 "An analytical duplicate sample on which the finding of non-compliance is made should, where possible, be made available to the exporting country to enable it to confirm or dispute the result concerned", and "when it was not possible to implement this step" the current recommendation at the beginning of Section 3 would be followed.

33) Several delegations recalled that the procedure under consideration, including the four steps, resulted from detailed discussion and consensus in the last session and expressed their concern with this major change to the current approach to dispute settlement. They noted that the new proposal would require competent authorities to carry out duplicate sampling and to send a sample to the exporting country before the comparison of results described in Step 1 had taken place, and proposed to retain the current provisions whereby results were compared and the preferred option was the settlement of the dispute without new analysis or sampling.

34) Some delegations proposed to consider the insertion of this proposal under Section 3.3 as it could be more acceptable in relation to Step 3, which requires new analyses. After an extensive discussion, the Committee agreed not to include this new proposal and to retain the text at the beginning of Section 3 unchanged.

3.1 Step 1

35) The Committee agreed to introduce several amendments in the first sentence, referring to the fact that "the difference between the test results are between the existing reproducibility limit" rather that the results themselves, and that the "mean value" to be used to assess conformity was "the mean value of the test results of the two laboratories". As the end of the paragraph referred to "measurement uncertainty", some delegations proposed to change this term to "uncertainty of the mean", while other delegations proposed to retain the current text or made some alternative proposals. After some discussion, the Committee agreed to

refer to the "measurement uncertainty of the mean" and to include in the Annex an equation to calculate the measurement uncertainty of the mean from the measurement uncertainty of each individual test result.

36) The Delegation of Malaysia asked for clarification as to whether there were two values for reproducibility in the first paragraph of this section, as reference was made to two results, which could be from two different methods with two published reproducibility limits. The Delegation of France pointed out that the second paragraph referred to the situation where both laboratories used the same method so there was only one reproducibility limit for the same method, as this was a scientific value published in literature and that the issue raised by Malaysia was addressed in the third paragraph.

37) Some editorial amendments were also made to the second and third sentence for clarification purposes. The Committee agreed to add a sentence at the end of the section addressing the case where the models described could not be applied.

3.2 Step 2

38) The Committee agreed to reorganize the list of relevant information in a more logical order according to the methods, the data and the laboratory, to delete some parts of the text to avoid duplication and to refer to the "official" accreditation status of the laboratories.

3.3 Step 3

39) The Delegation of Thailand expressed the view that the Guidelines should not allow the importing country to decide on the laboratory that would conduct the analysis when there was no consensus, and therefore proposed to delete the end of the third indent. The Delegation of France recalled that the section put emphasis on the need for selection of the laboratory by consensus but that the guidelines also needed to address the case when such consensus could not be reached. The Committee agreed to retain the current text with some editorial clarifications.

3.4 Step 4

40) The Committee agreed to refer to competent authority in order to ensure consistency throughout the text and with current Codex terminology

Annex

41) The Committee agreed to insert a flow chart providing an overview of the steps of the procedure in an Annex, as proposed by some delegations. Some delegations expressed the view that the procedures described in the document were clear and that there was no need for a flow chart, and it should be deleted in the final version. Other delegations supported developing the flow chart with some more detailed explanation.

42) The Committee discussed whether the revised document should be advanced for adoption by the Commission. Several delegations supported its advancement for final adoption as the text had been reviewed in detail and there were few substantial changes, but mostly amendments for clarification purposes. Several other delegations expressed their general support for the document and its advancement to Step 5 in view of the progress achieved, but indicated that they needed more time to consider it carefully before it was finalized. The Committee therefore agreed to advance the document to Step 5 and to consider it further at its next session, with the objective of advancing it to Step 8 for adoption by the 30th Session of the Commission in 2007.

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

43) The Committee agreed to advance the Proposed Draft Guidelines to Step 5 of the Procedure for adoption by the 29th Session of the Commission (see Appendix III).

REVIEW OF THE *ANALYTICAL TERMINOLOGY FOR CODEX USE* IN THE PROCEDURAL MANUAL (Agenda Item 4)[5]

44) The Committee recalled that its last session had agreed that the Delegation of the United States, with assistance of an electronic working group would revise the document identifying which definitions could be

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[5] CX/MAS 06/27/5; CX/MAS 06/27/06-Add.1, CRD 6 (Comments of Iran); CRD 14 (Comments of the EC), CRD 17 (document on terminology prepared by the United States)

harmonized and amended for inclusion in the Procedural Manual and which new definitions addressing methodological issues would be identified.

45) The Delegation of the United States introduced the document and indicated that the definitions were presented in three Appendices. Appendix I covered definitions that could be harmonized and included in the Procedural Manual, Appendix II contained definitions that are required in addition to those of the Procedural Manual and Appendix III contained the definitions that were under revision by international organizations and should not be considered until revision is completed.

46) The Delegation of the United Kingdom informed the Committee that ISO intends to publish statistical definitions (ISO 3534-2) soon; therefore it was proposed not to consider changes to such definitions until the ISO document had been published and Inter-Agency Meeting (IAM) members could get consensus on internationally harmonized definitions.

47) It was indicated that this matter had also been considered at the IAM, which had proposed to take the analytical definitions out of the Procedural Manual and to develop a separate Guideline for governments as this would facilitate their updating. The Committee agreed with this proposal.

48) It was proposed not to consider this matter in detail but rather to focus on general issues and work on up-dating CRD 17 which contained Guidelines on analytical terminology for Codex use with the understanding that specific comments presented for the current session would be taken into account in future development of this document. It was also proposed not to list definitions such as limit of determination and specificity which were no longer used in Codex.

49) Several delegations supported the proposals for developing a Guideline for use by governments and were of the view that it was essential to obtain consensus at the IAM before making changes on definitions in the Procedural Manual.

50) The Delegation of Australia suggested that the Committee should not be restricted by current international definitions and be able to amend those that did not meet Codex purposes. The use of these definitions by Codex might lead to revision of the corresponding international definitions in the future. However some other delegations emphasized that such revision should only be in cases where there was sufficient justification. It was proposed to clarify some definitions such as “limit of determination” and “limit of quantification” as they seemed to be the same in the case of determination of dioxins, and the use of “limit of quantitation” instead of “limit of quantification”.

51) The Delegation of Cuba proposed to clarify that the notes to some definitions were not part of the definitions.

52) The Secretariat indicated that CRD 17 contained definitions of types of methods for Codex purposes and that this should not be included in the future Guideline as this part was only for Codex purposes and should be retained in the Procedural Manual.

53) The Committee recalled that the revision of the Analytical Terminology had been approved as new work by the 26th Session of the Commission and that some amendments had already been adopted by the 27th Session. The Committee agreed to seek the approval of the Commission to continue this work with the following amendment: transferring the Analytical Terminology section in the Procedural Manual to a separate Proposed Draft Guideline on Analytical Terminology, that would be developed as a Codex document through the Step Procedure. The Guideline, when adopted, would replace the current section on Analytical Terminology in the Procedural Manual.

54) The Committee recalled that this was ongoing work that would probably be developed progressively and agreed that its objective was to finalise at least part of the definitions for adoption by the 31st Session of the Commission in 2008.

55) The Committee agreed that, following the approval of the Commission the electronic working group led by the United States in cooperation with all interested delegations would revise CRD 17 to propose a first draft of the Guideline for comments at Step 3 and consideration by the next Session of the Committee.

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS (Agenda Item 5(a))[6]

56) 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.

Part I. Methods of Analysis

Ad hoc Intergovernmental Task Force on Fruit and Vegetables Juices

General Standard for Fruit Juices and Nectars

57) The Committee recalled that it was in a position to consider for endorsement methods to determine quality and authenticity of fruit juices which were essential to determine composition of fruit juices despite their being no numerical values in the standard following the amendment made by the Commission to Section 3.4 of the Standard.

Determination of C^{13} / C^{12} ratio of ethanol / Carbon stable isotope ratio for apple juice

58) To the concern raised on the need for two Type II methods for the determination of carbon-stable isotope ratios, it was clarified that the procedures applied to different substrates.

Determination of carotenoids

59) The Committee noted that the EN and equivalent IFU methods had been validated while no repeatability data was available for the ISO method, and therefore agreed to the proposal of the Observer from IFU to withdraw the ISO method since it had not been fully validated.

Determination of proline

60) It was pointed out that analysis for free amino acids was essential when assessing quality and authenticity of fruit juices and that in some cases a whole range of amino acids needed to be looked at , while in other cases, only one or two. The Committee noted that the determination of proline was a useful method to detect the adulteration of apple juice with grape juice and that there was correlation between determination of proline by photometry and determination by liquid chromatography, therefore it agreed to endorse the method as Type I rather than the proposed temporary endorsement as Type III.

