



Food and Agriculture
Organization of the
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World Health
Organization

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REP16/MAS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty ninth Session

Rome, Italy, 27 June - 1 July 2016

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

Budapest, Hungary

22 – 26 February 2016

This report incorporates CL 2016/4-MAS.

CODEX ALIMENTARIUS COMMISSION



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CL 2016/4-MAS
March 2016

TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
FAO, 00153 Rome, Italy

SUBJECT: Distribution of the Report of the 37th Session of the Codex Committee on Methods of Analysis and Sampling (REP16/MAS)

MATTERS FOR ADOPTION BY THE 39th SESSION OF THE COMMISSION:

1. Methods of Analysis and Sampling in Codex Standards (para. 44 and Appendix II); and
2. Amendments to the Procedural Manual (paras 60 and 73, and Appendix III).

Governments and interested international organizations wishing to comment on the above documents should do so in writing to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, email: codex@fao.org before **30 May 2016**.

REQUEST FOR COMMENTS:

3. Comments are requested on the Information document on Practical examples on the selection of appropriate sampling plans (para. 98 and Appendix V).

Governments and interested international organizations wishing to comment should do so to the above address before **30 November 2016**.

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SUMMARY AND CONCLUSIONS

The 37th Session of the Codex Committee on Methods of Analysis and Sampling reached the following conclusions:

Matters for adoption by the 39th Session of the Codex Alimentarius Commission

The Committee forwarded the following for adoption:

- Methods of analysis and sampling in Codex Standards for adoption (para. 44, Appendix II); and
- Amendments to the Procedural Manual (paras 60 and 73, Appendix III).

Matters of interest to the Commission

The Committee:

- noted that food integrity/food authentication was an important issue and might need to be addressed by CCMAS, but would wait on the outcome of the discussion at CAC39 (paras 9 – 11);
- noted that it was not in a position to reply to the question posed by CAC38 on the appropriate protein conversion factors for soy products as this was in the remit of other Codex committees; and noted that it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors (paras 12 – 13);
- agreed to discontinue consideration of procedures/guidelines for determining equivalency to Type I methods until further information becomes available (para. 51); to continue work on (i) guidance on the criteria approach for methods which use a “sum of components” (para. 62); (ii) the criteria approach for endorsement of biological methods used to detect chemicals of concern (para. 70); and (iii) to identify areas for improvement and amendments to the *Guidelines for Measurement Uncertainty* (CAC/GL 54-2004) to address possible procedures for determining uncertainty of measurement results (para. 109); and to work on the review of the *General Guidelines on Sampling* (CAC/GL 50-2004) to identify areas for potential revision (para. 22);
- agreed to request comments on the information document on practical examples to assist with the understanding of the implementation of the *Principles for the use of sampling and testing in international food trade* (CAC/GL 83-2013) for finalisation by CCMAS38 (paras. 98 – 99, Appendix V); and
- agreed to continue with the review and update of methods of analysis in CODEX STAN 234-1999, using the internal process for such review and update (paras 75 – 76, Appendix IV); and to develop a preamble for CODEX STAN 234-1999 (para. 86).

Matters referred to other Committees

Executive Committee of the Codex Alimentarius Commission (CCEXEC)

The Committee agreed that there was no need to develop a new approach for the management of its work, but that such an approach could be considered in future if needed (para. 8).

Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

The Committee:

- agreed that it was not in a position to reply to the questions posed by CCNFSDU37 as the determination of conversion factors was in the remit of CCNFSDU (paras 12 – 13);
- agreed that the two methods (R5 and G12) are not comparable, that comparability data for the two methods were not available, and mixed matrices are not included in the scope of either of the methods obtained during their validation (para. 23); and
- endorsed some methods of analysis for provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*; made additional proposals; or requested clarification on some matters (paras 30 – 39 and 44, Appendix II).

Committee on Fish and Fishery Products (CCFFP)

The Committee:

- endorsed the methods of analysis as presented by CCFFP, and proposed that the nitrogen factors be made available on a single FAO website (para. 29).

Committee on Spices and Culinary Herbs (CCSCH)

The Committee made recommendations for methods of analysis for consideration by CCSCH (paras 26 – 28 and 44, Appendix II).

Committee on General Principles (CCGP)

The Committee agreed to request endorsement of the amendments to the Procedural Manual (paras 60 and 73, Appendix III).

FAO/WHO Coordinating Committee for Asia (CCASIA)

The Committee reconfirmed AOAC 983.23 for determination of lipids in tempe (para. 41).

Relevant Codex committees

The Committee agreed to remind Codex committees that ex-RM methods should be replaced by internationally validated methods and that recommendations should be made to CCMAS for endorsement (para. 81).

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling held its 37th Session in Budapest, Hungary, from 22 to 26 February 2016, at the kind invitation of the Government of Hungary. The Session was chaired by Professor Dr Árpád Ambrus, Chief Scientific Advisory, National Food Chain Safety Office (NFCSO). Dr Andrea Zentai, Food Safety Coordinator (NFCSO) acted as the Vice-Chairperson.
2. The Session was attended by 47 Member countries, 1 Member Organization and Observers from 17 international organizations. The list of participants is given in Appendix I.

OPENING OF THE SESSION

3. The Session was opened by Dr Márton Oravecz, President of the National Food Chain Safety Office and Dr Raimund Jehle, the FAO Deputy Regional Representative for Europe and Central Asia.

Division of Competence

4. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission, as presented in [CRD 1](#).

ADOPTION OF THE AGENDA (Agenda Item 1)¹

5. The Committee adopted the Provisional Agenda as its Agenda for the Session.

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

6. The Committee noted that some matters were for information only, and that several matters would be considered under other relevant agenda items.
7. In addition, the Committee took the following decisions.

Work management

8. The Committee recalled its response on the monitoring of the strategic plan from its last session ([REP15/MAS](#), Appendix II), that there was no need to develop a new approach for management of its work, but that such an approach could be considered in future if needed.

Food integrity / food authentication

9. The Committee noted the request for guidance from the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) on issues regarding methods of analysis and sampling in relation to food integrity/authenticity.³
10. The Delegation of Iran explained the need to deal with this issue in Codex and offered to develop a discussion paper to further outline the issues of concern and how this could be addressed by CCMAS.
11. The Committee acknowledged that food integrity/authenticity was an important issue and might need to be also addressed in CCMAS. The Committee further recognised that this issue was already addressed in Codex through standards developed by commodity committees, such as in the case of fruit juices, olive oils, fish and fishery products, amongst others. The Committee noted that this matter would be discussed at the 39th Session of the Commission and therefore decided not to consider this matter further, but to wait for the discussion and decision from the Commission.

¹ [CX/MAS 16/37/1](#)

² [CX/MAS 16/37/2](#); [CX/MAS 16/37/2 Add.1](#); Report of the pWG on endorsement ([CRD2](#)); comments of IDF ([CRD 5](#)); AOCs ([CRD 7](#)); Ecuador, India, Kenya, Nigeria, ENSA, EUVEPRO ([CRD 8](#)); Kenya ([CRD 9](#)); Ecuador ([CRD 12](#)); India ([CRD 14](#)); Republic of Korea ([CRD 18](#)); Indonesia ([CRD 20](#)); Iran ([CRD 22](#)); Uruguay ([CRD 30](#)); ICUMSA ([CRD 32](#)); Argentina ([CRD 33](#)).

³ [REP16/FICS](#), para 70.

Codex Alimentarius Commission (CAC) and Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)**Protein conversion factors**

12. The Committee agreed that it was not in a position to reply to the questions posed by CAC38 and CCNFSDU37 as the determination of conversion factors was in the remit of other Codex committees. The Committee agreed to inform the CAC and CCNFSDU accordingly.
13. The Committee agreed that conversion factors are scientifically based and that these factors should be harmonized between different Codex standards. The Committee noted that it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors and to possibly update the report of the joint FAO/WHO/UNU expert consultation, Protein and Amino Acid Requirements in Human Nutrition (2002).

Committee on Fish and Fishery Products (CCFFP)**Sampling plans in standards for fish and fishery products**

14. The Committee noted that when considering sampling plans in standards for fish and fishery products, CCFFP34 had found that the *General guidelines on sampling* (CAC/GL 50-2004) were difficult to understand and use and had proposed that CCMAS consider improving the user-friendliness of the guidelines.
15. The Committee recalled that the development of practical examples in the framework of the *Principles for the use of sampling and testing in international food trade* (CAC/GL 83-2013) was intended to address the need to provide guidance on sampling plans to member countries (see Agenda Item 8). In addition, the paper on sampling to be developed by the Interagency Meeting (IAM) should also assist CCMAS in examining how best principles of sampling could be demonstrated practically in Codex standards and in providing guidance to Codex committees on how to interpret sampling principles.
16. The Observer from the International Commission for Uniform Methods of Sugar Analysis (ICUMSA) noted that the over-riding concern should be the request from CCFFP to give information on sampling in a simplified way to Codex committees. The Observer also noted that, in view of the existence of CAC/GL 50-2004 and the practical examples related to CAC/GL 83-2013, it might be helpful to reconsider the Codex Sampling Principles produced 40 years ago (in the light of concerns at that time) taking into account that other approaches to sampling were now being developed by organizations such as ISO, albeit not in the food sector. Such approaches introduced the concept of uncertainty derived from sampling and not only acceptance of sampling, the approach on which CAC/GL 50-2004 was based. It would thus be helpful for any review to consider alternative procedures to acceptance sampling, which the paper on sampling from IAM attempted to achieve.
17. The Observer further stressed that it was important that the whole issue of sampling be now fully addressed in CCMAS given that a disproportionate amount of effort was directed to methods of analysis whereas it was generally accepted that it was the sampling, which had the greatest effect in control work.
18. The Codex Secretariat noted that it might be helpful to review CAC/GL 50-2004 to assess their usefulness, and whether there was room for revision to simplify or add more clarity to the provisions contained in the guidelines, or whether another type of document e.g. a manual for committees and/or member countries could be developed outside Codex. This would be similar to the approach taken by CCFH for microbiological criteria i.e. set principles and guidance but for the "how to" have a comprehensive manual developed by an FAO/WHO expert group. The Secretariat added that the Committee might wish to assess these options against the practical examples being developed as an information document and consider whether they would meet the needs of Codex committees and/or member countries as to the user-friendliness of CAC/GL 50-2004.
19. The Chairperson agreed that an eWG could identify areas for potential revision of CAC/GL 50-2004 and outline possible ways forward for consideration by the next session of CCMAS.
20. The Committee noted general support for the review of CAC/GL 50-2004 in order to evaluate the need for their revision and an examination of how such work should proceed if necessary.

