

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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WORLD
HEALTH
ORGANIZATION

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ALINORM 05/28/23

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-eighth Session
Rome, Italy, 4 – 9 July 2005

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

Budapest, Hungary
4 - 8 April 2005

Note: This document incorporates Codex Circular Letter CL 2005/21-MAS

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CX 4/50.2

**CL 2005/21-MAS
May 2005**

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 26th Session of the Codex Committee on Methods of Analysis and Sampling (ALINORM 05/28/23)**

A. MATTERS FOR ADOPTION BY THE 28th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

METHODS OF ANALYSIS AND SAMPLING

1. Methods of Analysis in Codex Standards at different steps and addition of a note to CODEX STAN 234-1999 (paras. 53-83 and 88, Appendix III)

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, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 10 June 2005.**

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

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

2. Inclusion of recommendations on *The Use of Analytical Results : Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards* (para. 107, 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, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 15 March 2006.**

Note: This text will be forwarded for endorsement to the 23rd Session of the Committee on General Principles, to be held in 2006, and will be considered for adoption by the 29th Session of the Commission (2006).

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 26th Session of the Codex Committee on Methods of Analysis and Sampling are as follows:

Matters for consideration by the 28th Session of the Commission:

The Committee:

- endorsed several methods of analysis in Codex standards at different steps of the Procedure; and proposed to include a note in CODEX STAN 234-1999 concerning the use of the most updated version of methods of analysis (paras. 53-83 and 88, Appendix III);

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

- agreed to propose the inclusion of new recommendations on *The Use of Analytical Results: Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards* in the Procedural Manual (para. 107, Appendix II);

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. 20);
- agreed to return to Step 2/3 the Proposed Draft Guidelines for Settling Disputes on Analytical (Test) Results (para. 42);
- agreed to postpone consideration of the Proposed Draft Recommendations on the Fitness-for-purpose Approach (para. 26);
- agreed to proceed with the review of the current *Analytical Terminology for Codex Use* in the Procedural Manual (para. 50);
- agreed to consider further at its next session the conversion of methods for trace elements into criteria (para. 99); the criteria for methods of analysis for foods derived from biotechnology (para. 116); and the methods for the determination of dioxins and PCBs (para. 123);
- agreed to consider at its next session the revision of the IUPAC/ISO/AOAC Protocol for Proficiency Testing; and sampling uncertainty (paras. 141-143).

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INTRODUCTION

1) The Codex Committee on Methods of Analysis and Sampling held its Twenty-sixth Session in Budapest, Hungary, from 4 to 8 April 2005, by courtesy of the Government of Hungary. The Session was chaired by Professor Peter Biacs, Director-General of the Hungarian Food Safety Office and by the Vice-Chairperson, Prof. Pál Molnár, Department of Food Science, University of Szeged. The Session was attended by 133 delegates and observers representing 46 Member Countries, one Member Organization (EC) and 14 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 Emil Keleti, the Head of Food Department of Ministry of Agriculture and Rural Development who emphasized that it was a great honour for Hungary to host the Codex Committee on Methods of Analysis and Sampling (CCMAS), as it had been doing for many years. He pointed out the increasing interest and participation of members for this Committee, whose work is of great importance to other Codex Committees and informed the Committee that a new Food Law, passed by the Hungarian Parliament, dedicated a special chapter to Codex Alimentarius and that it had established a new National Codex Committee. Emphasizing the role of the Codex Alimentarius standards in assuring the protection of the health of consumers and harmonization of legislation on international food trade, Dr Keleti 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 decided to consider Agenda Item 4 before Item 3, in view of relevance of terminology for other items and with this amendment it adopted the Provisional Agenda as the Agenda for the Session.

MATTERS REFERRED 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 27th Session of the Codex Alimentarius Commission (CAC), and other Codex Committees such as information regarding the amendments to the Procedural Manual, were for information purposes or would be discussed in more detail under relevant Agenda Items. It was agreed that the issue of raised by the CCFO as to whether to retain the reference to the year of publication when referencing methods would be discussed from a general point of view under Agenda Item 5 (a).

6) The Delegation of New Zealand drew the attention of the Committee to the fact that the Guidelines on Measurement Uncertainty adopted by the CAC did not provide enough guidance on how the information on uncertainty would be used and indicated that the Codex Committee on Pesticide Residues (CCPR) had initiated work in this area. The Delegation noted that it was useful for CCMAS to be aware of their work and proposed to consider the possibility of similar work in the Committee.

7) The Committee noted that this matter could be considered when discussing Agenda Item 6 on the Use of Analytical Results.

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

8) The Committee recalled that the 27th Session of the Commission had adopted the proposed draft Guidelines for Evaluating Acceptable Methods of Analysis at Step 5 and that comments were asked by the CL 2004/36-GEN at Step 6.

¹ CX/MAS 05/26/1

² CX/MAS 05/26/2, CRD 3 (Division of Competence between the EC and their Member States)

³ ALINORM 08//27/23, Appendix V, CL 2004/36-GEN, CX/MAS 05/3 (comments from European Community, New Zealand, United States of America), CRD 4 (comments of Argentina), CRD 5 (comments of Chile), CRD 10 (comments from the United States), CRD 15 (comments of New Zealand)

9) The Committee discussed the text of the draft Guidelines Section by Section and made the following comments.

General comments

10) The Delegation of the Netherlands, speaking on behalf of the Member States of the EU present at the current Session, drew the attention of the Committee to the fact that the wording of definitions cited in the Guidelines should be consistent with the definitions used in the Codex Procedural Manual.

11) The Delegation of New Zealand proposed to clarify what was meant by “acceptable methods of analysis” and “evaluation” as not in every case criteria were given. The Delegation also proposed to clarify the purpose of the draft Guidelines and how they related to other Codex or IUPAC documents in order to avoid duplication and to ensure consistency.

Scope and Requirements

12) The Committee had a lengthy discussion on the Scope and Section on Requirements and recalled that the Commission had approved new work on the Guidelines intended for governments.

13) The Committee agreed to delete the reference to “determination” in the third bullet and to add “quantification” to limits of detection.

14) Some delegations proposed to clarify the Scope to emphasize that the document was only applicable in the context of the criteria approach adopted by Codex. Other delegations were of the view that clarification of the Scope was not necessary as it might create further confusion regarding the applicability of the document. Some delegations proposed to delete the Section on definitions while maintaining the reference to the Codex Procedural Manual and to the approach to their estimation. Some delegations indicated that, since it was not directly related to the criteria approach, the Section on definitions was useful and should be maintained.

15) The Committee noted that the deletion of definitions by leaving a reference to Procedural Manual could ensure consistency in their use, however, in case of their amendments, it would be necessary to revise the document to make sure that amended definitions were appropriate for the purpose of the Guidelines.

16) There were proposals to amend the definition of “precision”; however the Committee could not come to conclusions on the above proposals.

17) The Delegation of New Zealand indicated that Section on “Accuracy” was not correct and proposed to replace it by sections on Bias and Estimation as described in their written comments. The Delegation also indicated that it might be necessary to review other sections in order to make sure that the Guidelines provided sound and scientifically correct guidance to the governments. This view was supported by several delegations.

18) The Delegation of the United States proposed to add a few examples on how to apply the Guidelines in a step by step manner for evaluating the acceptability of a specific analytical method.

19) The Committee noted that additional comments provided by Member Governments required careful consideration and agreed to establish a Working Group led by New Zealand⁴ which would work electronically in order to revise the document, preferably short, taking into account the discussion above and written comments submitted at the current session.

Status of the Draft Guidelines for Evaluating Acceptable Methods of Analysis

20) The Committee agreed to return the draft Guidelines for Evaluating Acceptable Methods of Analysis to Step 6 of the Procedure for redrafting by the Working Group. It also agreed that the revised document would be circulated for comments well in advance before the next session of the Committee.