Other provisions

61) The titles of the methods for anthocyanins, beet sugar and starch were amended to indicate that the methods referred to detection rather than determination since they were of a qualitative nature and the Committee corrected the principle for the detection of starch to reflect that it was colorimetric.

62) The references for the determination of centrifugable pulp and determination of chloride were corrected; the method for determination of Vitamin C was replaced with EN14130:2004 (HPLC) and endorsed as a Type II method, while the microfluoremetric method was endorsed as Type III. In order to clarify the need for two Type I methods for the determination of total dry matter and for total solids, respectively, the footnote to these two methods was amended to indicate that the duplicate methods were included as they may lead to different results.

63) To the concern raised by the Delegation of Thailand, supported by the Delegation of Cuba, about the difficulties that developing countries may experience with the inclusion of isotope mass spectrometry methods which required sophisticated instrumentation, the Committee noted that it was only through the development of these procedures that detection of some fraudulent practices in the production of fruit juices was now possible.

Committee on Cereals, Pulses and Legumes

Draft Standard for Instant Noodles

64) The Committee recalled that the Delegation of Japan had presented a proposal for a method to determine moisture of fried and non-fried noodles and that the Delegation had been requested to conduct collaborative studies on the proposed methods, which were presented to the *ad hoc* Working Group on

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6 CX/MAS 06/27/6, CRD 1

Endorsement of Methods. The Committee was informed that the results of these studies were accepted for publication in the Journal of AOAC International. In view of this, the Committee agreed to endorse the method as Type I with an amendment in Section B to indicate the use of sieves with a mesh size 12 -8 for the selection of broken noodles.

Committee on Milk and Milk Products

Part A – Methods of analysis for standards currently being elaborated

65) In addition to several editorial changes made to the methods proposed, the Committee endorsed several typically Type I methods as Type IV in instances where the scope of the methods was being extended to include other matrices than those for which they had been validated and that were satisfactorily used in the dairy industry.

Dairy Fat Spreads

66) To the concerns raised on the endorsement of the method for total fat for the provision of milk fat in the Standard for Dairy Spreads, the Committee recognised that for dairy products, the establishment of milk fats was by the total fat method, whereas vegetable fats which were not allowed in dairy spreads were determined by specific methods with the objective of identifying possible contamination or frauds. The Committee noted that the development of new methods for vegetable fats was underway.

Part B – Updated list of methods of analysis for Codex Standards for milk products

67) The Committee noted the updated list of methods presented and extended its appreciation to the IDF and ISO for their work. It also noted that the AOAC methods were not included in the updated list since AOAC was no longer able to participate in the work of updating methods, but that their methods were still maintained in the relevant standards for milk and milk products and in the list of Codex methods. Several editorial amendments were made to list.

Codex Committee on Nutrition and Foods for Special Dietary Uses (Gluten-free Foods)

Draft Revised Standard for Gluten-Free Foods

68) The Committee recalled that at its last Session it had temporarily endorsed the Enzyme-Linked Immunoassay Sorbent R5 Mendez (ELISA) Method as Type I pending publication of the method and collaborative inter-laboratory studies.

69) Several delegations questioned the source against which the antibody used in the method had been raised, what reactive group it was sensitive to and the fact that another Type I method was being developed for the same toxic epitope. The Delegation of Canada expressed the view that the method should be classified as Type II.

70) It was clarified that R5 ELISA is a method based on a monoclonal antibody raised against secalin, the rye prolamin and that it was useful for detection of gluten in natural and heat-processed samples (sandwich ELISA); that the antibody reacts with the pentapeptide QQPFP, which is present in all gliadins, secalins and hordeins and that QQPFP is also present in coeliac-active epitopes; and for the detection of hydrolyzed gluten, a modification of the R5 assay (competitive ELISA) has to be applied.

71) In view of provision and publication of the collaborative studies and the clarifications provided, the Committee agreed to the recommendation of the Working Group to endorse the method as Type I.

Part II. Sampling

72) The Committee noted the updated list of methods of sampling for Codex Standards for Milk Products.

Other issues

73) The Committee noted that several methods previously adopted in the Codex Alimentarius were outdated, especially those emanating from adjourned committees and that there was a need to consider how to update these methods. It was agreed that the Committee need to be more proactive in this regard and that this question would be considered under Agenda Item 10.

74) The Secretariat drew the attention of the Committee to the General Instructions for the Selection of Methods of Sampling section on General Considerations[7] which stated that the Committee should organise its work in such a manner as to keep under constant review all methods of analysis and sampling published in the Codex Alimentarius as well as the Arrangements for the Amendment of Codex Standard Elaborated by Codex Committee which have been Adjourned *sine die* which was under review in the Committee on General Principles.

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

CONVERSION OF THE METHODS FOR TRACE ELEMENTS INTO CRITERIA

(Agenda Item 5(b))[8]

76) The Committee recalled that at its 26th Session it had requested the electronic working group[9] chaired by Sweden to develop a revised document on the conversion of methods for trace elements into criteria.

77) The Delegation of Sweden introduced the revised document and explained that the working group focused on commodities for which they assigned criteria and then identified applicable methods (Table 5). It was further explained that the approach taken in this exercise was based on the "fitness for purpose" approach. The Delegation explained that when more stringent criteria were applied, fewer methods met those criteria than when broader criteria were applied (Table 2) and indicated that Tables 3 and 4 were more specific for lead in milk and fish, respectively, and that it had taken this approach in order to simplify the process.

78) Several delegations expressed their support and appreciation to the Delegation of Sweden and NMKL for their effort in developing the paper.

79) Several delegations, although supportive of the approach, indicated that both the conventional method of endorsement and the criteria approach should run in parallel for some years to come.

80) The Delegation of the United Kingdom reminded the Committee that this work arose from discussions in the ad hoc Working Group on Endorsement of Methods of Analysis on how to treat conversion of methods to criteria especially in instances where there were many methods identified for one analyte. The Delegation was of the view that many methods in the Codex system which had previously been endorsed should possibly not have been endorsed and that the conversion to criteria approach clearly demonstrated this. The Delegation further raised their concern on how to retain the document and how it should be used in future by Codex commodity committees and the analytical community and its status within the Codex system.

81) To the question raised that the use of the criteria approach would replace the need to adopt methods in Codex Standards, it was clarified that the criteria approach merely assisted in selecting the appropriate validated analytical methods and did not eliminate the possibility of endorsing certain methods.

82) With regard to the status of the document, the Secretariat pointed out several options available to the Committee in that it could be an Annex to or be included in the list of heavy metals in CODEX STAN 228 (General Methods for Contaminants) or could be developed as a separate document on the conversion of methods to criteria and if used for the endorsement process, then developed as a procedure for endorsement.

83) After considerable discussion on the status and use of the document the Committee agreed that the Delegation of Sweden in collaboration with NMKL would further develop criteria for trace elements for consideration by the *ad hoc* Working Group on Endorsement of Methods of Analysis during its work on endorsement of methods prior to the 28th Session of the Committee. It was noted that arsenic, cadmium and copper were useful examples for this purpose. It was further emphasized that the document should be considered as a study document for the moment and that at its next Session, the Committee would decide on

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7 Procedural Manual, 15th Edition, page 83

8 Replacement of CX/MAS 06/27/6-Add.1

9 Argentina, Brazil, European Community, Finland, France, Japan, Netherlands, United Kingdom, United States, IDF, ISO and NMKL (rappoteur).

whether to keep both the conventional approach and the criteria approach, or the criteria approach only and whether there was a need to revise the Working Instructions for the Implementation of the Criteria Approach in Codex[10].

CRITERIA FOR THE DETECTION AND IDENTIFICATION OF FOODS DERIVED FROM BIOTECHNOLOGY (Agenda item 6) [11]

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

85) The Delegation of the United Kingdom indicated that the paper had been revised in the light of the comments received; some of the annexes provided the information required for the validation of quantitative and qualitative methods, including the characteristics that could be used to consider existing validated methods and to assist laboratories in the determination of measurement uncertainty, while Annex VI contained a list of validated methods. Annex VII considered GMO proficiency testing and highlighted the difficulties of interpretation due to the lognormal distribution of results from a normal output, and the fact that the error was multiplicative rather than additive in GMO testing based on PCR.