Conclusion

21. In view of the above considerations, the Committee agreed to establish an eWG chaired by New Zealand and working in English to develop a discussion paper for consideration by the next session of CCMAS. In developing the discussion paper, the eWG would take note of the discussion at the present session and the work on practical examples on the selection of appropriate sampling plans as contained in the information document. It would also note feedback from Codex committees (as requested by CCMAS36⁴) who would provide examples from within their field of competence for which they would like to receive advice from CCMAS.
22. The Terms of Reference of the eWG are as follows:
 - Identify how CAC/GL 50-2004 is meeting the stated Rationale and Purpose (Preamble and Section 1 of the current Guidelines), and if required, update the Rationale and Purpose to ensure the revised Guidelines will be fit for purpose.
 - Identify any improvements needed to meet the Rationale and Purpose, including consideration of how the Guidelines should be structured to ensure coherence with other Codex documents dealing with sampling.
 - Prepare a proposal for new work and an associated project document.

Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

Examination of “ELISA G12” as a potential additional method for inclusion in the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979)*

23. The Committee agreed to inform CCNFSDU that the two methods (R5 and G12) for the determination of gluten are not comparable; that comparability data for the two methods were not available; and mixed matrices are not included in the scope of either of the methods obtained during their validation. The developers of these proprietary methods might be able to provide further information on the applicability of the methods.

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS AND SAMPLING PLANS IN CODEX STANDARDS (Agenda Item 3)⁵

24. The Committee considered the recommendations on methods of analysis and sampling plans proposed for endorsement and other related matters as presented in [CRD 2](#). The Committee agreed with some of the recommendations of the working group and the following amendments or recommendations. All decisions are presented in Appendix II.

Committee on Contaminants in Foods (CCCF)

Sampling plans and methods criteria:

Fumonisin (B1 + B2) in maize grain and maize flour and maize meal

DON in cereal based foods for infants and young children; in flour, meal, semolina and flakes derived from wheat, maize or barley; and in raw cereal grains (wheat, maize and barley) including sampling plans for raw cereal grains

25. The Committee endorsed the sampling plans for fumonisins and deoxynivalenol (DON) with the amendment to the titles as recommended.

⁴ [REP15/MAS](#), para 79.

⁵ [CX/MAS 16/37/3](#); Report of the pWG on endorsement ([CRD 2](#)); comments of AOAC, ISO and IDF ([CRD 6](#)); Kenya ([CRD 9](#)); Thailand ([CRD 10](#)); Ecuador ([CRD 12](#)); India ([CRD 14](#)); Nigeria ([CRD 15](#)); Chile ([CRD 17](#)); ISO ([CRD 19](#)); AOAC and IDF ([CRD 21](#)); vice-chair of the pWG on endorsement ([CRD 24](#)); AOAC, IDF, ISO ([CRD 27](#)); IDF and ISO ([CRD 31](#)).

Committee on Spices and Culinary Herbs (CCSCH)**Proposed draft Standards for Cumin and Thyme****Determination of Moisture**

26. An editorial correction was made to the suggested ISO method: ISO 939:1980. However, the Committee recommended the removal of ISO 939:1980 due to the complexity of the method and use of hazardous reagents. The Committee agreed to recommend the Karl Fischer titration methods: AOAC 2001.12 and ISO 760: 1978, but delayed typing the method. It is unclear if the provision should be water or moisture. If the provision is water then both the AOAC and ISO methods may be listed in the standard, with one designated as Type II and one as Type III. CCSCH should recognize that the ISO method has not been collaboratively studied, while the AOAC method is collaboratively studied, but not for cumin. If the two methods provide equivalent results, CCSCH should recommend which of the two methods should be considered Type II. If the provision should be moisture as listed, then only one method may appear in the standard as Type I, and CCSCH should recommend which method.

Determination of total ash, acid insoluble ash, volatile oils, extraneous matter and foreign matter

27. The Committee agreed to recommend the ISO methods as Type I recognizing that there can only be one Type I method. In cases where alternative methods were proposed by CCSCH (i.e. AOAC methods and/or the ASTA methods), these were deleted, as it could not be confirmed that they were identical to the ISO methods. The Committee agreed to recommend to change the provision "extraneous vegetable material" to "extraneous matter" for harmonization with the corresponding ISO method.

Determination of Insect Damage (for cumin and thyme) and mould damage (for thyme)

28. The Committee agreed to recommend endorsement of the methods as Type IV as the methods were not collaboratively studied.

Committee on Fish and Fishery Products (CCFFP)**Amendments to the methods of analysis for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets – Breaded or in Batter**

29. The Committee endorsed the method of analysis as presented by CCFFP. The Committee noted the concerns with having the nitrogen factors linked to two different websites and proposed that the nitrogen factors be made available on a single FAO website which would take the user directly to the nitrogen factors.

Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)**Methods of analysis in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)****Chromium, selenium and molybdenum**

30. The Committee did not endorse the methods as Type II as proposed by CCNSFDU as there were concerns that these methods (requiring expensive instrumentation) were recommended for dispute settlement. The current methods in CODEX STAN 234-1999 were considered by some delegations as equally suitable for use. It was clarified that the newer methods had been extensively validated specifically for infant formula, were more sensitive, precise and necessary for use to ensure the nutritional safety of the products. In order to provide flexibility to countries in the selection of methods, it was agreed to recommend numeric values for method criteria for the determination of chromium, selenium, and molybdenum for consideration by CCNFSDU.
31. The Committee noted that the method criteria developed (Appendix II) indicated that none of the current methods in CODEX STAN 234-1999, nor the newer proposed methods would meet the criteria, although the newer AOAC/ISO/IDF methods were closest to meeting the performance criteria. The Committee agreed to request CCNFSDU to review the numeric values for method criteria, specifically the minimum limit in column 2, and to inform CCMAS whether it had interpreted the limits in the related provisions correctly. If the values are correct then CCNFSDU should note that none of the methods (newly endorsed or existing) meet the numeric values for method criteria. If the values are incorrect then CCNFSDU should provide CCMAS advice on the correct values and how to proceed.

32. While CCNFSDU reviews the numeric values for method criteria, CCMAS has endorsed the proposed methods as Type III and maintained the typing of the existing methods in CODEX STAN 234-1999.

Determination of Vitamin B12

33. The Committee endorsed the method as Type II, and agreed to request CCNFSDU to clarify whether the existing method in CODEX STAN 234-1999 is still fit for purpose, and if so, this method would become Type III.

Determination of Iodine

34. The Committee endorsed the method as Type II and recommended the deletion of the existing method (AOAC 992.24), because it is not fit for purpose.

Determination of myo-inositol

35. The Committee agreed to request CCNSFDU to confirm that the AOAC 2011.18 and ISO 20637 determine the forms to be measured according to CODEX STAN 72-1981 for myo-inositol. The AOAC 2011.18 and ISO 20637 determine free and bound myo-inositol as phosphatidylinositol, but it is unclear if this is the definition (inclusion of free and bound) in CODEX STAN 72-1981. Provided that the definition and the scope of the methods harmonize, CCMAS recommended endorsement of AOAC 2011.18 and ISO 20637 as Type II. (It does not need to come back for re-endorsement by CCMAS.)

Determination of Vitamin A, Total nucleotides and Pantothenic Acid

36. The Committee endorsed the methods as Type II.

Determination of Vitamin E

37. The Committee agreed to request CCNSFDU to confirm that the scope of AOAC 2012.10 and ISO 20633 is in line with the provision for the isomers of Vitamin E in the CODEX STAN 72-1981. The methods do not discriminate both d and dl-alpha-tocopherol, neither do the currently endorsed methods (AOAC 992.03 and EN 12822) and Vitamin E is listed in the *Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CAC/GL GL10-1979)*, with sources listed as D-alpha-Tocopherol, DL-alpha-Tocopherol, D-alpha-Tocopheryl acetate, DL-alpha-Tocopheryl acetate, D-alpha-Tocopheryl acid succinate, DL-alpha-Tocopheryl acid succinate, DL-alpha-Tocopheryl polyethylene glycol 1000 succinate. However in CODEX STAN 72-1981 the footnote only refers to d-alpha-tocopherol. Provided that the provision and the scope of the methods harmonize, CCMAS recommends endorsement of AOAC 2012.10 and ISO 20633 as Type II. (It does not need to come back for re-endorsement by CCMAS.)