PROPOSED DRAFT RECOMMENDATIONS ON THE FITNESS-FOR-PURPOSE APPROACH TO EVALUATING METHODS OF ANALYSIS (Agenda Item 3 (b))⁵

21) The Delegation of the United Kingdom introduced the document and reminded the Committee that there were two possible approaches to evaluating acceptable methods of analysis: a) to identify specific

⁴ Argentina, Australia, Austria, Brazil, Dominica, European Community, Honduras, Japan, Republic of Korea, Netherlands, South Africa, Spain, United Kingdom, United States of America

⁵ CX/MAS 05/27/4, CRD 10 (comments of the United States)

performance parameters and assign numeric values to these (the traditional approach) or b) to identify a “fitness-for-purpose” approach, taking all values into account by defining a single parameter – a fitness function. The Delegation indicated that the last session of the CCMAS had considered Proposed Draft Guidelines for Evaluating Acceptable Methods of Analysis and recalled that the Committee had agreed that the Proposed Draft Guidelines applying the traditional approach would be advanced to Step 5 and that the Delegation of the United Kingdom would redraft the document on “fitness for purpose” with the assistance of a drafting group for further consideration.

22) The Delegation informed the Committee that the document containing the fitness for purpose approach took all values into account by defining a fitness function as a single parameter and that the document also defined the related uncertainty function, explained how the estimated characteristic function could be constructed from precision, and presented some examples of the application of this new procedure. The Delegation also indicated that the document on fitness for purpose was given in the form of a scientific publication and that comments from the Delegation of New Zealand were included in an Appendix. The Delegation proposed that the Committee should decide whether to develop the document further within the framework of the CCMAS or to keep a “watching brief” on the international activities in this area.

23) The Delegation of Germany expressed its view that the “fitness for purpose” approach was important; however it relied too much on assumptions at this moment and more work was necessary in the scientific area concerning this approach before its applicability in Codex could be considered.

24) The Delegation of New Zealand expressed its reservations to the approach proposed and indicated that the fitness function was arbitrary and that method performance was multidimensional, so it did not seem realistic to expect that the performance could be summarized by a single number, suitable for every application. The Delegation pointed out that the fitness for purpose approach did not consider the purpose i.e. how the test results were actually used to make an assessment of conformity. The Delegation expressed the view that the evaluation of the fitness of a method should go beyond the performance of the method; consider bias and examine the effect of measurement error on the decision made using test results generated by the method; this principle seemed consistent with the definition of fitness for purpose as described in the paper on Analytical Terminology.

25) Some other delegations pointed out that the document did not yet address uncertainty of sampling; that there was a need to maintain uniformity of concept and that internationally accepted terminology should be used; and that fitness for purpose could be expanded to include more description on applicability and practicability.

26) The Committee noted that it was premature to apply fitness for purpose for regulatory purposes and agreed to postpone the consideration of this matter for the time being and to monitor the international activities currently on-going in this area.

PROPOSED DRAFT GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS (Agenda Item 3 (c))⁶

27) The Committee recalled that the development of the proposed draft Guidelines had been approved by the 26th Session of the Commission and that it had agreed that the Delegation of France would develop Proposed Draft Guidelines to address disputes arising from differences in laboratory results.

28) The Delegation of France introduced the document and informed the Committee that this matter had a long history of development and that first it had first been considered as regards the use of analytical results at the 24th Session of the Committee. The Delegation indicated that, basically, disputes arise when the official laboratory in the importing country does not find the same test results as the official laboratory in the exporting country for the same product lot, and pointed out that this document addressed disputes related to analytical methodology and did not consider sampling problems. The Delegation indicated that the document provided guidance on consecutive steps how to resolve disputes over analytical results between two laboratories.

⁶ CX/MAS 05/27/5, CX/MAS 05/27/5-Add. 1 (comments of New Zealand), CRD 10 (comments of the United States)

29) The Delegation of New Zealand indicated that disagreement may arise concerning the compliance of the product with specifications and not merely because of disagreement concerning analytical results and that other possible causes of dispute should be described, as not only laboratories but also regulatory bodies were involved in case of disputes. The Delegation pointed out that some sections could be strengthened, especially as regards laboratory performance and offered their assistance to revise them. This view was supported by several delegations.

30) The Delegation of Spain drew the attention of the Committee to the fact that situations were more complex than described in the document. For example contamination of a lot with aflatoxins could increase during transportation and this should be taken into account.

31) The Delegation of Brazil proposed that terms such as “official laboratory of the exporting country” should be revised as in some countries this activity was carried out by private laboratories or exporting companies and the document should cover all situations.

32) The Delegation of Morocco indicated that decisions on products under dispute involve not only laboratories but also other parties and this matter should involve all interested parties and all steps in the process from sampling up to the interpretation of the results of analysis.

33) Several delegations supported the development of guidance for governments in order to facilitate dispute settlements and pointed out that there had not been not enough time to send comments due to the late arrival of the document.

34) The Committee agreed to convene an *Ad Hoc* Working Group during the session in order to accommodate concerns and to make more rapid progress on the document.

35) The Delegation of France presented CRD 18 and informed the Committee that the Working Group had considered comments received and made several changes in the document, such as the following: the structure was changed by introducing the Scope and a step wise procedure for settling disputes; the title, Scope and definition of laboratory were clarified; a new wording regarding an independent assessment of the laboratory generating results was inserted; and a new section on reserve samples when they were tested by a third laboratory was proposed.

36) The Committee expressed its appreciation to the Delegation of France and the members of the Working Group and, while considering the text, in addition to editorial changes, made the following comments and amendments.

37) The Committee deleted the reference to “official” in relation to laboratories as the definition of laboratories was given in footnote 1 and also the reference to “under recovery” in the fourth bullet of the Scope.

38) The Delegation of Japan was of the view that in the Guidelines for governments there was no need to set a specific limit of 20% of repeat analysis results.

39) The Delegation of the EC indicated that the Scope did not properly reflect the real situation in relation to disputes as, in a majority of cases, disputes arise not from different results of test laboratories but from non acceptance of the lot, and proposed to modify the text to that effect. The Committee could not come to a conclusion on this issue and agreed that it required further consideration.

40) The Delegation of New Zealand expressed their concern that the wording of the second bullet in Prerequisites put undue pressure on producers and proposed to delete this bullet; however other delegations were of the view that this wording was useful in order to prevent disputes.

41) The Committee concluded that, despite significant progress made on the revision of the document, there was still a need to discuss it in more detail, however due to time constraints it was not feasible at the current session.

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

42) The Committee agreed that the Proposed Draft Guidelines would be circulated at Step 3 in a separate Circular Letter, by the end of May 2005, after editorial review by the Delegation of France. The comments would be directed to the Delegation of France who would revise the document with assistance of an electronic Working Group, for further comments if time allowed, and consideration at the next session.

REVIEW OF THE ANALYTICAL TERMINOLOGY FOR CODEX USE IN THE PROCEDURAL MANUAL (Agenda Item 4)⁷

43) The Committee recalled that its last session had initiated the review of the analytical terminology and had proposed some amendments to the Analytical Terminology that were subsequently adopted by the Commission and incorporated into the Procedural Manual. The Committee had also agreed that the Delegation of the United States with the assistance of interested members and observers would prepare recommendations and rationale for appropriate definitions.

44) The Delegation of the United States presented the revised document and indicated that the list compiled by the Inter Agency Meeting had been used as a first step and that the definitions had been revised in the light of the comments received. The Delegation pointed out that a number of definitions were under revision by international organizations and that it would be premature to revise them at this stage in the Committee.

45) The Committee discussed whether the revision of the terminology should be deferred until relevant organizations had completed the revision of their terminology and noted that this question had been discussed in the Inter Agency Meeting. The Observer from BIPM informed the Committee that the revision of the International Vocabulary of Metrology (VIM) was underway but its completion was not expected in the near future. Several delegations suggested that, as a first stage, the Committee focus on the definitions that were not under revision in the international organizations concerned and could be updated for the purposes of Codex.

46) Some delegations pointed out that the proposals in the working document went beyond the revision of the definitions in the Procedural Manual and the Committee discussed whether these definitions should be included when required in specific Guidelines or related texts (such as the Draft Guidelines for Evaluating Acceptable Methods of Analysis).

47) Some delegations expressed the view that it would be preferable to include the definitions in a Glossary rather than in the Procedural Manual. The Chair recalled that the current terminology in the Manual was directly related to the provisions concerning the criteria for the selection of methods of analysis. In reply to some questions, the Secretariat indicated that it was possible to develop a Glossary as a Codex document through the Step Procedure, as had been done in the area of veterinary drugs.