86) The Delegation of Germany drew the attention of the Committee to the provisions in the texts on risk analysis of foods derived from biotechnology developed by the *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (TFBT), especially the need to ensure traceability, which required adequate methods of analysis, and recalled that a number of validated methods existed, as appeared in the list considered by an earlier session of the TFBT. The Delegation also noted that ISO and CEN had developed several methods both for quantitative and qualitative determination.

87) The Delegation of the EC stressed the importance of this work as several problems of methodology existed in the identification of foods derived from biotechnology and expressed the view that it was premature to undertake new work at this stage, but that the document should be revised for further consideration by the Committee. The Delegation also drew the attention of the Committee to its specific comments in CRD 18.

88) Some delegations proposed to delete the reference to GMO in the document and to replace it with a reference to foods derived from biotechnology or from "modern biotechnology". The Delegation of Brazil suggested that the terminology should be harmonized with the document already approved by the *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology.

89) The Delegation of the United States referred to its specific comments in CRD 5 and proposed to consider the revised discussion paper at the next session. The Delegation proposed that the document should be considered for publication by FAO rather than considered in the framework of Codex as this might make this important document available to governments more rapidly. The Secretariat indicated that this proposal would be referred to FAO and WHO but that usually FAO and WHO published the results of expert consultations or related work conducted by the organisations themselves.

90) The Delegation of Cuba expressed the view that priority should be given to the qualitative protein based methods as the use of DNA detection with PCR methods were not available or too costly for developing countries.

91) Some delegations drew the attention of the Committee to their detailed comments on specific sections of the document. The Committee however agreed that the document would not be considered in detail at this stage, as it should be redrafted before the Committee could take a decision as to further work. The Committee expressed its appreciation to the Delegations of Germany and the United Kingdom for their comprehensive work in this complex area and agreed that they would redraft the discussion paper in the light of the written comments, with the assistance of interested delegations, for consideration at the next session.

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[10] Procedural Manual, 15th Edition

[11] CX/MAS 06/27/7, CRD 4 (comments of ILSI), CRD 5 (comments of the United States), CRD 7 (comments of Japan), CRD 8 (comments of Chile), CRD 13 (comments of Kenya), CRD 16 (comments of Republic of Korea), CRD 18 (comments of the EC),

METHODS OF ANALYSIS FOR THE DETERMINATION OF DIOXINS AND PCBS (Agenda Item 7)[12]

92) The Committee recalled that at its last Session it had requested the Delegation of Germany to revise the document on Methods of Analysis for the Determination of Dioxins and PCBs with a view of converting these methods into criteria and at the same time had requested the Committee on Food Additives and Contaminants (CCFAC) to clarify what it would do with this work.

93) The Delegation of Germany introduced the revised document and informed the Committee that it had based the revision on two validated methods and the current EU legislation in this field. It further acknowledged the receipt of two further methods submitted by Japan and Republic of Korea, respectively as well as other late comments received. However, due to technical problems in communication related to the method submitted by Japan and the late receipt of the Korean proposal, these two methods were not taken into account during the revision of the document.

94) The Delegation indicated that the reply from CCFAC was not clear enough on what it wanted to do with the document and asked the Committee for guidance on how to proceed with this work.

95) The Committee noted the response from CCFAC that methods for dioxins were needed for screening and confirmatory purposes, but in view of the clarifications by the Secretariat, noted that since no specific provisions were being developed for dioxins, the Committee was not in a position to endorse already existing methods. Furthermore it was noted that in order to proceed with future work in converting methods for dioxins to criteria, it would also be necessary to clarify the range of levels to be considered as well as the matrices for which these levels are to be applied. Therefore the Committee agreed to request the CCFAC to provide precise information on these questions.

96) To the concerns raised by several Delegations with regard to the range of levels of interest for performance of methods of analysis indicated in the Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-Like PCB Contamination in Foods and Feeds, it was noted that this Committee could no longer make specific comments on this Code to CCFAC since the Code has been forwarded to the Commission for adoption at Step 8, however, members were still in a position to make relevant comments to the Commission.

97) The Committee expressed its appreciation to the Delegation of Germany and all those who had contributed to the excellent work presented and agreed that the current document would be forwarded to CCFAC for their information and that new work in this regard would only be resumed pending a reply from CCFAC.

REVISION OF THE IUPAC/ISO/AOAC PROTOCOL FOR PROFICIENCY TESTING (Agenda Item 8)[13]

98) The Delegation of the United Kingdom introduced this item and recalled that at the last Session of this Committee it has requested that this item be placed on the agenda in anticipation of the publication of the revised "International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories" developed by IUPAC/ISO/AOAC. The Committee was informed that this Protocol had been published in the Journal of Pure and Applied Chemistry in January of this year.

99) The Delegation recalled that the IUPAC/ISO/AOAC Protocol had been adopted by the Commission in 1995. The Delegation indicated that the intent and principles of the Protocol remained unchanged, but were clarified where appropriate and that revision of the Protocol was done through wide consultation internationally.

100) The Secretariat indicated that, as mentioned in the working document, the proposal for the revision of the Protocol required approval as new work and revision through the Step Procedure, as this document had been adopted by the Commission as a specific Codex text, and noted that this was different from the update

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12 CX/MAS 06/27/8, CRD 10 (Proposed Draft Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-Like PCB Contamination in Foods and Feeds), CRD 14 (comments of European Community), CRD 19 (comments of China)

13 CX/MAS 06/27/9

of a reference to a method or protocol developed by another organisation, that did not require such procedure.

101) The Committee noted that this Protocol was referred to in the *Codex Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food* (CAC/GL 27-1997) and that in view of its revision it was necessary for the Committee to consider updating this reference.

102) After some discussion on the Protocol and in view of the general agreement with the revised Protocol, the Committee agreed to ask the Commission to approve an editorial amendment to the above Guidelines to reflect the new reference to the Protocol.

UNCERTAINTY OF SAMPLING (Agenda Item 9)[14]

103) The Committee recalled that at its last Session it had agreed to consider how to address the uncertainty of sampling in relation to its ongoing work as there was substantial work carried out at the international level.

104) The Delegation of the United Kingdom introduced the discussion paper and indicated that there was increased recognition that measurement uncertainty should include analytical uncertainty and uncertainty related to sampling. The Delegation indicated that an international EURACHEM Working Group was formed including representatives from a wide range of disciplines and currently preparing guidance for the evaluation of uncertainties in measurement arising from the process of sampling and that guidance would be applicable to all chemical measurements that require sampling.

105) The Delegation pointed out that it was only an initial discussion paper which discusses variability arising from sampling and chemical analysis and focused on a measurement process that results in quantitative data by using real examples of nitrate concentration in glasshouse lettuce, infant wet meals and moisture in wholesale butter. The Delegation indicated that these examples clearly demonstrated that sampling contributed to greater estimate of uncertainty than was due to chemical analysis and that it has consequences for compliance.

106) The Delegation, while questioning whether the Committee should develop recommendations in this area as was done for analytical measurement uncertainty, was of the view that it was important to update the Committee with EURACHEM Working Group results in order to evaluate its impact on the work of the Committee.

107) The Delegation of Australia drew the attention of the Committee to the fact that in order to make a decision on what uncertainties should be associated with an analytical result the quantity intended for measurement needs to be clearly defined as this would automatically define whether uncertainty arising from sampling should be included. Which quantity is intended for measurement will depend on the wording of the limit against which a decision is to be made. If compliance is defined in terms of a sample drawn from a lot in accordance with specific sampling regime, as was the case with respect to Codex MRLs and other Codex limits, then only the uncertainty associated with laboratory operations should be included, therefore the Australian position is in line with the approach taken by the CCPR which states that the expanded uncertainty of the result should be calculated from the standard uncertainty of the laboratory operations and that new work in this area was not needed.

108) The Delegation of the EC indicated that sampling was a critical step in the calculation of uncertainty and supported further work in this area.

109) The Delegation of New Zealand supported the view expressed by the Delegation of Australia and indicated that considerable underestimation of uncertainties could take place, given the minimum sample size (8 sets of duplicates) and that there is no limit specified for number of lots that could be assessed using these potentially imprecise estimates of uncertainty and that there is also concern that they could be taken as universal figures, whereas in fact the situation could vary between manufacturers and even between specifications. The Delegation indicated that tolerances should allow for reproducibility–type variation unless an explicit correction is made for run bias and that the proposed procedure seemed to incorporate only

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[14] CX/MAS 06/27/10; CRD 2 (Report of the 18th Interagency Meeting), CRD 15 (Proposed Draft Guidelines on Estimation of Uncertainty of Results from CCPR)

repeatability type variation. The Delegation therefore supported the general principle of using tolerances to allow for uncertainty and the use of duplicate samples to estimate these.