Determination of fatty acid profile

38. The Committee noted that the provisions in CODEX STAN 72-1981 are total fat, linoleic acid, and α -linolenic acid and that the scope of the AOAC 2012.13 and ISO 16958|IDF 231 are appropriate for those provisions. The Committee recommended to change the wording of the provision (Appendix II), endorsed the method as Type II and further recommended the existing method (AOAC 996.06) be changed to Type III.

General considerations

39. The Committee noted that composition provisions in CODEX STAN 72-1981 were expressed on the basis 100 kcal and 100kJ, but that methods results would be expressed in mg/kg or μ g/kg, and recommended that CCNFSDU consider including a formula for conversion of units in the Standard as described in Appendix II to provide clarity to analysts.

Committee on Fats and Oils

Determination of sterols (*Standard for Olive Oils and Olive Pomace Oils*)

40. The Committee confirmed that ISO 12228-2:2014 was equivalent to COI/T.20 doc. No. 30-2013.

FAO/WHO Coordinating Committee for Asia (CCASIA)

Determination of lipid content (*Regional Standard for Tempe*)

41. The Committee, based on the information received, reconfirmed AOAC 983.23 for determination of lipids in tempe. The Delegation of Indonesia informed the Committee that they were using an

amended version of the Soxhlet extraction method for determination of fat in cocoa products. The Committee encouraged Indonesia to carry out validation studies for this method in temper products.

Other

42. The Committee agreed to update the method of sampling for milk products as proposed by IDF (Appendix II).
43. The Committee agreed to remove AOCS Ce 1h-05 and replace with AOCS Ce 1i-07, for use in Fatty acids for Infant Formula as proposed by AOCS.

Conclusion

44. The Committee agreed to send the methods and sampling plans, as endorsed, to the 39th Session of the Commission for adoption (Appendix II), and the recommendations on the methods for cumin and thyme, and infant formula, to CCSCH and CCNFSDU, respectively, for their consideration (Appendix II).
45. The Committee agreed to re-establish the physical working group on endorsement to be chaired by the United States of America and working in English only, to meet immediately prior to the next session.

DEVELOPMENT OF PROCEDURES/GUIDELINES FOR DETERMINING EQUIVALENCY TO TYPE I METHODS (Agenda Item 4)⁶

46. The Delegation of the United States of America introduced the discussion paper and recalled the decisions of the last session of the Committee. The Delegation pointed out that while the procedure was intended for determining a statistical approach for establishing equivalence to existing Type I methods, the recommended procedures could be applicable to establishing equivalence between any two methods, regardless of type (Type I – IV). The delegation noted that the most suitable approach was the TOST⁷ procedure but that before the procedures could be further developed the Committee should provide guidance to the questions raised in [CX/MAS 16/37/4](#), paragraph 27.
47. The Delegation also emphasized that equivalency was intended for establishing equivalency between any two Type I methods, while not imparting any status to the equivalent methods, and that identified methods would still need to go through the endorsement process and be agreed to by Codex committees, where applicable.
48. Views were expressed that the approach could provide an opportunity to replace old and outdated, and difficult to replace Type I methods; that it should not change the current typing system or current levels in commodity standards; that while equivalent methods might help the analytical community in the light of technological advances, it had to be clear that the equivalent methods would be used only for routine control purposes and that in dispute situations, the Type I method should be preferred.
49. Varying views were expressed on what this work should entail; whether it was needed since a procedure already existed in Codex to replace Type I methods with newer methods; how the approach would be used; whether the approach would apply to determining equivalence between Type I methods or other methods more broadly and where the resulting document would reside.
50. Concerns were also expressed that the proposed statistical approach to test equivalency to Type I methods would not be feasible in the analytical field due to difficulties in application, and that comparable work and many protocols outside of Codex already existed to help analysts in this regard.

Conclusion

51. The Committee could not reach consensus on the use and scope of the equivalency approach and agreed to reconsider this matter in the future when more information became available. The Committee noted that most of the work in determining equivalence falls on the Standards Development Organisations (SDOs), and noted the offer of the SDOs, through the Inter-agency Meeting (IAM), to look into this matter and provide recommendations to a future session of CCMAS.

⁶ [CX/MAS 16/37/4](#); comments of Kenya ([CRD 9](#)); Thailand ([CRD 10](#)); Ecuador ([CRD 12](#)); India ([CRD 14](#)); Nigeria ([CRD 15](#)); European Union ([CRD 16](#)); Ghana ([CRD 23](#)).

⁷ two one-side t-test (TOST)

CRITERIA APPROACH FOR METHODS WHICH USE A 'SUM OF COMPONENTS' (Agenda Item 5)⁸

52. The Delegation of the United Kingdom, as chair of both the eWG and pWG, introduced the reports of the eWG and pWG. He reminded the Committee of the decision of CCMAS36 for the work to continue with the mandate as outlined in [CX/MAS 16/37/5](#), paragraph 4. The pWG had looked at examples, and concluded that there was no single mechanism for determining numeric method performance criteria for methods and that performance criteria should be addressed on a case-by-case basis.
53. The Delegation further noted that the current procedures in the Procedural Manual are for single analytes only, and an amendment might be necessary to indicate that the process was not always suitable for 'sum of components'.
54. The Delegation reported that the pWG had considered the report of the eWG and discussed the way forward. He clarified that the document did not address toxic equivalency factors (TEFs), analyte weighting or situations where maximum levels involve both a single component and multi-component analysis and that the pWG were of the opinion that should the work proceed, then those examples where performance criteria have already been generated should be included.
55. The Delegation concluded that guidance was needed from the Committee on whether work should proceed, and if so, what the format of this work would be, i.e. what type of document was needed.
56. There was general agreement that further work was needed, as it was clear that the current procedures were not necessarily fit for purpose. Discussion was held on whether it should be an internal procedure for Codex use, or a Codex guidance directed at governments.
57. There was also support to amend the Procedural Manual to clarify that the procedures were not always suitable for a "sum of components".
58. Concerns were raised on the complexity of the issue and that the type of document that would result, would not be suitable for inclusion in the Procedural Manual.
59. The Secretariat clarified that if the procedure was developed for use by CCMAS and other Codex committees, then it was a procedural matter and it would not be appropriate to have it as a document outside of Codex. This would not preclude governments from consulting the Codex procedure. The Committee should proceed with the work and a decision could be taken at a later stage on how to make it available for use in Codex.

Conclusion

60. The Committee agreed to amend the *General Criteria for the Selection of Methods of Analysis* section of the Procedural Manual and to send it to the 30th Session of the Committee on General Principles (CCGP) for endorsement and adoption by the 39th Session of the Commission (Appendix III).
61. The Committee noted that Codex Committees should consider seeking guidance from CCMAS if they wish to develop numeric values for method criteria where a sum of components is required.
62. The Committee agreed to re-establish the eWG led by the United Kingdom and working in English with the following terms of reference:
 - develop a document in the style of guidance to Codex committees and CCMAS;
 - concentrate on chemical methods of analysis only;
 - use CX/MAS 16/37/5 as a starting point, the eWG will continue to develop guidance on how MLs and methods of analysis which involve a sum of components could potentially be converted to method performance criteria;
 - note that the guidance, to be used on a case-by-case basis, will contain some of the current potential approaches available;
 - include examples of where approaches have already been successfully undertaken and cover methods with TEQs/TEFs, analyte weighting and instances where an ML includes both a single analyte and sum of components; and

⁸ [CX/MAS 16/37/5](#), Report of the pWG on 'sum of components' ([CRD 3](#)); comments of Thailand ([CRD 10](#)); Ecuador ([CRD 12](#)); India ([CRD 14](#)); Chile ([CRD 17](#)).

- investigate the existence of practical examples of sum of components outside the Codex framework.

63. The next session of the Committee will take a decision on how to take this work forward.

DISCUSSION PAPER ON CRITERIA FOR ENDORSEMENT OF BIOLOGICAL METHODS USED TO DETECT CHEMICALS OF CONCERN (Agenda Item 6)⁹

64. The Delegations of Chile and France, as chair and co-chair of the eWG, introduced the discussion paper. It was explained that the eWG had only addressed the first point of its terms of reference, viz. classify biological methods according to the nature, principles, characteristics, etc. The eWG first looked at biological methods typed in Codex and noted that most of these were Type II and III, with one typed I (rat bioassay for determination of the protein efficiency ratio), while the methods for determination of marine biotoxins were Type IV. The vast majority of the methods were for the determination of vitamins. The Delegation of France pointed out that an obstacle was that some of the methods in CODEX STAN 234-1999 either needed to be removed because there were no longer provisions for them, e.g. methods for minarine and margarine, or needed to be reviewed by the Committee since vitamins were now quantified by chromatographic methods. It was therefore suggested to revise the list and not define criteria for the methods which might be removed from the list. A proposal could then be put to the relevant Codex committee to review the methods and inform CCMAS whether they still wished to retain the biological methods.
65. The Delegations proposed that the eWG should be reconstituted to continue working on the classification of biological methods and to address the remaining two points of the terms of reference agreed at the last session of the Committee, viz. i) identify for which classes of the methods the criteria approach applies; and ii) recommend criteria to endorse each class of biological methods defined in the classification of biological methods.
66. The Delegation of Chile further pointed out that there was no definition for biological methods in Codex. It was noted that three types of classification exist. Definitions were provided and explained in Annex 2 to [CX/MAS 16/37/6](#).
67. The Committee had a general discussion and noted that there was general support for the work so that it would be clear to which classes of biological methods the criteria approach would apply.
68. The Committee also noted that the list of biological methods should be cleaned up and that the relevant Codex committees should be consulted. It was noted that there are two sorts of biological methods listed in the paper, with the majority (microbiological assay) being targeted towards the determination of vitamins. For these determinations many 'modern' methods are now available, some of which are already included in CODEX STAN 234-1999. It would be helpful, to aid future consideration, for information to be forthcoming as to how often the microbiological assay methods are currently used. A comparison exercise should be carried out to consider the effectiveness of both types of method and whether the microbiological assay methods should continue to be endorsed and listed in CODEX STAN 234-1999.
69. This matter was not taken further in the Committee and it was agreed that the eWG would identify those chemical methods for vitamins already adopted by Codex which could be possible replacements for the current biological methods and to identify appropriate questions that could be put to the relevant Codex committees.