48) The Delegation of the United Kingdom drew the attention of the Committee to the definitions that were also included in the Draft Guidelines for Evaluating Acceptable Methods of Analysis and proposed to replace the term “limit of determination” with “limit of quantification”, in view of the importance of this amendment to avoid confusion. Several delegations supported this change while some other delegations cautioned against making any change to the terminology at this stage, in view of the implications for other definitions or for provisions in current texts.

49) The Committee recognized that it was not feasible to amend definitions at the present session, due to time constraints and as the implications of even limited amendments should be considered carefully. Some delegations proposed that further comments should be requested as to the definitions that should be revised for inclusion in the Manual, or for other purposes. Other delegations pointed out that the revised definitions had already been circulated twice and that several comments had already been submitted.

50) After some further discussion the Committee agreed that the Delegation of the United States, with the assistance of an electronic Working Group open to all interested members and observers, would revise the document on the basis of the comments received and the discussion at the present session. It was agreed that the document should clearly identify:

- the definitions that could be harmonized and amended for inclusion in the Procedural Manual;
- the definitions that were under revision by the international organizations concerned and should not be considered until such revision had been completed; and
- the definitions that were required in addition to those in the Procedural Manual, especially for the purposes of Codex texts addressing methodology issues.

⁷ ALINORM 04/27/23, Appendix V, CL 2004/36-GEN, CX/MAS 05/26/6, CX/MAS 05/26/6-Add.1 (comments of Argentina, India, IDF), CX/MAS 05/26/6-Add.2 (comments of the United States)

51) The Committee expressed its appreciation to the Delegation of the United States and to the working group for their considerable work on the complex revision and update of analytical terminology.

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS IN CODEX STANDARDS (Agenda Item 5(a))⁸

52) The report of the Ad hoc Working Group on Endorsement of methods of analysis (CRD 1) was presented by its Chair, Dr Roger Wood (United Kingdom). The Committee considered the methods proposed for endorsement and made the following amendments and comments.

Committee on Fats and Oils

Draft Standard for Fat Spreads and Blended Fat Spreads

Fat Content

53) The Committee agreed that there was an average percentage of 3.42 % butyric acid in milk fat and therefore an average conversion factor based on the average content should be used for the calculation of milk fat from the determined butyric acid content. The Committee also agreed to include a footnote clarifying that the method was endorsed as Type I due to the conversion factor.

Water, solids-non fat, and fat content

54) The Delegation of the EC pointed out that the method for the determination of moisture was used for butter and questioned its applicability for fat spreads since the moisture content was higher in those products. The Committee agreed to endorse temporarily the methods for the determination of moisture, solids-non fat and fat content and to ask the Committee on Fats and Oils to clarify the applicability of the method to fat spreads.

Other provisions

55) The Committee corrected the reference to the joint ISO/IDF method for salt content (determination of chloride expressed as sodium chloride).

56) The Committee endorsed the methods for Vitamins A, D and E as Type III and noted that the principle was HPLC for all three methods.

Standard for Olive Oil and Olive Pomace Oils

57) The Committee endorsed the ISO method for stigmastadienes as Type III and noted that it was generally used for routine analyses whereas the Type II method endorsed by the last session was used as the reference method.

Committee on Processed Fruits and Vegetables

58) The Committee agreed to endorse temporarily the ISO method for the determination of pH in processed fruit and vegetables as Type IV and to endorse the NMKL method as Type II. All other methods proposed by the CCPFV were endorsed.

Ad hoc Intergovernmental Task Force on Fruit and Vegetable Juices

59) The Committee recalled that its last session had endorsed a number of methods that corresponded to specific provisions in the standard, and had temporarily endorsed several other methods pending the establishment of numerical values by the Task Force.

60) The Secretariat indicated that according to the current procedures, methods should correspond to the provisions in the standard and that the methods proposed by the Task Force referred to analytes that were not mentioned in the standard.

61) The Committee agreed to ask the advice of the Commission as to whether, from the procedural point of view, these methods could be considered for endorsement in relation to authenticity and quality criteria, as no numerical value had been established. Several delegations proposed that the Committee make a more positive statement supporting the endorsement of the methods. The Observer from IFU stressed the

⁸ CX/MAS 05/26/7, CX/MAS 05/26/7-Add.2, CRD 6 (R5 ELISA method), CRD 7 (comments of Japan on the methods for instant noodles)

importance of the methods propose to ensure the authenticity and quality of fruit juices for the purposes of international trade.

62) Some delegations expressed the view that not all the methods proposed by the Task Force were available in literature and that it would be very difficult for developing countries to use them, although it was very important for developing countries to be able to use internationally recognized methods for the purposes of food control.

63) The Committee discussed the proposal of the Observer from IFU in CRD 19 to amend section 3.4 of the Draft Standard in order to provide clarification on the verification of authenticity and quality of fruit juices and the methods proposed. Some delegations pointed out that allowance should be made for natural and seasonal variations in the fruit.

64) After some discussion, the Committee agreed to propose to the Commission to add the following provisions at the end of section 3.4 Verification of Composition, Quality and Authenticity

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.

Several delegations expressed the view that the addition of this paragraph would allow the CCMAS to endorse the methods for fruit juices proposed by the Task Force.

Committee on Fish and Fishery Products

Draft Amendment to the Standard for Salted Fish and Dried Salted Fish of the *Gadidae* Family

65) The Delegation of Germany pointed out that the Draft Amendment should refer to moisture content instead of water content. The Delegation of Malaysia recalled that the standard referred to the determination of water content in order to calculate the percentage salt saturation of the fish and supported the proposed text. The Committee noted that the term water content was used in the context of fish and fishery products and that a change in the terminology at this stage would have implications for other texts. The Committee endorsed the Draft Amendment with an editorial correction to the principle and agreed to draw the attention of the Committee on Fish and Fishery Products to the question of terminology.

Committee on Nutrition and Foods for Special Dietary Uses

Draft Standard for Gluten Free Foods

66) The Committee discussed the recommendation of the Working Group to endorse the R5 ELISA Method as a Type I method.

67) Some delegations expressed their objections to the endorsement of the method for the following reasons: the method and the report of the inter-laboratory studies were not available in literature and the description of the method was not detailed enough, especially as regards the solvent used for extraction; and the method had given positive results for oats, which might prevent the marketing of oats that were currently available for celiac patients and provided an important source of fibre.

68) Other delegations supported the endorsement of the method. Some of these delegations proposed to change the Type to Type II, which would be consistent with the Type of other ELISA methods. Other delegations referred to the importance of Type I. Some delegations also raised the question as to whether it was appropriate to endorse a commercial kit as a method within the framework of Codex.

69) The Observer from the PWGAT indicated that the method had been published in scientific journals and was described in detail; as regards the results obtained for oats, scientific studies using the R5 method had showed that a large percentage of oats sold on the market in certain countries were contaminated with gluten from barley, wheat and rye. The Observer pointed out that the R5 method detected gluten from barley, which was not detected by AOAC 991.19.

70) The Delegation of the Netherlands stated that the provision should be clarified by the CCNFSDU. In particular, it should indicate how this method relates to other methods for the determination of gluten.

71) The Observer from AO ECS stressed the need for a reliable method of analysis for gluten in order to address the health problems of celiac patients and therefore supported the endorsement of the method.

72) The Committee agreed to endorse temporarily the R5 ELISA method for the determination of gluten as a Type I method, and to inform the Committee on Nutrition and Foods for Special Dietary Uses.

Committee on Cereal Pulses and Legumes (Draft Standard for Instant Noodles)

73) The Committee noted that the Draft Standard for Instant Noodles was being developed by correspondence, that the section on methods of analysis had been drafted by the Secretariat of the host country (United States) on the basis of the comments received, and that the Draft Standard would be submitted to the Commission at Step 8.

74) The Committee agreed to ask for clarification from the CCCPL on the method that should be used for moisture and endorsed the method proposed by Japan and presented in CRD 1 for acid value as Type I, with some editorial corrections.