110) The Committee noted that there was no consensus on initiation of new work but in recognition of the importance of this work decided to wait until the EURACHEM working document is published in order to evaluate its impact and consequences and agreed that further update would be presented at the next session.

Use of analytical results

111) The Delegation of Thailand, while referring to the interpretation of the document on the *Use of Analytical Results: Sampling Plans, Relations Between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards* discussed under Agenda Item 2, indicated that there was not enough time for their experts to study CRD 11 and proposed to reconsider the endorsement of the above Recommendations for adoption by the forthcoming Commission.

112) The Committee noted the clarification of the Secretariat that this document was intended for application by Codex Committees and not for governments and that additional guidance for governments in this area could be developed, if necessary.

Codex sampling procedures

113) The Delegation of Japan drew the attention of the Committee to the fact that the *Principles for the Establishment or Selection of Codex Sampling Procedures* in the Procedural Manual referred to the *Sampling Plans for Prepackaged Foods*, that had been superseded by the *General Guidelines on Sampling* adopted by the Commission, therefore proposed to revise and update the section of the Procedural Manual dealing with this matter, taking into account the adoption of the *Guidelines*.

114) The Committee agreed to this proposal and accepted the kind offer of the Delegation of Japan to prepare a revised section for consideration by the next session of the Committee.

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS AND SAMPLING (Agenda Item 10)[15]

115) The Chair of the Inter-Agency Meeting, Dr Roger Wood, on behalf of the IAM Secretariat, introduced the draft report of the 18th IAM presented in CRD 2. In noting that several outputs of this report (harmonisation of analytical terminology; EURACHEM meeting on Uncertainty of Sampling Working Group; incorporation of change of methods/methods corrections in the Codex) had been considered under earlier items on the agenda or at the *ad hoc* Working Group on Endorsement of Methods, he highlighted the following important issues discussed at the IAM.

116) It was indicated that the since the criteria approach had been adopted by the Commission, users of analytical methods would require more information than was currently included in the "Standards Methods". Such information included accuracy, sensitivity, linearity, detection limit, applicability, quantification limit and the Committee was informed that members of IAM would identify the practicality of collating and making available such information.

117) The Committee was informed that in future the IAM website would provide links to relevant information regarding recently-published standards rather than PDF documents.

118) He further informed the Committee that activities of IAM might be supported through the EU-funded FP6 "Network of Excellence" "HARMONY" project that would include NGOs in its membership.

119) Finally, he informed the Committee that the Secretariat of the meeting, the AOCS, would remain for the next meeting and that he would continue to chair this meeting for another year to maintain continuity.

120) The Committee expressed its appreciation to the IAM and Dr Wood for their constructive work and contribution to the work of the Committee and to the Hungarian Food Safety Office for hosting the IAM. It also noted that the next IAM would be held before the next Session of the Committee.

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[15] CRD 2 (Draft Report of the 18th Meeting of the International Organisations Working in the Field of Methods of Analysis and Sampling (Interagency Meeting))

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

Other Business

121) The Delegation of the United Kingdom informed the Committee that at its next session an update on the IUPAC development of International Guidelines for Validation of Qualitative Methods through Collaborative Trials would be presented for information purposes.

122) The Delegation of the Netherlands drew the attention of the Committee to the fact that the Committee faced difficulties in developing or endorsing methods of analysis for which there were no provisions in Codex Standards and proposed that the Committee consider the possible amendment of its Terms of Reference. This view was supported by several other delegations.

123) The Committee agreed that the Delegation of the Netherlands together with other interested delegations would prepare a discussion paper on this matter for consideration by the next Session of the Committee.

Future Work

124) The Committee noted that, as a result of its discussions at the present Session, the Agenda of its next Session would include the following items, in addition to standing items (matters referred and IAM report):

- Draft Guidelines for Evaluating Acceptable Methods of Analysis
- Draft Guidelines for Settling Disputes over Analytical (Test) Results
- Review of the Analytical Terminology for Codex Use
- Endorsement of methods of analysis, including their possible conversion into criteria, and methods of sampling
- Criteria for the Methods for the Detection of Foods Derived from Biotechnology
- Revision of the Principles for the Establishment of Codex Sampling Procedures in the procedural Manual
- Discussion paper on the terms of reference of the Committee

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

125) The Committee was informed that the 28th Session of the Committee would be held in Budapest from 19 to 23 March 2007. The exact venue would be determined by the host country and the Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 06/29/23
Endorsement of methods of analysis in Draft Standards and existing Standards		Governments 29th CAC	paras. 57-75 Appendix II
Revision of the IUPAC/ISO/AOAC Protocol for Proficiency Testing		29th CAC	para. 102
Draft Guidelines for Evaluating Acceptable Methods of Analysis	6	New Zealand/ Governments 28th CCMAS	para. 22
Proposed Draft Guidelines for Settling Disputes on Analytical (Test) Results	5	Governments 29th CAC	para. 43 Appendix III
Review of *Analytical Terminology for Codex Use* (to be transferred from the Procedural Manual to a Proposed Draft Guidelines)	2/3	29th CAC United States/ Governments 28th CCMAS	para. 55
Conversion of methods for trace elements into criteria		Sweden/NMKL 28th CCMAS	para. 83
Criteria for methods of analysis for foods derived from biotechnology		United Kingdom/ Germany 28th CMAS	para. 91
Revision of the Principles for the Establishment of Codex Sampling Procedures	(*)	29th CAC Japan/Governments 28th CCMAS	para. 113-114
Methods of analysis for dioxins and PCBs		CCFAC	para. 97

(*) Procedural Manual

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STATUS OF ENDORSEMENT OF METHODS OF ANALYSIS

PART I METHODS OF ANALYSIS

A. *Ad hoc* Intergovernmental Task Force on Fruit and Vegetable Juices

B. Codex Committee on Cereals, Pulses and Legumes (Draft Standard for Instant Noodles)

C. Codex Committee on Milk and Milk Products

D. Codex Committee on Nutrition and Foods for Special Dietary Uses

Note: All methods presented in the Tables were endorsed with the Type specified and therefore no additional column on the status of endorsement was included.

PART II. SAMPLING

Codex Committee on Milk and Milk Products

PART I. METHODS OF ANALYSIS

A. *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FRUIT AND VEGETABLE JUICES[1]

GENERAL STANDARD FOR FRUIT JUICES AND NECTARS (CODEX STAN 247-2005)

PROVISION	METHOD	PRINCIPLE	TYPE
	Determination of acetic acid EN 12632; IFU Method No 66 (1996)	Enzymatic determination	II
	Determination of alcohol (ethanol) IFU Method No 52 (1996)	Enzymatic determination	II

[1] ALINORM 05/28/39, Appendix II, adopted by the 28th Session of the Commission as CODEX STAN 247-2005.

[2] **3.4 Verification of Composition, Quality and Authenticity**

Fruit juices and nectars should be subject to testing for authenticity, composition, and quality where applicable and where required. The analytical methods used should be those found in Section 9, Methods of Analysis and Sampling.

The verification of a sample's authenticity / quality can be assessed by comparison of data for the sample, generated using appropriate methods included in the standard, with that produced for fruit of the same type and from the same region, allowing for natural variations, seasonal changes and for variations occurring due to processing.