Conclusion

70. The Committee agreed to re-establish the eWG chaired by Chile and co-chaired by France and working in English to identify those methods already adopted by Codex as possible replacements for some of the biological methods for determination of vitamins and to identify clear questions that could be put to the relevant Codex committees in relation to these methods; to continue with the classification of biological methods; and to identify to which classes of methods the criteria approach applies and recommend criteria to endorse each class of biological methods defined.

⁹ [CX/MAS 16/37/6](#), comments of Kenya ([CRD 9](#)); Thailand ([CRD 10](#)); Ecuador ([CRD 12](#)); El Salvador ([CRD 13](#)); European Union ([CRD 16](#)); Chile ([CRD 17](#)); Ghana ([CRD 23](#)).

REVIEW AND UPDATE OF METHODS IN CODEX STAN 234-1999 (Agenda Item 7)¹⁰

71. The Delegation of Brazil, as chair of the eWG on the review and update of CODEX STAN 234-1999 introduced the item and drew the attention of the Committee to the first part of [CX/MAS 16/36/7](#). The Delegation highlighted, in particular, the recommendations relating to the internal procedure to be followed by CCMAS to proceed with the maintenance of CODEX STAN 234-1999 and the amendments to the Procedural Manual aimed at identifying the Standard as the single source for methods of analysis and sampling adopted by CAC for conformity with the provisions in Codex standards.

Amendment to the Procedural Manual – CODEX STAN 234-1999 as a single source of methods of analysis and sampling for Codex standards

72. The Committee reaffirmed its earlier decision¹¹ to have CODEX STAN 234-1999 as the single reference for methods of analysis in Codex standards and recalled the reply of CCGP29 that the amendment to the Procedural Manual to indicate a single reference for methods of analysis was possible, but that CCMAS should prepare the proposed amendments for endorsement by CCGP and adoption by CAC.
73. The Committee agreed to amend the section on methods of analysis and sampling in the *Format for Codex Commodity Standards* (Procedural Manual) to insert a statement referring methods of analysis and sampling in Codex standards to those listed in CODEX STAN 234-1999 for the provisions relevant to the scope of the standard (Appendix III).
74. The Committee noted that:
- The amendment would not imply the automatic removal of methods of analysis and sampling currently contained in Codex standards.
 - The removal of methods of analysis and sampling from Codex standards would be done as the review and updating of CODEX STAN 234-1999 progressed and inconsistencies and other pending issues requiring action from the Codex Secretariat, Codex committees as well as international standards development organizations were resolved.
 - The standards currently being developed by Codex committees would refer to CODEX STAN 234-1999 in the section on methods of analysis and sampling.
 - The relevant Codex committees would still continue to identify relevant methods of analysis and sampling plans for endorsement by CCMAS or could request CCMAS to identify appropriate methods of analysis and/or sampling plans for consideration by Codex committees. Thus the practice in place for methods of analysis and sampling would not be affected by this amendment.
 - The concerns raised by Observer from IFU to have a single source for methods of analysis would be addressed through a hyperlink to the relevant Codex standards.

Internal procedure to be followed by CCMAS – Process to update methods of analysis and sampling in CODEX STAN 234-1999

75. The Committee agreed to an internal procedure for the maintenance of CODEX STAN 234-1999 as presented in the Flowchart I – Steps of the methods of analysis updating procedure and described in paragraphs 38 – 41 of [CX/MAS 16/37/7](#) (Appendix IV).
76. The Committee noted that the internal procedure could be improved in future as experience was gained in its application for the updating of CODEX STAN 234-1999.

Other issues for action by the Codex Secretariat, CCMAS, Codex committees and SDOs

77. The Delegation of Japan, as Co-Chair of the eWG on CODEX STAN 234-1999, introduced [CX/MAS 16/36/7 Add.1](#) and drew the attention of the Committee to three sets of questions (a, b and c) for action by different bodies involved in CCMAS work as follows:
- (a) Issues for CCMAS to discuss and decide on necessary action(s) (including issues that may require confirmation of previous decisions of CCMAS).

¹⁰ [CX/MAS 16/37/7](#); [CX/MAS 16/37/7 Add.1](#); [CX/MAS 16/37/7 Add.2](#); comments of Kenya ([CRD 9](#)); Thailand ([CRD 10](#)); Israel ([CRD 11](#)); Ecuador ([CRD 12](#)); El Salvador ([CRD 13](#)); India ([CRD 14](#)); Nigeria ([CRD 15](#)); European Union ([CRD 16](#)); Chile ([CRD 17](#)); Ghana ([CRD 23](#)); Switzerland ([CRD 28](#)); IFU ([CRD 29](#)).

¹¹ [REP15/MAS](#), para 111.

- (b) Issues for the standards developing organizations to clarify and, subsequently, CCMAS to decide on necessary action(s).
- (c) Issues for future action by the Codex Secretariat or the eWG on CODEX STAN 234-1999, as they are editorial or format-related.

78. The Committee considered the three actions as follows:

(a) Issues for CCMAS to discuss and decide on necessary action(s)

79. The Committee agreed that:

- CODEX STAN 234-1999 would not refer to numerical provisions from Codex standards, but a hyperlink to Codex standards would be sufficient (question (a) – 4).
- the eWG should further examine the question about the use of the term “Codex general method” in CODEX STAN 234-1999 (question (a)-5) in order to provide a definition and/or explanation of its use when developing the preamble for consideration by the next session of CCMAS;
- the Codex Secretariat would send those methods of analysis and sampling with questions for consideration/reply by Codex committees which have already been identified in the document, e.g. methods for which there are no provisions or provisions for which there are no methods ([CX/MAS 16/37/7 Add.1](#), Appendix). Replies from the Committees will be for consideration by the PWG on Endorsement for action by the next session of CCMAS; and
- the remaining questions should be further examined by the eWG in order to provide a consolidated set of questions/issues for consideration by the pWG on Endorsement and action by the next session of CCMAS.

(b) Issues for the standards developing organizations to clarify and, subsequently, for CCMAS to decide on necessary action(s)

80. The Committee agreed that questions described in (b)-1 to (b)-4 should be referred to the SDOs for clarification. The Committee agreed to invite the SDOs to consider the questions in [CX/MAS 16/36/7 Add.1](#) and provide their replies / clarification to the Chair of the eWG so that appropriate actions could be taken by CCMAS based on the advice of the PWG on Endorsement.

(c) Issues for future action by the Codex Secretariat or the eWG on CODEX STAN 234-1999, as they are editorial or format-related.

81. The Committee agreed that:

- the Codex Secretariat would liaise with the Chair of the eWG to take action on those editorial adjustments that need to be carried out in CODEX STAN 234-1999;
- the Codex Secretariat would remind Codex committees of a previous decision that ex-RM methods should be replaced by internationally validated methods and that recommendations should be made to CCMAS for endorsement; and
- other matters that could not be fixed immediately by the Codex Secretariat would be further examined / compiled by the eWG for consideration by the pWG on Endorsement and action by the next session of CCMAS.

Proposal for an introduction text / preamble to CODEX STAN 234-1999

82. The Codex Secretariat introduced [CX/MAS 16/36/7 Add.2](#) and explained that the provisions in the proposed Preamble should be considered as a preliminary basis for further discussion in the eWG and consideration by the next session of CCMAS.

83. The Committee noted comments on the proposed Preamble as follows ([CX/MAS 16/36/7 Add.2](#), Appendix I):

Introduction

- The first paragraph should be amended to remove the term “authoritative” as not relevant for the Preamble.
- The second paragraph should also consider other relevant documents related to e.g. recovery, accreditation, measurement of uncertainties, etc. in addition to the *General guidelines on sampling* (CAC/GL 50-2004).

Typing

84. The Committee noted that the Preamble was a description of how CCMAS identifies or endorses methods of analysis for adoption by CAC and therefore some language from the Procedural Manual relevant to CCMAS work could also be reproduced in the Preamble either as is, or with a slightly different style as CODEX STAN 234-1999 was directed to Codex members and the analytical community in general.