Committee on Milk and Milk Products

75) The Committee recalled that the 24th Session of CCMAS (2002) had referred back several questions concerning methods of analysis for milk and milk products to the CCMMP and considered the clarifications provided by that Committee (CX./MAS 04/27/7-Add.2).

Fermented Milks

Lactic Acid

76) The Delegation of Nigeria, supported by other delegations, expressed its concerns with the method proposed as it was not specific for lactic acid and there were interferences with benzoic acid that was not allowed in some types of fermented milks. The Observer from IDF informed the Committee that the IDF 139:1987 method was used for the determination of benzoic acid. The Delegation of Gambia expressed the view that the AOAC method should have been retained as it was reliable and specific to lactic acid, and that it was difficult for developing countries to use methods that were not easily available.

77) After an exchange of views, the Committee agreed to endorse the ISO and IDF methods for lactic acid (total acidity expressed as lactic acid).

Starter cultures

78) The Committee noted that no collaborative study had been carried out and endorsed the IDF method as Type IV.

Streptococcus and Lactobacillus in Yoghurt

79) The Committee noted that a comprehensive inter-laboratory study had been carried out in 1978 for the IDF 117B: 1997 and ISO 7889 method, although the results used for the calculation of the precision figures were no longer available, and endorsed the ISO/IDF method as proposed in CRD 1 as Type I method because the figures for the repeatability limit and the reproducibility limit were still available. The Committee also endorsed the ISO 9232/IDF 146:2003 method as a Type I method, with additional clarification as to the principle of the methods covered by this reference.

Individual Cheeses

Dry Matter (total solids)

80) The Committee endorsed the ISO and IDF methods as Type I and deleted the AOAC method, with the understanding that the CCMMP would have the opportunity to discuss this question further at its next session and provide further clarification.

Sampling

81) The Committee noted the statement referring to the General Guidelines on Sampling in the Draft Standard for Instant Noodles and agreed that such statements did not require endorsement since they did not refer to a sampling plan.

82) The Delegation of the EC pointed out that the General Guidelines did not propose specific sampling plans but provided guidance for their selection and that commodity Committees should select sampling plans on that basis for endorsement by the Committee.

83) The Committee recommended that Commodity Committees should not include statements referring to the General Guidelines in commodity standards but should select specific sampling plans for the commodities covered by the standards, taking into account the guidance provided in the Guidelines.

General Issues

Year of Publication

84) The Committee noted that the Inter Agency Meeting and the Working Group had discussed the reference to the year of publication in methods of analysis. It was recalled that the last session of the CCMAS had discussed the proposals from the Committee on Fats and Oils to delete the year of publication but had decided to retain it, as it was supported by several delegations.

85) The Committee recalled that in application of ISO/IEC 17025: 1999, referred under CAC/GL 27, analysts were required to use the most updated version of methods of analysis. However, the year of publication mentioned in methods endorsed by the CCMAS was often outdated and reference was made to methods that were no longer “deemed to exist”, which created serious difficulties.

86) The Delegation of Japan expressed the view that, if the year of publication was deleted, methods could be modified automatically without being considered and endorsed by the Committee. The Committee noted that the update of the year of publication reflected only editorial changes and that when the method was substantially amended the reference number was revised.

87) The Delegation of Brazil proposed that standard setting organizations develop a single system of reference for methods of analysis and supported the criteria approach, rather than referring to specific methods.

88) After some discussion, the Committee agreed to include a note for clarification purposes in the list of methods (CODEX STAN 234-1999) to the effect that the most updated version of the method should be used, in application of ISO/IEC 17025: 1999.

89) The Observer from AOCS expressed the view that the inclusion of a note would only be a temporary measure and that only the deletion of the year of publication would entirely address the problem.

Other issues

90) Some delegations expressed the view that the information provided by commodity committees for the purpose of endorsement of methods was not presented uniformly and should follow a consistent format in order to facilitate the endorsement process. The Committee recalled that the *Recommendations for a Checklist of Information Required to Evaluate Methods of Analysis Submitted to the CCMAS* had been developed to provide guidance to Codex Committees when submitting methods of analysis for endorsement. However in practice methods were not reported according to the Checklist. Some delegations noted that Codex Committees could not provide this level of detail in practice as they generally relied on methods developed by international organizations.

91) After some discussion, the Committee agreed that the Delegation of Finland, in cooperation with the Delegations of Brazil and Australia, would prepare a discussion paper considering the revision of the *Recommendations for a Checklist of Information*.

92) The Committee expressed its appreciation to Dr Wood and to the Working Group for their excellent work in order to facilitate the discussions 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 III.

CONVERSION OF THE METHODS FOR TRACE ELEMENTS INTO CRITERIA

(Agenda Item 5 (b))⁹

93) The Committee recalled that at its 25th Session it had agreed to initiate the conversion of the methods for trace elements into criteria for consideration in the framework of the Agenda Item on Endorsement of Methods of Analysis.

⁹ CX/MAS 05/27/7-Add.1, CRD 12 (comments of United States of America)

94) The Observer of NMKL introduced the document and informed the Committee that NMKL, with the assistance of ISO, had collected information on method characteristics of the trace elements, such as arsenic, cadmium, copper, iron, lead, mercury, tin and zinc, methods recommended by Codex and that review of a number of methods for trace elements referred to in Codex Standards had been carried out. The Observer indicated that method's characteristics were listed in the table along with the element, method, method type and commodities of interest and pointed out that there were recommended criteria for a method for determination of trace elements in foodstuffs only for methods listed in Codex Standards 234-1999 and 228-2001.

95) Several delegations supported this work as it could provide clear guidance that would allow a consistent interpretation of the criteria approach across Codex and would assist in selecting appropriately validated analytical methods for monitoring compliance with Codex Standards related to trace elements in foodstuffs, so that Commodity Committees would be aware about the quality of methods.

96) Some delegations drew the attention of the Committee to the need to clarify the validated range of characteristics and precision of the method, definitions and terminology. It was proposed to clarify under which circumstances the lowest validated level should be more than 3 times the detection limit. It was also noted that recovery might not be appropriate in trace elements analysis therefore this should be reflected in the text.

97) It was suggested that this text might serve as an example for criteria for evaluating acceptable methods; however no agreement was reached on this proposal.

98) The Delegation of the United Kingdom indicated that in further revision of the document it was necessary to prepare it in a more descriptive way to provide working instructions for the implementation of the criteria approach and conversion of specific methods of analysis to criteria, as described in the Procedural Manual. The Delegation drew the attention of the Committee to the fact that some already adopted Codex methods would not comply with the criteria proposed for trace elements and that this should be stated in the paper.

99) The Committee agreed that the Working Group chaired by Sweden¹⁰, with NMKL as Rapporteur, working electronically would prepare a revised more descriptive version of the document for consideration by the next Session of the Committee, including the status of the document.

THE USE OF ANALYTICAL RESULTS: SAMPLING PLANS, RELATIONSHIP BETWEEN THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND PROVISIONS IN CODEX STANDARDS (Agenda Item 6)¹¹

100) The Committee recalled that the last session had agreed to redraft the document on the Use of Analytical Results with the understanding that it would be used by commodity committees, and included in the Procedural Manual as it was intended for use in the framework of Codex. The Committee had also agreed to seek the advice of Commodity Committees on the revised document and noted their comments as presented in CX/MAS 05/26/8-Add.1 and CRD 16. The Committee discussed the document and made the following amendments and comments.

101) Some delegations proposed to change the title to refer to the expression or to the interpretation of analytical results. Other delegations however supported the reference to the use of results as it described clearly the purpose of the document and the Committee agreed to retain the current title.

102) The Committee agreed to retain the section on "Issues involved" in the final document as it provided the background to the recommendations. The Committee agreed that the third paragraph should refer to harmonization in the framework of Codex as the use of the term "equivalence" could create confusion.

103) The Delegation of the United Kingdom recalled that the initial working paper provided detailed recommendations, and had been shortened in order to provide simple instructions intended for commodity committees. Taking into account the views of the Committee on Fats and Oils that more explanatory material

¹⁰ Argentina, Brazil, European Community, Finland, France, Japan, Netherlands, United Kingdom, United States, IDF, ISO and NMKL

¹¹ ALINORM 04/27/23, Appendix VI, CX/MAS 05/26/8 (comments of Mexico, United States), CX/MAS 05/26/8-Add.1 (comments of commodity Committees), CRD 4 (comments of Argentina), CRD 14 (comments of the EC), CRD 16 (comments of the CCMMP)

would be useful, the Delegation therefore proposed to include a reference to document CX/MAS 02/13 and to the relevant website of the European Union.