Sections 3.2 Quality Criteria and 3.3 Authenticity[2]	Detection of anthocyanins IFU Method No 71 (1998)	HPLC	I
	Determination of ash in fruit products AOAC 940.26; EN 1135 (1994); IFU Method No 9 (1989)	Gravimetry	I
	Detection of beet sugar in fruit juices AOAC 995.17	Deuterium NMR	II
	Determination of benzoic acid as a marker in orange juice AOAC 994.11	HPLC	III
	Determination of C^{13}/C^{12} ratio of ethanol derived from fruit juices JAOAC 79, No. 1, 1996, 62-72	Stable isotope mass spectrometry	II
	Determination of carbon stable isotope ratio of apple juice AOAC 981.09 - JAOAC 64, 85 (1981)	Stable isotope mass spectrometry	II
	Determination of carbon stable isotope ratio of orange juice AOAC 982.21	Stable isotope mass spectrometry	II
	Determination of carotenoid, total/individual groups EN 12136 (1997); IFU Method No 59 (1991)	Spectrophotometry	I
	Determination of centrifugable pulp EN 12134 (1997); IFU Method No 60 (1991)	Centrifugation/% value	I
	Determination of chloride (expressed as sodium chloride) EN12133 (1997); IFU Method No 37 (1991)	Electrochemical titrimetry	III
	Determination of chloride in vegetable juice AOAC 971.27 (Codex general method) ISO 3634:1979	Titration	II
	Determination of essential oils (Scott titration AOAC 968.20; IFU 45b*	(Scott) distillation, titration	I
	Determination of essential oils (in citrus fruit) (volume determination)* ISO 1955:1982	Distillation and direct reading of the volume determination	I
	Determination of fermentability IFU Method No 18 (1974)	Microbiological method	I

	Determination of formol number EN 1133 (1994); IFU Method No 30 (1984)	Potentiometric titration	I
	Determination of free amino acids EN 12742 (1999); IFU Method No 57 (1989)	Liquid Chromatography	II
	Determination of fumaric acid IFU Method No 72 (1998)	HPLC	II
Glucose and fructose (permitted ingredients)	Determination of glucose fructose and saccharose EN 12630; IFU Method No 67 (1996) NMKL 148 (1993)	HPLC	II
Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of gluconic acid IFU Method No 76 (2001)	Enzymatic determination	II
	Determination of glycerol IFU Method No 77 (2001)	Enzymatic determination	II
	Determination of hesperidin and naringin EN 12148 (1996); IFU Method No 58 (1991)	HPLC	II
HFCS & HIS in apple juice (permitted ingredients)	Determination of HFCS & HIS by Capillary GC method JAOAC 84, 486 (2001)	CAP GC Method	IV
Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of hydroxymethylfurfural IFU Method No 69 (1996)	HPLC	II
	Determination of hydroxymethylfurfural ISO 7466:1986	Spectrometry	III
	Determination of isocitric acid-D EN 1139 (1999); IFU Method No 54 (1984)	Enzymatic determination	II
	Determination of Lactic acid- D and L EN 12631 (1999); IFU Method No 53 (1983/1996)	Enzymatic determination	II
	Determination of L-malic/total malic acid ratio in apple juice AOAC 993.05	Enzymatic determination and HPLC	II

	Determination of naringin and neohesperidin in orange juice AOAC 999.05	HPLC	III
	Determination of pH-value NMKL 179:2005	Potentiometry	II
	EN 1132 (1994); IFU Method No 11 (1989); ISO 1842: 1991		IV
	Determination of phosphorus/phosphate EN 1136 (1994); IFU Method No 50 (1983)	Photometric determination	II
	Determination of proline by photometry – non-specific determination EN 1141 (1994); IFU Method No 49 (1983)	Photometry	I
Quinic, malic & citric acid in cranberry juice cocktail and apple juice (permitted ingredients and additives)	Determination of quinic, malic and citric acid in cranberry juice cocktail and apple juice AOAC 986.13	HPLC	III
Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of relative density EN 1131 (1993); IFU Method No 1 (1989) & IFU Method No General sheet (1971)	Pycnometry	II
	Determination of Relative density IFU Method No 1A	Densitometry	III
	Determination of sodium, potassium, calcium, magnesium in fruit juices EN 1134 (1994); IFU Method No 33 (1984)	Atomic Absorption Spectroscopy	II
	Determination of sorbitol-D IFU Method No 62 (1995)	Enzymatic determination	II
	Determination of stable carbon isotope ratio in the pulp of fruit juices ENV 13070 (1998) Analytica Chimica Acta 340 (1997)	Stable isotope mass spectrometry	II

Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of stable carbon isotope ratio of sugars from fruit juices ENV 12140 Analytica Chimica Acta.271 (1993)	Stable isotope mass spectrometry	II
	Determination of stable hydrogen isotope ratio of water from fruit juices ENV 12142 (1997)	Stable isotope mass spectrometry	II
	Determination of stable oxygen isotope ratio in fruit juice water ENV 12141(1997)	Stable isotope mass spectrometry	II
	Detection of starch AOAC 925.38 (1925) IFU Method No 73 (2000)	Colorimetric	I
	Determination of sugar beet derived syrups in frozen concentrated orange juice $\delta^{18}O$ Measurements in Water AOAC 992.09	Oxygen isotope ratio analysis	I
	Determination of titrable acids, total EN 12147 (1995); IFU Method No Method No 3, (1968); ISO 750:1998	Titrimetry	I
	Determination of total dry matter (vacuum-oven drying at 70°C)* EN 12145 (1996); IFU Method No 61 (1991)	Gravimetric determination	I
	Determination of total solids (Microwave oven drying)* AOAC 985.26	Gravimetric determination	I
	Determination of Vitamin C (dehydro-ascorbic acid and ascorbic acid) AOAC 967.22	Microfluorometry	III
	Determination of Vitamin C EN 14130 (2004)	HPLC	II

* *Because there is no numerical value in the Standard duplicate Type I methods have been included which may lead to different results.*

B. CODEX COMMITTEE ON CEREALS PULSES AND LEGUMES

DRAFT STANDARD FOR INSTANT NOODLES (ELABORATION BY CORRESPONDENCE)*

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE	STATUS
Instant Noodles	Moisture	Described in the Standard (see below)	Gravimetry	I	E

9.2 Determination of Moisture

A. Apparatus

(a) Aluminum dish - diameter ≥55mm, height ≥ 15mm, and with inverted tight-fitting lid.

(b)Air-oven - **with control accuracy ±1°C**.

(c) Air-tight desiccator - silica gel heated at 150 °C is satisfactory drying agent.

B. Preparation of test sample

Remove instant noodles from package, and leave garnishing and seasoning in package. Transfer the noodles to plastic bag to prevent moisture change, and then break these into small fragments with hands or wooden hammer. Select broken noodles in the size range of 2.36 mm to 1.7 mm by using two sieves with 2.36 mm and 1.7 mm openings (mesh size 12-8), and mix well. Use these noodles for test sample. If noodles are too thin to screen with sieves, cut them into 1 to 2 cm lengths, mix well, and use these cut noodles for test sample.

C. Determination

1. Fried noodles

In cooled and weighed dish (with **lid**), previously heated to **105°C**, weigh ca 2 g well-mixed test portion to 1mg. Uncover test portion and dry dish, **lid**, and contents 2 h in oven provided with opening for ventilation and maintained at **105°C**. (The 2 h drying period begins when oven temperature is actually 105 °C.) After drying period, cover dish while still in oven, transfer to desiccator, and weigh to 1 mg soon after reaching room temperature. Report loss in weight as moisture (indirect method).

2. Non-fried noodles

For non-fried noodles, follow the directions for fried noodles, but dry test portion for 4 h.

D. Calculation

Calculate using the following equations.

Moisture (%) = {(g test portion before drying – g test portion after drying)/ g test portion before drying}×100

* *The results of the interlaboratory study will be published in the Journal of AOAC International.*

C. CODEX COMMITTEE ON MILK AND MILK PRODUCTS[3]

Part A – Methods of analysis for standards currently being elaborated

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
Blend of evaporated skimmed milk and vegetable fat	Total fat	IDF 13C:1987 | ISO 1737:1999	Gravimetry (Röse-Gottlieb)	IV
Blend of evaporated skimmed milk and vegetable fat	Milk solids-not-fat* (MSNF)	IDF 21B:1987 | ISO 6731:1989 IDF 13C:1987 | ISO 1737:1999	Calculation from total solids content and fat content Gravimetry (Röse-Gottlieb)	IV
Blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF*	IDF 20-part 1 or 2:2001 | ISO 8968-part 1 or 2:2001	Titrimetry (Kjeldahl)	IV
Reduced fat blend of evaporated skimmed milk and vegetable fat	Total fat	IDF 13C:1987 | ISO 1737: 1999	Gravimetry (Röse-Gottlieb)	IV
Reduced fat blend of evaporated skimmed milk and vegetable fat	MSNF *	IDF 21B:1987 | ISO 6731:1989 IDF 13C:1987 | ISO1737:1999	Calculation from total solids and fat contents	IV
Reduced fat blend of Evaporated skimmed milk and vegetable fat	Milk protein in MSNF*	IDF 20-1 or 2:2001 | ISO 8968-1 or 2:2001	Titrimetry (Kjeldahl)	IV
Blend of skimmed milk and vegetable fat in powdered form	Total fat	IDF 9C:1987 | ISO1736:2000	Gravimetry (Röse-Gottlieb)	IV
Blend of skimmed milk and vegetable fat in powdered form	Water**	IDF 26:2004 | ISO 5537:2004	Gravimetry, drying at 87°C	IV
Blend of skimmed milk and	Milk protein in	IDF 20-part 1 or part 2:2001 |	Titrimetry (Kjeldahl)	IV