Other matters

85. The Committee agreed that further development of the Preamble should be carried out within the eWG.

Conclusion

86. The Committee agreed to continue to work on the review and update of CODEX STAN 234-1999 by means of an eWG chaired by Brazil and co-chaired by Uruguay, working in English only. The Committee also agreed to schedule a pWG immediately prior to the next session of CCMAS. The eWG will have the following Terms of Reference:

- To continue working on the review and update of CODEX STAN 234-1999 to prepare workable packages to send to the Codex Secretariat in order to be considered by the PWG on endorsement.
- To make a recommendation about how to deal with the term “codex general methods” ([CX/MAS 16/37/7 Add.1](#)).
- To draft a Preamble for CODEX STAN 234-1999 using the text in [CX/MAS 16/37/7 Add.2](#) and the comments made at the CCMAS37 and any other relevant information.

87. The prioritization of the above activities, in particular the first two bullet points, will be carried out in line with the points in [CX/MAS 16/37/7](#) (paragraph 30).

INFORMATION DOCUMENT ON PRACTICAL EXAMPLES ON THE SELECTION OF APPROPRIATE SAMPLING PLANS (Agenda Item 8)¹²

88. The Delegation of Germany, as chair of the eWG on the development of practical examples for the selection of appropriate sampling plans, introduced the item and recalled that the practical examples were intended to assist governments in choosing appropriate sampling plans to avoid disputes and as such they were not of prescriptive nature but should assist governments in the implementation of the *Principles for the use of sampling plan and testing in international trade* (CAC/GL 83-2013).

89. The Delegation drew the attention of the Committee to adjustments made to the examples presented in [CX/MAS 16/36/8](#) as indicated below and clarified that the revised examples were available in [CRD25](#):

- Illustration of the switching rules of inspection levels for the first example FV-Q.
- A more detailed description of the decision criteria for the second example MI-Q.
- Specified references for food hygiene examples, which were submitted by NMKL.

90. The Delegation further recalled the decision of CAC38 to adopt the Principles with an amendment to remove the footnote¹³ to the Principles, indicating that the examples would be available on the Codex website. The Delegation noted that this decision was taken following advice of the FAO and WHO legal offices that it was not appropriate to reference information documents in Codex texts as these texts were not adopted Codex texts; and the further clarification of the Representative of the WHO Legal Office that any information essential to a standard or other Codex texts should rather be integrated into the text than contained in an information document. The Delegation highlighted the importance of the examples for the interpretation and application of the Principles and requested the advice of the Committee as to the best place where the examples should reside following removal of the footnote from the Principles e.g. as an Annex to the Principles.

91. Views in support of keeping the examples as an Annex to the Principles argued that this would ease the reference to such examples.

¹² [CX/MAS 16/37/8](#); comments of Thailand ([CRD 10](#)); Ecuador ([CRD 12](#)); Germany ([CRD 25](#)).

¹³ [REP15/MAS](#), para 76, Appendix IV; [REP15/EXEC](#), paras 8-9; [REP15/CAC](#), para 31, Appendix III.

92. Views in support of keeping the examples as an information document argued that the examples might become obsolete and so might require updating. As the Annex would be an integral part of the Principles, it would require adoption by the Commission and so its revision would require approval of new work by the Commission. Therefore, updating the examples as necessary would be easier to perform by having them placed in an information document with no status within the Codex system.
93. Following the above, the Codex Secretariat gave a short presentation on how information documents would be presented on the Codex website and how they will be linked to relevant Codex texts. The Secretariat also clarified that the CCGP had noted that the WTO/SPS/TBT Agreements made no distinction between provisions in the body or the annexes of Codex texts nor between the different types of Codex texts e.g. standards, guidelines, guidance, etc. As a result, the question on whether provisions in the annexes were essential or not, or whether they were applicable to governments or commercial partners, did not change the status of Codex standards and related texts under these Agreements.
94. In view of the above, the Committee agreed to leave the examples as an information document that would be available on the Codex website for consultation.
95. The Committee further noted comments on whether examples of sampling plans on food hygiene, pesticide residues and veterinary drug residues were appropriate as consideration of such sampling plans did not fall within the remit of CCMAS.
96. The Chairperson reminded the Committee that CCMAS36 had clarified that the practical examples did not interfere with sampling and testing procedures developed by other committees e.g. CCFH, CCPR, CCRVDF, etc. but would show how samples taken according to the procedures developed by these committees could be used for the decision-making process and that relevant committees would be informed of this work accordingly¹⁴. In view of this, the Committee agreed to retain these examples in the information document.
97. The Committee noted that there were still some technical comments to address in some of the examples, and therefore agreed that further comments should be requested, including the possibility to incorporate additional examples, with a view to finalizing the information document at the next session of CCMAS.

Conclusion

98. The Committee agreed to:
- maintain the examples as an information document available on the Codex website; and
 - attach the examples as an Appendix to the report for further comments, including the possibility to include other examples as necessary, and finalization by the next session of the Committee (Appendix V).
99. The Committee agreed that comments submitted in reply to the circular letter attached to the report (CL 2016/4-MAS) would be used for preparation of a revised text by the Delegation of Germany for consideration by the next session of CCMAS.

PROCEDURES FOR DETERMINING UNCERTAINTY OF MEASUREMENT RESULTS (Agenda Item 9)¹⁵

100. The Delegation of Germany, as chair of the eWG on determining uncertainty of measurement results, introduced the item and indicated that the document provided procedures to estimate measurement uncertainty without being prescriptive. The procedures should then be regarded as practical examples, which were applicable in many day-to-day situations. The list of the examples was not meant to be exhaustive and in special situations, other rational procedures might apply.
101. As to the placement of this document within the Codex system, the Delegation noted that the *Guidelines for measurement uncertainty* (CAC/GL 54-2004) provided important information including typical expanded measurement uncertainties for different analyte concentrations and therefore, an annex with practical procedures for determining these uncertainties of measurement would be helpful to supplement the provisions in the Guidelines. The Delegation further noted that, following the

¹⁴ [REP15/MAS](#), para 75

¹⁵ [CX/MAS 16/37/9](#); comments of Kenya ([CRD 9](#)); Thailand ([CRD 10](#)); Ecuador ([CRD 12](#)); El Salvador ([CRD 13](#)); European Union ([CRD 16](#)); Chile ([CRD 17](#)); Germany ([CRD 26](#)).

discussion on the practical examples on the selection of appropriate sampling plans (Agenda Item 8), the examples of procedures could be placed in an information document for easy access and updates as both (practical examples and procedures) were important information to prevent potential conflicts between importing and exporting countries.

102. The Delegation summarized the key points in relation to the content of the document as well as some revisions made to take into account late comments submitted to the eWG as contained in a revised version provided in [CRD26](#):
 - The procedures are developed for different classes of analytical methods in order to consider as many analytical situations as possible. These classes include defining and rational standard methods as well as in-house validated methods. The description of the procedures is supplemented by the estimation of the expanded measurement uncertainty and by methods for checking the acceptability of test results with regard to the measurement uncertainty.
 - The document takes into account the requirements of ISO/IEC 17025. The concepts of estimating the measurement uncertainty are based on the *Guide to the expression of uncertainty in measurement* (GUM), the EURACHEM Guide on quantifying uncertainty in analytical measurement and on the related ISO standards.
 - The in-house methods in section 4.2 are now named “single-laboratory validated methods”. In section 4.2.1.2 the terms “Type A” and “Type B” for estimation of precision, which are used in the international guidelines for estimations based on statistical analysis and other means respectively are omitted in order to avoid confusion. Consequently, the two general approaches are named as “The combination of the repeatability precision of all single steps of analysis” and “Precision estimated by series of analysis” respectively.
 - The measure of precision of the latter approach is the so-called “intermediate precision”, which is smaller than the reproducibility standard deviation based on inter-laboratory method validation.
103. The Committee noted the similar comments in relation to the status of examples in adopted Codex texts in the framework of the WTO/SPS/TBT Agreements and recalled that, according to the guidance provided by the Commission on the development and use of information documents by Codex committees, they should not be produced deliberately but rather as by-products of ongoing work of the Committee as was the case for the practical examples in CAC/GL 83-2013 (see Agenda Item 8). Consequently none of the two options were suitable for the location of this document.
104. The Committee also noted comments on examples of procedures applicable to e.g. microbiological methods, pesticide residues, etc. which were outside the mandate of CCMAS. In particular for pesticide residues, work on examples of procedures for estimation of uncertainty of measurement results developed by CCMAS as supplementary information to CAC/GL 54-2006 should not overlap with provisions in the *Guidelines on estimation of uncertainty of results* (CAC/GL 59-2006) developed by CCPR and therefore such work should be developed in such a way that both documents could co-exist and possibly reference each other.
105. The Committee further noted comments that if examples of procedures were needed, CAC/GL 54-2006 could be revised to facilitate the interpretation and application of these guidelines by Codex members, and such an exercise might also help to clarify the need for these examples and how best to deal with them within the Codex system.
106. The Observer from Eurachem expressed concern that the technical content of the document itself might not be sufficiently authoritative for issues that require Codex guidance. In particular:
 - The treatment of within-laboratory precision (“intermediate precision”) in the document would lead to underestimates of uncertainty because it did not make provision for assessment and inclusion of laboratory components of bias. This was a common problem in the use of intermediate precision data. Because of this, Eurachem would not recommend the use of intermediate precision alone, for regulatory purposes, without demonstration that the resulting uncertainty estimates were valid. Such demonstration typically relied on the use of certified reference materials and proficiency testing. The document did not currently reflect the need for demonstration of validity of uncertainty estimates based on within-laboratory studies.
 - ISO 21748 gave details of the use of repeatability and reproducibility data for the estimation of measurement uncertainty, which could usefully be referred to in the document.