104) In Section 1. Sampling Plans the Committee agreed to include a reference to the *General Guidelines on Sampling*, Section 2.1.2 on the selection of sampling plans, taking into account the comments from the Committee on Fish and Fishery Products in this respect.

105) The Committee noted the comments from the Committee on Milk and Milk Products but agreed that no substantial changes should be made to the document at this stage. It was proposed to develop a separate document to provide more detailed guidance on the use of analytical results. This document would include worked examples.

106) The Committee agreed with the rewording of Section 3. Recovery proposed in the written comments of the European Community, with some changes for clarification purposes.

Status of the recommendations on *The Use of Analytical Results : Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards*

107) The Committee agreed to forward the recommendations on *The Use of Analytical Results* to the 23rd Session of the Committee on General Principles (2006) for endorsement and to the 29th Session of the Commission for adoption and inclusion in the Procedural Manual, at the end of the sections on methods of analysis and sampling in the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts* (see Appendix II).

CRITERIA FOR THE METHODS FOR THE DETECTION AND IDENTIFICATION OF FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 7)¹²

108) The Committee recalled that at its 25th session it had agreed that the Delegations of the United Kingdom and Germany with the assistance of a Drafting Group would revise the document with a view to the elaboration of Guidelines for consideration at the next session.

109) The Delegation of Germany introduced the document and indicated that on the basis of the comments received the following major changes had been made: in the Section on Modular Approach to method validation it was explained how this method could be applied and in Annex V on Validation of a Protein-Based Method a new narrative was added.

110) The Delegation of the EC supported the development of the paper and expressed the view that it had been elaborated for the endorsement of methods for detection and identification of foods derived from biotechnology in the CCMAS and proposed to send this paper to the Task Force on Biotechnology for their information.

111) The Delegation of the Republic of Korea indicated that there were still some uncertainties in Table 1 on the Criteria for scoring Qualitative PCR analyses especially in expressing of the scoring of test when GM analyte in PCR was positive and endogenous PCR result was negative and proposed that the expression of “±” should be changed to “indeterminate” in the scoring of test expression.

112) The Delegation of the United States supported the view expressed by the Delegation of the Republic of Korea and indicated that it had provided general and detailed written comments presented in CX/MAS 05/26/9-Add.1. The Delegation proposed that this document should be retained in the Committee until it had been improved and technical issues resolved. This view was supported by several delegations.

113) The Delegation of Malaysia proposed to include a wider description of protein based testing as it was less costly and wider applied, especially in developing countries.

114) The Delegation of Brazil urged the Committee to proceed with this work as a matter of urgency as the trade in GMO food was growing and governments needed to receive advice on this matter.

115) As regards to the status of the document, the Secretariat clarified that the Committee at its 24th session, following the request from the Committee on Food Labelling and the Task Force on Foods Derived from Biotechnology, had considered the methods of analysis for foods derived from biotechnology and had concluded that the criteria approach should be applied in the selection of methods of analysis for foods

¹² CX/MAS 05/26/9, CX/MAS 05/26/9-Add.1 (comments of the United States and AOCS), CRD 5 (comments of Chile), CRD 8 (comments of ILSI), CRD 17 (comments of the EC).

containing genetically modified material, and that the selection or endorsement of methods without appropriate provisions was not possible. It was further agreed to prepare recommendations for quality control measures in laboratories and criteria for method of analysis. The Secretariat also indicated that the Intergovernmental Task Force on Biotechnology and the Committee on Food Labelling would be informed about the work of the CCMAS in this area.

116) The Committee agreed that a Working Group led by Germany and the United Kingdom with the participation of all interested Members and Observers would revise the paper for consideration by the next Session of the Committee, especially in order to arrive at a common understanding on how to proceed on this matter.

METHODS OF ANALYSIS FOR THE DETERMINATION OF DIOXINS AND PCBS (Agenda Item 8)¹³

117) The Delegation of Germany introduced the document and recalled that the Committee at its 25th Session had invited member Governments and international organizations to provide proposals and information on the current methods used for the determination of dioxins and related compounds to Germany in order to compile the list of methods, as requested by the Codex Committee on Food Additives and Contaminants (CCFAC). The Delegation indicated that only a few proposals were received from the delegations of Germany and the United States and that the compiled table contained the scope, principle, reference and comment in relation to method validation. The Delegation drew the attention of the Committee to ongoing research activities in this area in order to improve methodologies for determination of dioxins and pointed out that several new methods would be validated through collaborative studies and that results of this process would be available by the end of this year. The Delegation informed the Committee that in the legislation of the EC the criteria approach is taken.

118) The Delegation of Argentina, referring to its written comments, informed the Committee that analysts had been working on PCBs for more than 20 years and intended to start a programme for analysis of dioxins, however they experienced constraints in their detection as it was difficult to receive appropriate reference materials.

119) The Delegation of the Netherlands, speaking on behalf of the Member States of the EU present at the current session, supported further work on the document and suggested to develop criteria for the methods.

120) Some delegations indicated that a number of studies on validation and proficiency testing were ongoing and that it might be useful to ask additional information on these studies and on the methods of analysis.

121) The Delegation of the United Kingdom expressed the view that two issues should be taken into consideration: the problem of dioxin screening methods and the possibility of calculation of uncertainty of TEQ and the way they were estimated in analysis. However other delegations noted that it related more to the interpretation of results and the task of the CCMAS was to concentrate on analytical results.

122) The Delegation of Germany was of the view that analysts should not be involved in consideration of toxicological values. The Delegation of the Netherlands indicated that it was necessary to do more work on the uncertainty of individual contributions as they contribute to the overall uncertainty.

123) The Committee decided to inform the Committee on Food Additives and Contaminants (CCFAC) about the status of its work on methods of analysis for dioxins and related compounds and asked the CCFAC to clarify what it intended to do with this work. The Committee requested the Delegation of Germany to revise the paper with the view of converting the proposed methods into criteria approach. It also encouraged countries to submit additional information relevant to methods of analysis for the determination of dioxins and PCBs to the Delegation of Germany.

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS AND SAMPLING (Agenda Item 9)¹⁴

124) The Chair of the Inter-Agency Meeting (IAM), Dr Roger Wood, introduced the draft report of the 17th IAM presented in CRD 2 and highlighted the following important issues discussed at the IAM.

¹³ CX/MAS 05/26/10, CRD 4 (comments of Argentina), CRD 9 (comments of the United States).

¹⁴ CRD 2 (Report of the 17th Meeting of international organizations working in the field of methods of analysis and sampling (Inter-Agency Meeting), Budapest, Hungary 1st April 2005).

125) It was indicated that the criteria approach had been adopted by the Commission and that users of analytical methods would require more information than was currently included in “Standard Methods” and that IAM “customers” will not be able to select one of Codex methods in its entirety but will want information on particular attributes of these methods, therefore efforts should be made to make this information available.

126) The Committee was informed that following the 16th Meeting a collation of Published Method Titles had been prepared from the information then supplied by IAM members and that the collation was currently published on the IAM Website.

127) Dr Wood drew the attention of the Committee to the fact that EURACHEM had prepared documents dealing with Uncertainty from Sampling and Qualitative Analysis and this would lead to the eventual development of two EURACHEM Guides. NMKL was developing a specification for customer requirements/fitness for purpose and it had established a project group on the validation of qualitative analytical methods.

128) The Committee was informed that the current IUPAC/ISO/AOAC Protocol for Proficiency Testing was being revised and would be published, however there were some practicalities to overcome to implement it in practice.

129) Dr Wood informed the Committee that the issue of the year of publication of methods had been extensively discussed in the IAM, and recalled that it had also been considered in the current meeting of the CCMAS (see Agenda Item 5 a).

130) The Committee was informed that the IAM would be looking at various existing protocols and participants were asked to notify the Secretariat of the IAM of existing protocols under development or revision.