[3] ALINORM 06/29/11, Appendix XXVI

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

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

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
vegetable fat in powdered form	MSNF*	ISO 8968-part 1 or part 2:2001		
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Total fat	IDF 9C:1987 | ISO 1736:2000	Gravimetry (Röse-Gottlieb)	IV
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Water**	IDF 26:2004 | ISO 5537:2004	Gravimetry, drying at 87°C	IV
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Milk protein in MSNF*	IDF 20-part 1 or part 2:2001 | ISO 8968-part 1 or part 2:2001	Titrimetry (Kjeldahl)	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Total fat	IDF 13C:1987 | ISO 1737:1999	Gravimetry (Röse-Gottlieb)	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Milk solids-not-fat* (MSNF)	IDF 15B:1991 | ISO 6734:1989 IDF 13C:1987 | ISO 1737:1999	Calculation from total solids content and fat content Gravimetry (Röse-Gottlieb)	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF*	IDF 20-part1 or part 2:2001 | ISO 8968-part 1 or part 2:2001	Titrimetry (Kjeldahl)	IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	Total fat <= 8% m/m >= 1%m/m	IDF 13C:1987 | ISO 1737: 1999	Gravimetry (Röse-Gottlieb)	IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	MSNF * >= 20% m/m	IDF 15B:1991 | ISO 6734:1989 IDF 13:1987 | ISO1737:1999	Calculation from total solids and fat contents	IV

* Milk total solids and Milk solids-not-fat content including water of crystallization of lactose
** Water content excluding the crystallized water bound to lactose (in fact to read moisture content)

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	Milk protein in MSNF*	IDF 20-part 1 or part 2:2001 | ISO 8968-part 1 or part 2:2001	Titrimetry (Kjeldahl)	IV
Individual Cheeses	Milkfat in dry matter (FDM)	IDF 5:2004 | ISO 1735:2004	Gravimetry after solvent extraction	I
Emmental	Calcium >= 800mg/100g	ISO 8070 | IDF 119[4]	Flame atomic absorption	IV
Cottage cheese	Milkfat	IDF 5:2004 | ISO 1735:2004 IDF 124-3:2005 | ISO 8262-3:2005	Gravimetry (Schmid-Bondzinski-Ratzlaff) Gravimetry (Weibull-Berntrop)	IV
Cottage cheese	Fat-free dry matter	IDF 4:2004 | ISO 5534:2004	Gravimetry, drying at 102°C Calculation from dry matter and fat contents	IV
Cream cheese	Moisture on fat free basis	IDF 4:2004 | ISO 5534:2004 and IDF 5:2004 | ISO 1735:2004	Calculation from fat content and moisture content	IV
Cream cheese	Dry matter	IDF 4:2004 | ISO 5534:2004	Gravimetry drying at 102°C	IV
Mozzarella	Milkfat in dry matter – with high moisture	IDF 5:2004 | ISO 1735:2004	Gravimetry after solvent extraction	IV
Mozzarella	Milkfat in dry matter – with low moisture	IDF 5:2004 | ISO 1735:2004	Gravimetry after solvent extraction	IV

[4] *Draft international standard*

Whey cheeses including Whey cheeses by concentration	Total fat	IDF 59A:1986 ISO 1854:1999	Gravimetry (Röse Gottlieb)	I
Whey cheeses by coagulation	Total fat	IDF 5:2004 | ISO 1735:2004	Gravimetry (Schmid-Bondzynski-Ratzlaff	I
Whey cheeses by concentration	Dry matter (total solids)	IDF 58:2004 ISO 2920:2004	Gravimetry, drying at 88 °C	I
Whey cheeses by coagulation	Dry matter (total solids)	IDF 4:2004 ISO 5534:2004	Gravimetry, Drying at 102°C	IV
Whey cheese	Fat on the dry basis	IDF 59 A:1986 | ISO 1854:1999 and IDF 58:2004 | ISO 2920:2004	Calculation from fat content and dry matter content	I
Creamed whey cheese	Fat on the dry basis	IDF 59 A: 1986 | ISO 1854: 1999 and IDF 58:2004 | ISO 2920:2004	Calculation from fat content and dry matter content	I
Skimmed whey cheese	Fat on the dry basis	IDF 59 A:1986 | ISO 1854:1999 and IDF 58:2004 | ISO 2920:2004	Calculation from fat content and dry matter content	I
Dairy fat spreads	Total fat	IDF 194:2003 | ISO 17189:2003	Gravimetry Direct determination of fat using solvent extraction	I
Dairy fat spreads	Vegetable fat	IDF 54:1970 | ISO 3594: 1976 IDF 32:1965 | ISO 3595:1976	Gas liquid chromatography Phytosterol acetate test	II III

Part B - Updated list of methods of analysis for Codex Standards for milk products

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
Milk products	Iron	IDF Standard 103A:1986 ISO 6732:1985	Photometry (bathophenanthroline)	IV
Milk products (products not completely soluble in ammonia)	Milkfat	IDF 124-3 | ISO 8262-3:2005	Gravimetry (Weibull-Berntrop)	I
Butter	Milk solids-not-fat	IDF 80-2 | ISO 3727-2:2001	Gravimetry	I
Butter	Milkfat	IDF 80-3 | ISO 3727-3:2003	Gravimetry	I
Butter	Salt	IDF 12 | ISO 1738:2004	Titrimetry (Mohr: determination of chloride, expressed as sodium chloride)	II
Butter	Salt	IDF 179 | ISO 15648:2004	Potentiometry (determination of chloride, expressed as sodium chloride)	III
Butter	Vegetable fat	ISO 17670 / IDF 202	Gas liquid chromatography	II
Butter	Water	IDF 80 | ISO 37271:2001	Gravimetry	I
Cheese	Citric acid	IDF RM 34 | ISO TS 2963:2006	Enzymatic method	II
Cheese	Milkfat	IDF 5 | ISO 1735:2004	Gravimetry (Schmid-Bondzynski-Ratslaff)	I
Cheese (and cheese rind)	Natamycin	IDF Standard 140A:1992 ISO 9233:1991	Molecular absorption spectrophotometry or HPLC after extraction	III II
Cheeses in brine	Milkfat in dry matter	IDF 5 | ISO 1735:2004	Gravimetry (Schmid-Bondzynski-Ratslaff)	I
Cream	Milkfat	IDF Standard 16C:1987 ISO 2450:1999	Gravimetry (Röse-Gottlieb)	I
Cream	Solids	IDF Standard 21B:1987 ISO 6731:1989	Gravimetry (drying at 102°C)	I
Edible casein products	Acids, free	IDF Standard 91:1979 ISO 5547:1978	Titrimetry (aqueous extract)	IV
Edible casein products	Ash (including P_2O_5)	IDF Standard 90:1979 ISO 5545:1978	Furnace, 825°C	IV

Edible casein products	Copper	IDF 76 | ISO 5738:200**4**	Colorimetry (diethyldiethiocarbamate)	III
Edible casein products	Lactose	IDF 106 | ISO 5548:2004	Photometry (phenol and H_2SO_4)	IV
Edible casein products	Lead	IDF RM 133 | ISO TS 6733: 2006	Spectrophotometry (1,5-diphenylthiocarbazone)	III
Edible casein products	Milkfat	ISO 5543 | IDF 127: 2004	Gravimetry (Schmid-Bondzynski-Ratslaff)	I
Edible casein products	Moisture	IDF 78 | ISO 5550:2006	Gravimetry (drying at 102°C)	I
Edible casein products	pH	IDF Standard 115A:1989 ISO 5546:1979	Electrometry	IV
Edible casein products	Protein (total N x 6.38 in dry matter)	IDF Standard 92:1979 ISO 5549:1978	Titrimetry, Kjeldahl digestion	IV
Edible casein products	Sediment (scorched particles)	IDF 107 | ISO 5739:2003	Visual comparison with standard disks, after filtration	IV
Evaporated milks	Milkfat	IDF Standard 13C: 1987 ISO 1737:1999	Gravimetry (Röse-Gottlieb)	I
Evaporated milks	Total solids	IDF Standard 21B:1987 ISO 6731:1989	Gravimetry (drying at 102°C)	I
Milk powders and cream powders	Milkfat	IDF Standard 9C: 1987 ISO 1736:2000	Gravimetry (Röse-Gottlieb)	I
Milk powders and cream powders	Protein (in milk solids-not-fat)	IDF 20-1 | ISO 8968-1:2001	Titrimetry, Kjeldahl digestion	I
Milk powders and cream powders	Scorched particles	IDF 107 | ISO 5739:2003	Visual comparison with standard disks, after filtration	IV
Milk powders and cream powders	Solubility	IDF 129 | ISO 8156:2005	Centrifugation	I
Milk powders and cream powders	Acidity, titratable	IDF Standard 86:1981 ISO 6091:1980	Titrimetry, titration to pH 8.4	I
Milk powders and cream powders	Water	IDF 26 | ISO 5537:2004[5]	Gravimetry (drying at 102°C)	IV