107. In reply to a question on the revision of ISO 5725, on which the document relied, the Observer from Eurachem informed the Committee that as a member of ISO TC69, the responsible ISO committee, and as project leader for the revision of ISO 5725 Part 2, all parts of ISO 5725 were under revision. However, ISO TC69 was aware that it was important to maintain compatibility with historical estimates of reproducibility and intended that the revision of 5725 Part 2 should not significantly affect estimates of reproducibility. Rather, amendments would focus on appropriate study size and clarification of the statistical treatment to improve harmonisation. The intention for other parts of the standard was to add new methods of calculation for the convenience of study organisers and give guidance on their selection and use.
108. The Observer from ICUMSA expressed concerns as to how this work would fit into the Codex system. The Observer noted that CAC/GL 54-2004 is an over-arching document, which gives a simple explanation on the significance of measurement uncertainty and also provides explanatory notes. In the document presented for consideration by CCMAS, procedures for the estimation of measurement uncertainty are given by reference and would therefore need to be up-dated as the references are dated and have been further developed by the international standard organizations. The Observer noted that if CAC/GL 54-2004 were to be updated, it should be kept simple as it is currently published and that incorporation of the example procedures presently under discussion might not be advisable and had not been internationally reviewed by experts in the field.

Conclusion

109. Based on the above considerations, the Committee agreed to establish an eWG, chaired by Germany and working in English only that would proceed as follows, taking as a basis the document contained in CRD26:
- Identify areas for improvement and amendments of CAC/GL 54-2004.
 - Recommend procedures if necessary for determining uncertainty of measurement results including sub-sampling, sample processing and analysis into CAC/GL 54-2004.
 - Avoid any kind of overlapping with the CAC/GL 59-2006.

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 10)¹⁶

110. The Observer of the American Oil Chemists' Society (AOCS), as secretariat of IAM, introduced the report of the IAM in [CRD 4](#) and highlighted the various issues discussed in the IAM with respect to the work of CCMAS and other related matters.
111. The Committee noted that several of the issues raised in [CRD 4](#) had been considered under the relevant agenda items.
112. The Committee thanked the members of IAM for their contribution to the work of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

113. The Committee noted that no other business had been put forward during the adoption of the Provisional Agenda.

DATE AND PLACE OF NEXT SESSION (Agenda Item 12)

114. The Committee was informed that the 38th Session was tentatively scheduled to take place within the next 12 to 18 months, in Budapest, Hungary, the final arrangements being subject to confirmation by the host country and the Codex Secretariat.

Other

115. In view of the extensive work for the next CCMAS; the Chairperson encouraged Codex members and observers to actively participate and contribute to the work of the various eWGs established at the present session. This would greatly facilitate discussion and agreement at the next session of CCMAS.

Retirement of Dr Árpád Ambrus

116. The Committee noted the retirement of Dr Árpád Ambrus as chairperson of CCMAS. Dr Ambrus had served as chairperson of the Committee since 2009. The Committee acknowledged the service of Dr Ambrus not only to the work of CCMAS, but in many other spheres of Codex and wished him well in

¹⁶ Report of the 26th meeting of the IAM ([CRD 4](#))

his future endeavours. The Committee hoped that he would continue to serve Codex in future, albeit in another capacity, and that his vast scientific knowledge would not be lost to Codex and its community at large.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP16/MAS)
Methods of analysis and sampling in Codex standards	-	Governments CAC39	Para. 44 Appendix II
Amendments to the Procedural Manual	-	Governments CCGP30 CAC39	Paras. 60 and 73 Appendix III
Guidance on the criteria approach for methods which use a "sum of components"	-	Electronic Working Group (United Kingdom) CCMAS38	Para. 62
Criteria for endorsement of biological methods used to detect chemicals of concern	-	Electronic Working Group (Chile and France) CCMAS38	Para. 70
Review and update of methods in CODEX STAN 234-1999	-	Electronic Working Group (Brazil and Uruguay) CCMAS38	Para. 86
Practical examples and procedures for determining uncertainty of measurement results (information document)	-	Governments Germany CCMAS38	Paras 98 and 99 Appendix V
Procedures for determining uncertainty of measurement results (improvements and amendments of CAC/GL 54-2004)	-	Electronic Working Group (Germany) CCMAS38	Para. 109
<i>General guidelines on sampling</i> (CAC/GL 50 – 2004) (proposal for amendment)	-	New Zealand CCMAS38	Para. 22
<i>Development of procedures/guidelines for determining equivalency of type I methods</i>	discontinued	-	Para. 51

APPENDIX I**LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
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APPENDIX II**Part 1. ENDORSED METHODS OF ANALYSIS AND SAMPLING**

- A. Contaminants in Food
- B. Fish and Fishery products
- C. Nutrition and Foods for Special Dietary Uses
- D. Milk and Milk Products
- E. Fats and Oils

Part 2. METHODS OF ANALYSIS FOR CONSIDERATION BY RELEVANT COMMITTEES

- A. Spices and Culinary Herbs
- B. Nutrition and Foods for Special Dietary Uses

PART 1

A. CONTAMINANTS IN FOOD

SAMPLING PLAN AND METHOD PERFORMANCE CRITERIA FOR FUMONISINS (FB1 + FB2) IN MAIZE GRAIN AND MAIZE FLOUR AND MAIZE MEAL

Commodity	Sampling Plan and Performance Criteria
Fumonisin (FB1 + FB2) in maize grain and maize flour and maize meal	Described in the Standard ¹ (as presented in CX/MAS 16/37/3 with amendment to the title)

SAMPLING PLAN AND METHOD PERFORMANCE CRITERIA FOR DEOXYNIVALENOL (DON) IN CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN; IN FLOUR, MEAL, SEMOLINA AND FLAKES DERIVED FROM WHEAT, MAIZE OR BARLEY; AND IN CEREAL GRAINS (WHEAT, MAIZE AND BARLEY) DESTINED FOR FURTHER PROCESSING

Commodity	Sampling Plan and Performance Criteria
Deoxynivalenol(DON) in cereal-based foods for infants and young children; in flour, meal, semolina and flakes derived from wheat, maize or barley; and in cereal grains (wheat, maize and barley) destined for further processing	Described in the Standard ² (as presented in CX/MAS 16/37/3 with amendment to the title)

¹ CAC38 adopted the ML and the sampling plans and performance criteria for methods of analysis subject to endorsement by CCMAS (REP15/CAC, paragraph 36).

B. FISH AND FISHERY PRODUCTS

AMENDMENTS TO SECTION 7.4 OF THE STANDARD FOR QUICK FROZEN FISH STICKS (FISH FINGERS), FISH PORTIONS AND FISH FILLETS - BREADED OR IN BATTER (CODEX STAN 166 – 1989)

7.4 Estimation of Fish Content

AOAC Method 996.15. (End Product Method)

Calculation:

$$\% \text{ Fish Content} = (W_d/W_b) \times 100 + \text{Adjustment Factor}^*$$

W_d = weight of debattered and/or debreaded test unit

W_b = weight of battered and/or breaded test unit

*Raw Breaded Frozen Coated Fish and Fishery Products: 2.0%

*Batter-dipped Frozen Coated Fish and Fishery Products: 2.0%

*Precooked Frozen Coated Fish and Fishery Products: 4.0%

Reference: J. AOAC Int. 80, 1235(1997)

Other Methods

(1) Chemical Analysis Method (Nitrogen Factor End-Product Method)

Appropriate in cases where there is reason to doubt the composition of the fish core (i.e., appears to contain non-fish ingredients). Except for fully cooked products, this method requires confirmation with the AOAC Method 996.15., or with Method #2 (Determination of Fish Content) in conjunction with investigation at the processing plant when determining product compliance with the labelling provisions in this Standard. This method should trigger in-factory investigation (e.g. raw ingredient recipe checks) when suspect products are identified.

The percentage fish content, corrected for the non-fish flesh nitrogen contributed by the carbohydrate coating, is calculated as follows.

$$\% \text{Fish} = \frac{(\% \text{ total nitrogen} - \% \text{ non- fish flesh nitrogen})}{\text{N factor}^*} \times 100$$

*appropriate N (nitrogen) factor

The non-fish flesh nitrogen is calculated as follows:

$$\% \text{ non-fish flesh nitrogen} = \% \text{ carbohydrate} \times 0.02$$

² CAC37 adopted the MLs and the sampling plans and performance criteria for methods of analysis subject to endorsement by CCMAS (REP14/CAC, paragraph 85)

Where the carbohydrate is calculated by difference:

$$\% \text{ carbohydrate} = 100 - (\% \text{ water} + \% \text{ fat} + \% \text{ protein} + \% \text{ ash})$$

References

Determination of nitrogen: ISO 937:1978

Determination of moisture: ISO 1442:1997

Determination of total fat: ISO 1443:1973

Determination of ash: ISO 936:1978

Average nitrogen factors to be used for fish flesh for specific fish species used as raw material for the product can be found at the following website:

<http://www.globefish.org/seafood-nitrogen-factors.html>

<http://www.fao.org/fishery/topic/1514/en>

The uncertainty of each nitrogen factor should be taken into account from the statistical data presented with the published nitrogen factor (e.g. 2 standard errors about the mean).