131) Dr Wood informed the Committee that the IAM would be hosting the URLs for the Website that would contain all freely available information about methods of analysis where no copyright exist. These URLs are:

<http://iam.aocs.org>

<http://www.aocs.org/meetings/iam/>

132) Finally Dr Wood informed the Committee that the Secretariat of the IAM had been transferred to AOCS and that he would continue to chair the IAM for one more year.

133) The Committee expressed its appreciation to the IAM and Dr Wood for their constructive work and contribution to the work of the Committee and noted that the final report would be made available from the website of the IAM. It also noted that the next IAM would be held before the next session of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)¹⁵

FAO/IAEA Activities

134) The Representative of IAEA introduced CRD 11 that presented the activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture of interest to the Committee.

135) The Representative indicated that the Food and Environmental Protection Section and the Agrochemicals Unit of the FAO/IAEA Agriculture and Biotechnology Laboratory provided food safety related assistance primarily in the areas of food irradiation, pesticide and veterinary drug residues and radioactive contamination of foodstuffs, and that its mission was to strengthen capacities for the use of nuclear methods in food and agriculture, methods of analysis and sampling being one of the main area of work.

136) The Representative pointed out that the Joint Division had been cooperating with Codex for a long time in the areas related to food irradiation, methods of analysis, residues of pesticides and veterinary drugs and intended to strengthen its technical input as regards methodologies for veterinary drugs, pesticide residues and contaminants; training of trainers in the application of methods of analysis for compliance purpose; web-based programmes on sampling of analysis of food for contaminants; and additional research and training. The Committee was also informed that the list of Codex methods for pesticide residues was

¹⁵ CRD 11 (activities of FAO/IAEA)

being incorporated into the IAEA Food Contaminants and Residue Information System (INFOCRIS) and that the database was being updated to include additional data on methods of analysis for veterinary drugs residues.

Other Business

137) The Delegation of Brazil expressed the view that the term “endorsement” was used in the Procedural Manual but was not defined and should be clarified. The Secretariat indicated that endorsement was a general term used throughout the Manual and that this issue should be raised in the Committee on General Principles.

138) The Delegation of Brazil expressed the view that it would be useful to have bibliographical references available concerning the working documents of the Committee. The Chair indicated that the host country would attempt to provide the required references at the next session. The Committee noted that reports and working documents of recent sessions were available on the Codex website and that earlier documents (more than ten years) were available in printed form from the Codex Secretariat upon request.

139) The Delegation of Tanzania, supported by the Delegation of Gambia, expressed the view that the unavailability of methods was a serious problem for developing countries, especially in the framework of the WTO SPS and TBT Agreement. The Chair noted that the responsibility of the Committee was to develop methods of analysis and sampling, identified by reference in most cases, and as a standard setting committee it was not competent to address such issues. The Secretariat indicated that although Codex as such did not provide technical assistance, its parent organizations FAO and WHO carried out many training and cooperation activities in the area of food control and food safety, including capacity building in food analysis and sampling, training and upgrading of laboratories, and that interested countries could contact FAO and WHO to ask for technical assistance in these areas.

140) The Delegation of Sweden drew the attention of the Committee to the document on the Review of the Codex committee Structure and Mandates of Codex Committees and Task Forces for consideration by the 28th Session of the Commission (CL 2005/12-CAC) and especially Recommendation 17 related to methods of analysis and sampling, that could have significant implications for the work of the Committee, and urged delegates to consider this proposal so as to provide relevant comments in cooperation with their Codex Contact Point, if required.

Future Work

141) The Delegation of the United Kingdom recalled that, as mentioned under the report of the Inter Agency Meeting, the *IUPAC/ISO/AOAC Protocol for Proficiency Testing: the International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories*, already adopted by Codex by reference was being revised and proposed to prepare a discussion paper on the revised Protocol for consideration by the next session.

142) The Delegation also proposed that the Committee consider how to address the uncertainty of sampling since substantial work had been carried out on this issue of concern at the international level and the Committee needed to consider sampling uncertainty in relation to its ongoing work.

143) The Committee welcomed the proposal of the Delegation of the United Kingdom to prepare two discussion papers to address these important issues, for consideration by the next session.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 11)

144) The Committee was informed that the 27th Session of the Committee would be held in Budapest from 15 to 19 May 2006. 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 05/28/23
Proposed amendments to the Procedural Manual: Recommendations on the Use of Analytical Results	(*)	23 rd CCGP (2006) Governments 29 th CAC (2006)	para. 107 Appendix II
Endorsement of methods of analysis in Draft Standards, including the addition of a note to CODEX STAN 234-1999		Governments 28 th CAC	paras. 53-83 and 88 Appendix III
Draft Guidelines for Evaluating Acceptable Methods of Analysis	6	Governments 27 th CCMAS	para. 20
Proposed Draft Guidelines for Settling Disputes on Analytical (Test) Results	2/3	France/Governments 27 th CCMAS	para. 42
Proposed Draft Recommendations on the Fitness-for-purpose Approach (for inclusion in the <i>Proposed Draft Guidelines for Evaluating Acceptable Methods of Analysis</i>)	4	postponed	para. 26
Further Review of <i>Analytical Terminology for Codex Use</i> (Procedural Manual)	(*)	United States/ Governments 27 th CCMAS	para. 50
Conversion of methods for trace elements into criteria		Sweden/NMKL Governments 27 th CCMAS	para. 99
Criteria for methods of analysis for foods derived from biotechnology		United Kingdom/ Germany Governments 27 th CCMAS	para. 116
Methods of analysis for dioxins and PCBs		Germany/Governments 27 th CCMAS	para. 123
Consideration of proposals for new work:			para.
Revision of the IUPAC/ISO/AOAC Protocol for Proficiency Testing		United Kingdom 27 th CCMAS	para. 141
Uncertainty of Sampling		United Kingdom 27 th CCMAS	para. 142

(*) For inclusion in the Procedural Manual

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ALINORM 05/28/23
APPENDIX II

THE USE OF ANALYTICAL RESULTS: SAMPLING PLANS, RELATIONSHIP BETWEEN THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND PROVISIONS IN CODEX STANDARDS

(To be included in the Codex Procedural Manual at the end of sections on methods of analysis and sampling in the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts*)

ISSUES INVOLVED

There are a number of analytical and sampling considerations which prevent the uniform implementation of legislative standards. In particular, different approaches may be taken regarding sampling procedures, the use of measurement uncertainty and recovery corrections.

At present there is no official guidance on how to interpret analytical results in the framework of Codex. Significantly different decisions may be taken after analysis of the “same sample”. For example some countries use an “every-item-must-comply” sampling regime, others use an “average of a lot” regime, some deduct the measurement uncertainty associated with the result, others do not, some countries correct analytical results for recovery, others do not. This interpretation may also be affected by the number of significant figures included in any commodity specification.

It is essential analytical results are interpreted in the same way if there is to be harmonization in the framework of Codex.

It is stressed that this is not an analysis or sampling problem as such but an administrative problem which has been highlighted as the result of recent activities in the analytical sector, most notably the development of International Guidelines on the Use of Recovery Factors when Reporting Analytical Results and various Guides prepared dealing with Measurement Uncertainty.

RECOMMENDATIONS

It is recommended that when a Codex Commodity Committee discusses and agrees on a commodity specification and the analytical methods concerned, it states the following information in the Codex Standard:

1. Sampling Plans

The appropriate sampling plan, as outlined in the Guidelines for Sampling (CAC/GL 50-2004), Section 2.1.2 Guidelines on Sampling to control conformity of products with the specification. This should state:

- whether the specification applies to every item in a lot, to the average in a lot or the proportion non-conforming;
- the appropriate acceptable quality level to be used;
- the acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on the sample.

2. Measurement Uncertainty

An allowance is to be made for the measurement uncertainty when deciding whether or not an analytical result falls within the specification. This requirement may not apply in situations when a direct health hazard is concerned, such as for food pathogens.

3. Recovery

Analytical results are to be expressed on a recovery corrected basis where appropriate and relevant.

In all cases it has to be stated when the result is corrected for recovery.

If a result has been corrected for recovery, the method by which the recovery was taken into account should be stated. The recovery rate is to be quoted where ever possible.