[5] *The replacing method has only been validated for milk powders, not for creams*

Milkfat products	Antioxidants (phenolic)	IDF Standard 165:1993	Reversed phase gradient liquid chromatography	II
Milkfat products	Fatty acids, free (expressed as oleic acid)	IDF 6 | ISO 1740:2004	Titrimetry	I
Milkfat products	Milkfat	IDF Standard 24:1964	Gravimetry (calculation from solids-not-fat and water content)	IV
Milkfat products	Vegetable fat (sterols)	IDF Standard 54:1979 ISO 3594:1976	Gas liquid chromatography	II
Milkfat products	Vegetable fat	IDF Standard 32:1965 ISO 3595:1976	Phytosteryl acetate test	III
Milkfat products	Water	IDF 23 | ISO 5536:2002	Titrimetry (Karl Fischer)	II
Processed cheese products	Citric acid	IDF RM 34 | ISO TS 2963:2006	Enzymatic method	II
Processed cheese products	Milkfat	IDF 5 | ISO 1735:2004	Gravimetry (Schmid- Bondzynski-Ratzlaff)	I
Processed cheese products	Phosphorus	IDF Standard 33C: 1987 ISO 2962:1984	Spectrophotometry (molybdate-ascorbic acid)	II
Processed cheese products	Salt	IDF 88 | ISO 5943:2004	Potentionmetry (determination of chloride, expressed as sodium chloride)	II
Sweetened condensed milk	Milkfat	IDF Standard 13C: 1987 ISO 1737:1999	Gravimetry (Röse-Gottlieb)	I
Whey cheese	Dry matter	IDF 58 | ISO 2920:2004	Gravimetry (drying at 88±2°C)	I
Whey cheese	Milkfat (in dry matter)	IDF Standard 59A:1986 ISO 1854:1999	Gravimetry (Röse-Gottlieb)	I
Whey powders	Ash	IDF Standard 90:1979 ISO 5545:1978	Furnace, 825°C	IV
Whey powders	Copper	IDF 76 | ISO 5738:2004	Photometry (diethyldiethiocarbamate)	III
Whey powders	Milkfat	IDF Standard 9C:1987 ISO 1736:2000	Gravimetry (Röse-Gottlieb)	I
Whey powders	Moisture, "Free"	IDF 58 | ISO 2920:2004	Gravimetry (drying at 88±2°C)	IV
Whey powders	Protein (total N x 6.38)	IDF Standard 92:1979 ISO 5549:1978	Titrimetry, Kjeldahl digestion	IV

Yoghurt products	*Lactobacillus bulgaricus & Streptococcus thermophilus*	IDF 117 | ISO 7889:2003	Colony count at 37°C	
Yoghurt products	*Lactobacillus bulgaricus & Streptococcus thermophilus*	IDF 146 | ISO 9232:2003	Test for identification	
Yoghurt products	Solids, Total	IDF 151 | ISO 13580:2005	Gravimetry (drying at 102°C)	I

D. CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (GLUTEN FREE FOODS)

Draft Revised Standard for Gluten-Free Foods (at Step 6 of the Procedure)

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE
Gluten-free foods	Gluten	Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method	Immunoassay	I

References: *Eur J Gastroenterol Hepatol* 2003; 15: 465-474

PART II. SAMPLING

COMMITTEE ON MILK AND MILK PRODUCTS: Uupdated list of methods of sampling for Codex Standards for milk products

Milk products	Sampling	IDF 50 | ISO 707[6]	General Instructions for obtaining a sample from a bulk
Milk products	Sampling	IDF 113 | ISO 5538:2004	Inspection by attributes
Milk products	Sampling	IDF Standard 136A:1992 ISO 8197:1988	Inspection by variables
Butter	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Cheese	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk

[6] *Draft standard which is publicly available*

Cheeses in brine	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Edible casein products	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Evaporated milks	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Milk powders and cream powders	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Milkfat products	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Sweetened condensed milks	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Whey cheese	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk
Whey powders	Sampling	IDF 113 | ISO 5538:2004	Inspection by attributes
Whey powders	Sampling	IDF 50 | ISO 707	General Instructions for obtaining a sample from a bulk

PROPOSED DRAFT GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS

(At Step 5 of the Procedure)

1. SCOPE:

These guidelines provide guidance to governments on the procedures to resolve disputes which arise between food control authorities about the status of a food consignment[1], when the test results by the laboratory[2] in the importing country disagree with test results by the laboratory in the exporting country over the same consignment.

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

These guidelines only address disputes related to methods of analysis or laboratory performance and do not address questions of sampling and/or of interpretation of test results[3]. It is recognised that disputes may arise from other cause(s), which should also be investigated. Guidance on issues related to measurement uncertainty is provided by *International Laboratory Accreditation Cooperation, annex A (ILAC-G8/1996)*.

2. PREREQUISITES:

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

- laboratories comply with quality assurance provisions and with the Codex *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and the Export of Food (CAC-GL 27)*; and
- at least, one representative analytical laboratory sample from the same food consignment has been taken in accordance with established sampling plans and/or good sampling practices, where applicable; the laboratory sample has been split for the purposes of analysis and for confirmatory analysis (reserve sample); the reserve sample should be kept in a satisfactory condition for the appropriate length of time.

3. PROCEDURE:

(see FLOWCHART)

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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 or recognised by a government agency having jurisdiction.

3 Possible reasons for disagreement may include one or several causes such as : differences in composition of the samples tested due to product inhomogeneity or changes occurring during storage and/or transport of the product; differences in the methods of analysis or the laboratory performance; differences in the specification or results; differences in the expression of results (corrected for recovery, etc),...

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

3.1. – STEP 1: The analytical results are compared using the reproducibility limit

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

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

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

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

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

3.2. – STEP 2: The results and procedures of the laboratory of the exporting country and its counterpart in the importing country are compared

In accordance with relevant Codex Guidelines[4], the following information should be shared between competent authorities of the importing and exporting country to allow comparison of the results and procedures of the laboratory of the exporting country and its counterpart in the importing country. The relevant information covers:

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

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

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

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

3.3. – STEP 3: New analyses are carried out

Prerequisites

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

- the sharing/swapping of the reserve samples,
- the methods of analysis,

[4] 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."

- the laboratories involved: each laboratory may undertake new analyses or one laboratory in the presence of a representative of the other; or a third laboratory may be selected by consensus of exporting and importing country, or, failing that, by the competent authority of the importing country; and
- the use of the new analytical results: either the initial results are discarded and the settlement of the dispute is determined by the comparison of the new results obtained; or the new results are used to confirm the validity of one of the two results obtained initially.

Available approaches

One (or more) may be selected.

A.– SEARCH FOR LABORATORY BIAS

It may be agreed to check for laboratory bias, by testing common samples.[5] Performances are compared by testing a common sample with a known analyte content, preferably certified reference material. The original results are then corrected according to the bias found. If the results are in agreement, within the reproducibility limit, the dispute is settled.

B.– IDENTIFICATION OF A SAMPLING PROBLEM

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

C.– ANALYSES OF RESERVE SAMPLES

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

(1) analyses are performed in one laboratory in the presence of a representative of the other laboratory. The new results are used to assess conformity.

(2) the two laboratories carry analyses separately: If the new results are in agreement, the dispute is settled. If no agreement is reached, resolution of the dispute may be sought by proceeding to step 4.