(2) Determination of Fish Content During Production

The fish content of a fish finger (fish stick) is calculated by using the following equation

$$\% \text{ Fish Content} = \frac{\text{Weight of ingoing fish}}{\text{Weight of final product}} \times 100$$

For most products, therefore, the fish ingredient weight is that of the raw ingredient. Any figure placed or declared on a product label would be a typical quantity reflecting the producer's normal manufacturing variations, in accordance with good manufacturing practice.

C. NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Commodity	Provision	Method	Principle	Type
Infant Formula	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate)	AOAC 2012.10 ISO 20633	HPLC	II
Infant Formula	Total nucleotides	AOAC 2011.20 ISO 20638	LC	II
Infant Formula	Pantothenic Acid	AOAC 2012.16 ISO 20639	UHPLC-MS/MS	II

D. MILK AND MILK PRODUCTS

Update to the current list of recommended IDF/ISO methods in the section Milk and Milk Products of CODEX STAN 234

Commodity Categories	Method of Sampling	Notes
Milk and Milk Products		
Milk products	IDF 136A ISO 8197 ISO 3951-1	Inspection by variables

E. FATS AND OILS AND RELATED PRODUCTS

Commodity	Provision	Method	Principle	Type
Olive Oils and Olive Pomace Oils	Sterol composition and content	<u>COI/T.20/Doc. no. 30 ISO 12228-2</u> AOCS Ch 6-91	Gas chromatography	II

PART 2**A. SPICES AND CULINARY HERBS****STANDARD FOR CUMIN – METHOD OF ANALYSIS**

Strike Through/Underline = Proposed edits

Commodity	Provision	Method	Principle	Type
Cumin	Moisture	ISO 760:1978 AOAC 2001.12	Titration	To be determined
Cumin	Total ash	ISO 928:1997	Gravimetry	I
Cumin	Acid-insoluble ash	ISO 930:1997	Gravimetry	I
Cumin	Volatile oils	ISO 6571:2008	Distillation / Volumetric	I
Cumin	Extraneous material matter <u>atter</u>	ISO 927:2009	Visual examination / Gravimetry	I
Cumin	Foreign matter	ISO 927:2009	Visual examination / Gravimetry	I
Cumin	Insect damage	Method V-8 Spices, Condiments, Flavours and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5)	Visual examination	IV

STANDARD FOR DRIED THYME - METHODS OF ANALYSIS

Strike Through/ Bold Underline = Proposed edits

Commodity	Provision	Method	Principle	Type
Dried Thyme	Moisture	ISO 760:1978 AOAC 2001.12	Titration	To be determined
Dried Thyme	Total ash	ISO 928:1997	Gravimetry	I
Dried Thyme	Acid-insoluble ash	ISO 930:1997	Gravimetry	I
Dried Thyme	Volatile oils	ISO 6571:2008	Distillation / Volumetric	I
Dried Thyme	Extraneous material <u>matter</u>	ISO 927:2009	Visual examination / Gravimetry	I
Dried Thyme	Foreign matter	ISO 927:2009	Visual examination / Gravimetry	I
Dried Thyme	Insect damage	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5)	Visual examination	IV
Dried Thyme	Mould damage	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5)	Visual examination	IV

B. NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Plain text = Methods and provisions as proposed by CCNFSDU37

BOLD = As currently listed in CODEX STAN 234-1999

Strike Through/Underline = Proposed edits to methods proposed by CCNFSDU37 and/or to CODEX STAN 234-1999

STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981) - METHODS OF ANALYSIS

Commodity	Provision	Method	Principle	Type
Infant Formula	Vitamin B12	AOAC 2011.10 ISO 20634	HPLC	II
		AOAC 986.23 Total B12 as cyanocobalamin	Turbidimetric	III
Infant Formula	Myo-Inositol	AOAC 2011.18 ISO 20637	LC-pulsed amperometry	II
Infant Formula	Chromium (Section B of CODEX STAN 72 only)	AOAC 2011.19 ISO 20649 IDF 235	ICP-MS	III
		EN 14082	Graphite furnace atomic absorption after dry ashing	<u>II</u>
		EN 14083	Graphite furnace AAS after pressure digestion	III
		AOAC 2006.03	ICP emission spectroscopy	III
Infant Formula	Selenium	AOAC 2011.19 ISO 20649 IDF 235	ICP-MS	III
		AOAC 996.16 or AOAC 996. 17	Continuous hydride generation Flame atomic absorption spectrometry (HGAAS)	III
		EN 14627	Hydride generation atomic absorption spectrometry (HGAAS)	<u>II</u>
		AOAC 2006.03	ICP emission spectroscopy	III

Infant Formula	Molybdenum	AOAC 2011.19 ISO 20649 IDF 235	ICP-MS	# III
	Molybdenum (Section B of CODEX STAN 72 only)	EN 14083	Graphite furnace AAS after pressure digestion	## II
	Molybdenum (Section B of CODEX STAN 72 only)	AOAC 2006.03	ICP emission spectroscopy	III
Infant Formula	Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate) Total Vitamin E (dl- α - Tocopherol and dl- α - Tocopherol Acetate)	AOAC 2012.10 ISO 20633	HPLC	II
	Vitamin E	AOAC 992.03 Measures all rac-vitamin E (both natural + supplemental ester forms) aggregated and quantified as α-congeners	HPLC	III
		EN 12822 (Measures Vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual tocopherol congeners (α, β, γ, δ).	HPLC	# III
Infant Formula	Total Fatty Acid Profile Fatty acids Fatty acids (including trans fatty acids)	AOAC 2012.13 ISO 16958 IDF 231	Gas Chromatography	II
	Fatty acids (including trans fatty acid)	AOAC 996.06	Gas chromatography	# III
		AOCS Ce 4h-05 1i-07	Gas chromatography	III
	Total fat	AOAC 989.05 ISO 8381 IDF 123	Gravimetry (Röse-Gottlieb)	I

Infant Formula	Iodine	AOAC 2012.15 ISO 20647 IDF 234	ICP-MS	II
		AOAC 992.24	Ion-selective potentiometry	Recommended to be revoked

PERFORMANCE CRITERIA FOR ELEMENTAL METHODS (for Consideration)

Provision	ML (minimum) (ug/kg)	ML (minimum) (ug/100kcal)	Applicable range (ug/kg)	LOD (ug/kg)	LOQ (ug/kg)	Precision RSDR (%)	Recovery (%)
Selenium	6	1	10-500	4	10	<15	90-110
Chromium	9	1.5	20-1600	7	20	<15	90-110
Molybdenum	9	1.5	20-1000	7	20	<15	90-110

Numeric Criteria were developed based on Standard Method Performance Requirements (SMPR) were developed for methods of analysis: AOAC 2011.19 | ISO 20649 | IDF 235

Numeric Criteria are referenced to “ready-to-feed” formula.

None of the methods currently listed in CODEX STAN 234 meet the numeric criteria.

EXPRESSION OF RESULTS BY USING PROPOSED METHODS OF ANALYSIS (PROPOSAL FOR INCLUSION IN CODEX STAN 72)

Results obtained by using the proposed methods of analysis for nutrients in infant formula are calculated and expressed in amounts per 100g powder, or per 100g Ready to Feed (RTF) product. RTF samples can be from liquid origin. When RTF is reconstituted from powders, 25 grams of powdered infant formula is to be mixed with 200 grams of water.

In the CODEX Standard for Infant Formula (CODEX STAN 72-1981), the essential composition is expressed in amounts per 100 available kilocalories, and amounts per 100 available kilojoules.

By using the amount of kcal and kjoules per 100g powder, or RTF product, on the product label of the sample analyzed, the nutrient concentrations can be calculated and expressed in amounts per 100 kcalories or kjoules as follows:

$$w = \frac{v}{y} \times 100 \times f$$

w = nutrient concentration in mg/100 kcal or kjoules

v = nutrient concentration in mg/100g

y = amount of kcal or kjoules per 100g powder or RTF as indicated on sample package

f = dilution factor:

Example 1: In case of analysis of powders and of liquid Infant formula, f=1

Example 2: In case of reconstituted powders (25 g powder with 200 g of water), f=9.

APPENDIX III

AMENDMENTS TO THE PROCEDURAL

(For endorsement by CCGP and adoption by CAC)

(note: the amendments are in **bold underlined** font)**Revision of the *Principles for the Establishment of Codex Methods of Analysis***

Section II: Elaboration of Codex Standards and related text

Guidelines for the inclusion of specific provisions in Codex Standards and related Texts

Principles for the establishment of Codex Method of Analysis

Working Instructions for the Implementation of the Criteria Approach in Codex

Note 1: These criteria are applicable to fully validated methods except for methods such as PCR and ELISA, which require other set of criteria.

Note 2: The approaches described for developing method performance criteria are intended for single-analyte provisions. The approaches described may not be suitable for provisions involving sum of components.

Revision of Format for Codex Commodity Standards

Section II: Elaboration of Codex Standards and related text

Format for Codex Commodity Standards

Methods of Analysis and Sampling

This section should contain the following wording:

“For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) relevant to the provisions in this standard, shall be used.”