When laying down provisions for standards, it will be necessary to state whether the result obtained by a method used for analysis within conformity checks shall be expressed on an recovery-corrected basis or not..

4. Significant Figures

The units in which the results are to be expressed and the number of significant figures to be included in the reported result.

STATUS OF ENDORSEMENT OF METHODS OF ANALYSIS AND SAMPLING

PART I. METHODS OF ANALYSIS

- A: CODEX COMMITTEE ON FATS AND OILS
 B: CODEX COMMITTEE ON PRECESSED FRUITS AND VEGETABLES
 C: *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FRUIT AND VEGETABLE JUICES
 D: CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS
 E: CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
 F: CODEX COMMITTEE ON CEREALS, PULSES AND LEGUMES (Draft Standard for Instant Noodles)
 G: CODEX COMMITTEE ON MILK AND MILK PRODUCTS

PART II. SAMPLING

CODEX COMMITTEE ON CEREALS, PULSES AND LEGUMES (Draft Standard for Instant Noodles)

A. CODEX COMMITTEE ON FATS AND OILS¹

COMMODITY	PROVISION	METHOD	PRINCIPLE	NOTE	TYPE	STATUS
Fat Spreads and Blended Spreads	Milk fat content (butyric acid)	AOAC 990.27 or AOCS Ca 5c-87 (97)	GC		I ²	E
	Moisture	ISO 3727-1/IDF 80-1: 2001; or AOAC 920.116	Gravimetry	CCFO to clarify the applicability to fat spreads (method used for butter)	I	TE
	Solids-non-fat content	ISO 3727-2/IDF 80-2: 2001	Gravimetry		I	TE
	Calculation of the fat content	ISO 3727-3/IDF 80-3: 2003	Calculation		I	TE
	Salt content	ISO 1738/IDF 12:2004 or AOAC 960.29	Titrimetry	Chloride expressed as sodium chloride	II	E
	Vitamin A	AOAC 985.30; AOAC 992.04; or JAOAC 1980, 63, 4	HPLC		III	E
	Vitamin D	AOAC 981.17.	HPLC		III	E

¹ ALINORM 05/28/17

² Endorsed as Type I due to the conversion factor

COMMODITY	PROVISION	METHOD	PRINCIPLE	NOTE	TYPE	STATUS
	Vitamin E	ISO 9936: 1997	HPLC		III	E
Olive Oils and Olive Pomace Oils	Stigmastadienes	COI/T.20/Doc. no. 11 or ISO 15788-1:1999 or AOCS Cd 26-96 (03)	GC		II	E
	Stigmastadienes	ISO 15788-2: 2003	HPLC		III	E

B. CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES³

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE	STATUS
Processed fruits and Vegetables (except canned bamboo shoots, pH determined by AOAC 981.12)	pH	ISO 1842:1991	Potentiometry	IV	TE
		NMKL 179:2005	Potentiometry	II	E
Processed fruits and vegetables	Drained Weight	AOAC 968.30 (Codex General Method for processed fruits and vegetables)	Sieving Gravimetry	I	E
Canned green peas	Alcohol Insoluble Solids	AOAC 938.10	Gravimetry including sieving	I	E
Jams, Jellies and Marmalades	Mineral Impurities (Sand)	AOAC 971.33	Gravimetry	I	E
Processed Tomato Concentrates	Mineral Impurities (Sand)	AOAC 971.33	Gravimetry	I	E

³ ALINORM 05/28/27, paras. 99-100 and Appendix VIII-Part I

C. AD HOC INTERGOVERNMENTAL TASK FORCE ON FRUIT AND VEGETABLE JUICES⁴

Draft General Standard for Fruit Juices and Nectars

COMMODITY	PROVISION	METHOD	PRINCIPLE	NOTE ⁵
Fruit Juices and Nectars	Sections 3.2 Quality Criteria and 3.3 Authenticity ⁶	Determination of Acetic acid EN 12632 or IFU Method No 66 (1996)	Enzymatic determination	CAC advice is requested (see para. 61-64)
		Determination of Alcohol (ethanol) IFU Method No 52 (1983/1996)	Enzymatic determination	- “ -
		Determination of anthocyanins IFU Method No 71 (1998)	HPLC	- “ -
		Determination of ash in fruit products AOAC 940.26 EN 1135 (1994) IFU Method No 9 (1989)	Gravimetry	- “ -
		Determination of Beet sugar in fruit juices AOAC 995.17	Deuterium NMR	- “ -
		Determination of Benzoic acid as a marker in orange juice AOAC 994.11	HPLC	- “ -
		Determination of C ¹³ /C ¹² ratio of ethanol derived from fruit juices JAOAC 79, No. 1, 1996, 62-72	Stable isotope mass spectrometry	- “ -

⁴ ALINORM 05/28/39, Appendix II

⁵ Temporarily endorsed by the 25th Session of the CCMAS (2004) (ALINORM 04/27/23, Appendix VI)

⁶ 3.2 Quality Criteria

The fruit juices and fruit nectars shall have the characteristic colour, aroma and flavour of juice from the same kind of fruit from which it is made.

The fruit shall retain no more water from washing, steaming or other preparatory operations than technologically unavoidable.

3.3 Authenticity

Authenticity is the maintenance of the product's essential physical, chemical, organoleptical, and nutritional characteristics of the fruit(s) from which it comes.

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.

		Determination of Carbon stable isotope ratio of apple juice AOAC 981.09 - JAOAC 64, 85 (1981)	Stable isotope mass spectrometry	- “ -
		Determination of Carbon stable isotope ratio of orange juice AOAC 982.21	Stable isotope mass spectrometry	- “ -
		Determination of Carotenoid, Total/individual groups EN 12136 (1997) - IFU Method No 59 (1991)	Spectrophotometry	- “ -
		Determination of Carotenoids, Total ISO 6558-2:1992	Column chromatographic separation and spectrometry	- “ -
		Determination of Centrifugable pulp EN 12134 - IFU Method No 60 (1991/1998)	Centrifugation/% value	- “ -
		Determination of Chloride (expressed as sodium chloride) EN12133 IFU Method No 37 (1968)	Electrochemical titrimetry	- “ -
		Determination of Chloride in vegetable juice AOAC 971.27 (Codex general method) ISO 3634:1979	Titration	- “ -
	Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of Essential oils AOAC 968.20 - IFU 45b	(Scott) distillation, titration	- “ -
		Determination of Essential oils (in citrus fruit) ISO 1955:1982	Distillation and direct reading of the volume	- “ -
		Determination of Fermentability IFU Method No 18 (1974)	Microbiological method	- “ -
		Determination of Formol number EN 1133 (1994) IFU Method No 30 (1984)	Potentiometric titration	- “ -
		Determination of Free amino acids EN 12742 IFU Method No 57 (1989)	Chromatography	- “ -
		Determination of Fumaric acid IFU Method No 72 (1998)	HPLC	- “ -

	Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of glucose fructose and saccharose EN 12630 - IFU Method No 67 (1996) NMKL 148 (1993)	HPLC	- “ -
		Determination of Gluconic acid IFU Method No 76 (2001)	Enzymatic determination	- “ -
		Determination of Glycerol IFU Method No 77 (2001)	Enzymatic determination	- “ -
		Determination of hesperidin and naringin EN 12148 (1996) - IFU Method No 58 (1991)	HPLC	- “ -
	HFCS & HIS in apple juice (permitted ingredients)	JAOAC 84, 486 (2001)	CAP GC Method	- “ -
	Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of Hydroxymethylfurfural IFU Method No 69 (1996)	HPLC	- “ -
		Determination of Hydroxymethylfurfural ISO 7466:1986	Spectrometry	- “ -
		Determination of Isocitric acid-D IFU Method No 54 (1984)	Enzymatic determination	- “ -
		Determination of Lactic acid- D and L EN 12631 (1999) IFU Method No 53 (1983/1996)	Enzymatic determination	- “ -
		Determination of L-malic/total malic acid ratio in apple juice AOAC 993.05	Enzymatic determination and HPLC	- “ -
		Determination of Naringin and neohesperidin in orange juice AOAC 999.05	HPLC	- “ -
		Determination of pH-value EN 1132 (1994) IFU Method No 11 (1968/1989) ISO 1842: 1991	Potentiometry	- “ -
		Determination of Phosphorus/Phosphate EN 1136 (1994) IFU Method No 50 (1983)	Photometric determination	- “ -