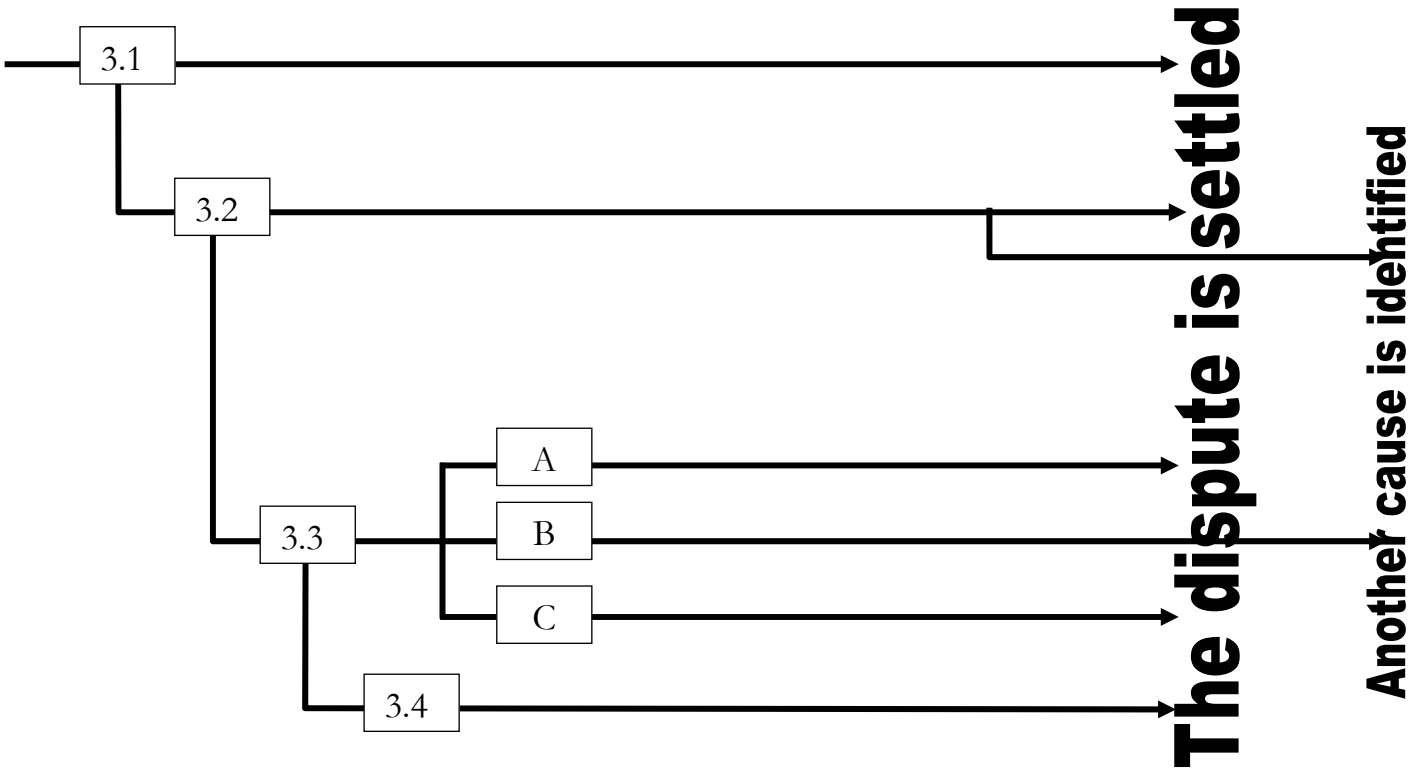
3.4 – STEP 4: New samples taken from the consignment are analysed

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

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

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

FLOWCHART


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

ANNEX

Definition of a maximum acceptable difference Δ_{max}

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

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

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

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

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

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

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

Then it comes:

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

Thus, the maximal acceptable difference (relative) is:

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

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

Measurement uncertainty of the mean

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

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

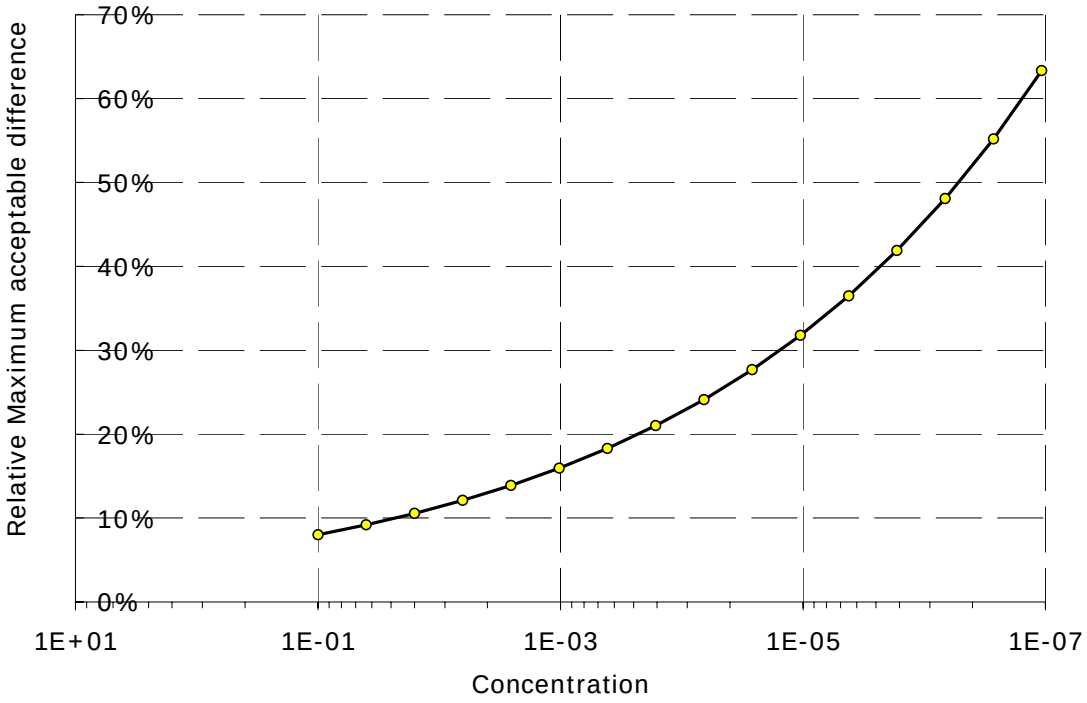


Figure 1. Relative Maximum acceptable difference based on Horwitz's model

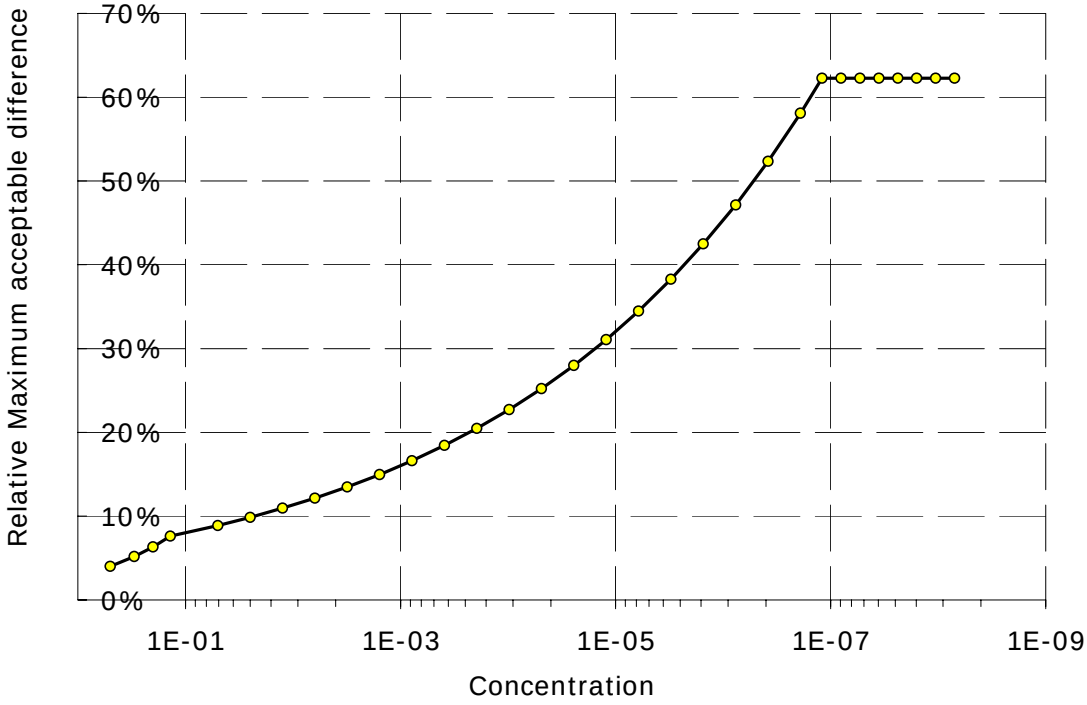


Figure 2. Relative Maximum acceptable difference based on Thompson's model

Table 1. Published recognized models

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

References

[1] Horwitz W. (1980) Quality Assurance in the Analysis of Foods for Trace Constituents, *J of the AOAC* 63:6, 1344-1354
[2] Thompson M. (2000) Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing, *Analyst* 125, 385-386