		Determination of Proline EN 1141 (1994) IFU Method No 49 (1983)	Photometry	- “ -
	Quinic, malic & citric acid in cranberry juice cocktail and apple juice (permitted ingredients and additives)	AOAC 986.13	HPLC	- “ -
	Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of Recoverable oil AOAC 968.20 - IFU Method No 45b	Distillation and titration Scott method	- “ -
		Determination of Relative density EN 1131 (1993) IFU Method No 1 (1989) & IFU Method No General sheet (1971)	Pycnometry	- “ -
		Determination of Relative density IFU Method No 1A	Densitometry	- “ -
		Determination of Sodium, potassium, calcium, magnesium EN 1134 (1994) IFU Method No 33 (1984)	Atomic Absorption Spectroscopy	- “ -
		Determination of Sorbitol-D IFU Method No 62 (1995)	Enzymatic determination	- “ -
		Determination of Stable carbon isotope ratio in the pulp of fruit juices ENV 13070 (1998) Analytica Chimica Acta 340 (1997)	Stable isotope mass spectrometry	- “ -
		Determination of Stable carbon isotope ratio of sugars from fruit juices ENV 12140 Analytica Chimica Acta.271 (1993)	Stable isotope mass spectrometry	- “ -
		Determination of Stable hydrogen isotope ratio of water from fruit juices ENV 12142 (1997)	Stable isotope mass spectrometry	- “ -

		Determination of Stable oxygen isotope ratio in fruit juice water ENV 12141(1997)	Stable isotope mass spectrometry	- “ -
		Determination of Starch AOAC 925.38 IFU Method No 73	Precipitation	- “ -
	Sections 3.2 Quality Criteria and 3.3 Authenticity	Determination of Sugar beet derived syrups in frozen concentrated orange juice $\delta^{18}\text{O}$ Measurements in Water AOAC 992.09	Oxygen isotope ratio analysis	- “ -
		Determination of Titrable acids, total EN 12147 (1995) IFU Method No Method No 3, (1968) ISO 750:1998	Titrimetry	- “ -
		Determination of Total dry matter EN 12145 (1996) IFU Method No 61 (1991)	Gravimetric Determination	- “ -
		Determination of Total solids AOAC 985.26	Microwave oven drying	- “ -
		Determination of Vitamin C AOAC 967.22	Microfluorometry	- “ -
		Determination of Vitamin C CEN/TC275/WG9 N60	DNA	- “ -

D. CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS⁷

Draft Amendment to the Standard for Salted Fish and Dried Salted Fish of the *Gadidae* Family of Fishes (Section on Sampling and Analyses) (at Step 8)

COMMODITY	PROVISION	METHOD	PRINCIPLE
Salted Fish and Dried Salted Fish of the <i>Gadidae</i> Family of Fishes	Salt Content Water content	Sampling and method described in the Standard	Gravimetry

⁷ ALINORM 05/28/18, paras. 29-34 and Appendix IV

E. CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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

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

F. CODEX COMMITTEE ON CEREALS PULSES AND LEGUMES**Draft Standard for Instant Noodles (elaboration by correspondence - CL 2005/5-CPL)**

COMMODITY	PROVISION	METHOD	PRINCIPLE	NOTE	TYPE	STATUS
Instant Noodles	Moisture	AAAC Method (440-15A) or AOAC Method 925.10 drying at temperature 130°C	Gravimetry	CCCPL should clarify the temperature to be used in the method	I	NE
	Moisture	Proposed Japanese Method, drying at temperature 105°C	Gravimetry		I	NE
	Extraction of oil from instant noodles	see below	Gravimetry		I	
	Acid Value	see below	Titrimetry		I	

Extraction of oil from instant noodles**A. Apparatus**

- a) Rotary evaporator
- b) Water bath

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, and mix well. Use these noodles for the test sample. If the noodles are too thin to screen with sieves, cut them into 1 to 2 cm lengths, mix well, and use these cut noodles for the test sample.

C. Extraction

Weigh 25 g test portion into 200 ml Erlenmeyer flask. Add 100 ml petroleum ether to the flask after replacing air in flask by N₂ gas. Stopper flask and leave for 2 hours. Decant supernatant through filter paper into separating funnel. Add 50 ml petroleum ether to residue and filtrate supernatant through filter paper into the separating funnel. Add 75 ml water to the separating funnel and shake well. Allow layers to separate and drain the lower aqueous layer. Add water, shake, and remove aqueous layer again as done previously. Decant the petroleum ether layer after dehydration with Na₂SO₄ into pear-shaped flask. Evaporate petroleum ether in the flask on rotary evaporator at below 40°C. Spray N₂ gas on extract in the flask to remove all petroleum ether.

Determination of Acid Value

A. Definition and Principle

Acid value of oil from fried instant noodles = mg KOH required to neutralize 1 g oil. Oil extracted from noodle is dissolved in alcohol-ether mixture and titrated with alcoholic KOH standard solution.

B. Apparatus

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

C. Reagents

(a) Alcoholic potassium hydroxide standard solution - 0.05 mol/L. Dissolve 3.5 g potassium hydroxide in equal volume of water (CO₂-free) and add ethanol (95%) to 1 L. After mixing, let solution stand for several days keeping the solution CO₂-free. Use supernatant after standardization.

Standardization

Weigh required quantity of amidosulfuric acid (certified reference material for volumetric analysis) and place it into desiccator (≤ 2.0 kPa) for 48 hour.

Next, accurately weigh 1 to 1.25 g (recording the weight to 0.1mg), dissolve in water (CO₂-free), and dilute to 250 ml.

Put 25 mL solution into Erlenmeyer flask, add 2 to 3 drops of bromothymol blue indicator and titrate with 0.05 mol/L alcoholic potassium hydroxide solution until color of solution change to faint blue.

Calculation:

Factor of molarity [g amidosulfuric acid \times purity \times 25] / 1.2136 / ml KOH

(b) Alcohol-ether mixture - Equal volumes ethanol (99.5%) and ether.

(c) Phenolphthalein solution - 1% in alcohol.

D. Titration

Before sampling, liquefy extracted oil using water bath. Weigh 1 to 2 g liquefied test portion into Erlenmeyer flask. Add 80 ml alcohol-ether mixture and a few drops of phenolphthalein solution. Titrate with 0.05 mol/L alcoholic KOH until faint pink colour appears and retain for more than 30 s.

Perform blank test using only alcohol-ether mixture and phenolphthalein solution.

E. Calculation

Calculate using following equation.

Acid value [mg/g] = (ml test portion – ml blank) × factor of molarity × 2.806 / g test portion

G. CODEX COMMITTEE ON MILK AND MILK PRODUCTS

COMMODITY	PROVISION	METHOD	PRINCIPLE	TYPE	STATUS
Fermented milks	Lactic acid (total acidity expressed as lactic acid)	IDF 150:1991 ISO 11869:1997	Potentiometry, titration to pH 8.30	I	E
	Microorganisms constituting the starter culture	IDF 149A:1997 (Annex A)	Colony count at 25°C, 30°C, 37°C and 45°C according to the starter organism in question	IV	E
Yoghurt	<i>Streptococcus thermophilus</i> & <i>Lactobacillus delbrueckii</i> subsp. <i>Bulgaricus</i> ≥ 10 ⁷ cfu/g	ISO 7889/IDF 117: 2003	Colony count at 37°C	I	E
Yoghurt	<i>Streptococcus thermophilus</i> & <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> ≥ 10 ⁷ cfu/g	ISO 9232/IDF 146:2003	Test for identification: morphological , cultural and biochemical characteristics	I	E
Individual cheeses	Dry matter (Total solids)	ISO 5534/IDF 4: 2004	Gravimetry, drying at 102°C	I	E

PART II. SAMPLING

CODEX COMMITTEE ON CEREALS PULSES AND LEGUMES (Draft Standard for Instant Noodles)

9.1. Sampling

Not endorsed (see paras. 81-83)