The methods of analysis and sampling considered necessary should be selected in accordance with the guidance given in the section on Methods of Analysis and Sampling in the *Relations between Commodity Committees and General Subject Committees*. Preference should be given to set performance criteria according to the guidance established in the General Criteria for the Selection of Methods of Analysis using the Criteria Approach. If two or more methods have been proved to be equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives.

APPENDIX IV

**Process to Update Methods of Analysis in CODEX STAN 234-1999
(for internal use by CCMAS)**

The revision purpose of the endorsement may be to include a new method, to withdraw a method, to amend or change the type of the method.

The revision to include, withdraw or amend a method is necessary when:

- the provision or the maximum level are changed and the method does not meet the required performance;
- the method has any wrong or ambiguous/insufficient information;
- the method does not meet the performance criteria or it uses reagents with safety concerns for the analyst or for the environment;
- the organization responsible for the method revoked or updated methodology;
- the Committee responsible for the establishment of the provision proposes a revision;
- there is a new method that is fit for purpose;
- two methods that are included for the same provision shown to be non-equivalent;
- every 10 years.

The revision to change the type of the method may occur when:

- the Type II method does not meet the current required performance or under normal laboratory conditions it is not practical and applicable;
- Type IV methods that fill the requirements to be a Type II or III;
- Type III methods that fit better to the purpose than the Type II method with better applicability in routine use, due to, for example: equipment, speed, accessibility, affordability, accuracy, precision and recovery;
- Type I methods defined for a parameter that currently can be assessed by validated methods that use another principle of determination, for example, protein determination by Kjeldahl or Dumas;
- the method was misclassified

At any time a Codex member or a committee may request revision of methods of analysis based on the criteria for revision mentioned in this document. Any such request for revision should identify clearly the reason and the information that justifies the change. The proposals should be sent to the Codex Secretariat that will prepare a list with the methods proposed by the committees and members and also with the ones that have been endorsed over 10 years previously an every CCMAS session. The working document with this list of methods of analysis should be evaluated in the “endorsement session” of CCMAS.

As already agreed to by the Committee as one of the 4 steps, related standard developing organizations (SDOs) will check the references of their methods¹. The Committee expressed gratitude to all SDOs that have continued to provide CCMAS with information regarding the status of various methods with respect to revision and update². It is essential for an updated and consistent single list of methods of analysis that any such revisions and updates are brought to the attention of CCMAS.

The proposal to replace methods on the list as the outcome of this evaluation will be forwarded to the originally proposing committee for the ratification of the endorsement. If the relevant committee agrees with the proposal, the proposed method should return to CCMAS for endorsement and the CODEX STAN 234-1999 should be updated accordingly. The CCMAS should take the responsibility to revise general methods and those from inactive/dissolved committees.

The flowchart I shows the steps of the updating procedure.

¹REP14/MAS. Para. 79

²REP14/MAS. Para. 80

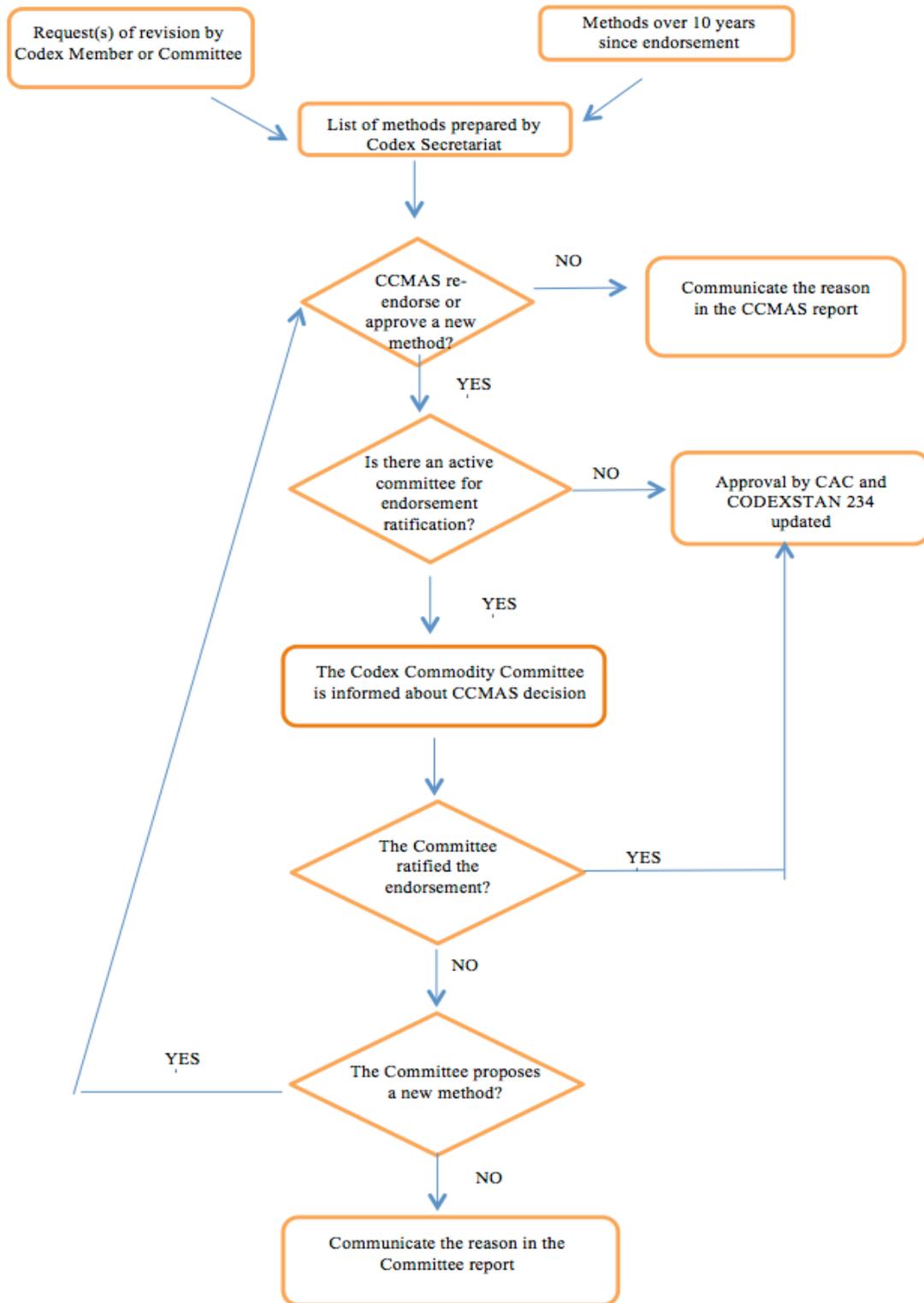


Fig 1. Steps of the Methods of Analysis Updating Procedure

APPENDIX V**Practical Examples on the Selection of Appropriate Sampling Plan
(For comments)**

1. This Information Document provides help in choosing appropriate sampling plans. These sampling plans are examples and should not be regarded as prescriptive. Therefore, they do not present fixed values but give reference to correspondent passages of the standards.
2. The justification of the choice („why“) of the individual sampling plans and the corresponding decision criteria ensues from the standards to be used in the individual situations. Usually the determination of the appropriate sampling plan is unambiguous, a fact, which will help avoid future conflicts between importing and exporting countries.
3. The given examples are intended for institutions specializing in sampling and compliance assessment. These institutions are familiar with the quoted standards (ISO, OIML, ICMSF, etc.) and should be able to understand the text in spite of the highly condensed presentation.
4. Sampling and decision concepts include wrong acceptance and wrong rejection of a lot, which are interrelated.

Examples of Sampling Plans:

The following Table 1 presents the matrix combinations vs measurand / provision with the reference codes of the corresponding examples (Table 2). The third dimension of product form of marketing (packages/bulk material/foodstuff for consumption) is implemented into the particular examples.

	Fruits/ vegetables	fats/oil	fish/fishery products	milk/milk products	meat/meat products	natural mineral waters	cereals
Qualitative/quantitative characteristics/sensory inspection	FV-Q	FO-Q	F-Q	MI-Q	M-Q	MW-Q	C-Q
food hygiene	FV-FH	n.r.	F-FH	MI-FH	M-FH	MW-FH	n.r.
pesticide residues	FV-P	FO-P	n.r.	MI-P	M-P	n.r.	C-P
contaminants	FV-C1/2	FO-C	F-C	MI-C	M-C	MW-C	C-C
residues of veterinary drugs	n.r.	FO-R	F-R	MI-R	M-R	n.r.	n.r.

n.r = not relevant

Table 1: Code of Examples

Example	Criteria	Type of Sampling Plan	Sampling and Decision Reference	
			Isolated Lots	Continuous series of lots
FV-Q	Visible defects in fruits	Attribute Plan Sampling uncertainty not applicable	<p>Consumer: CAC/GL 50 section 3.1, see specifically ISO 2859-2:1985:</p> <p>Sampling:</p> <p>Procedure A: A plan is identified by the lot size, limiting quality (LQ) and the inspection level (unless otherwise specified, level II shall be used). The sampling size (n) is given in table A.</p> <p>Procedure B: A plan is identified by the lot size, limiting quality (LQ) and the inspection level (unless otherwise specified, level II shall be used). The sampling size (n) is given in table B1 to B10.</p> <p>Decision:</p> <p>For given limiting quality (LQ) and number of samples <i>n</i>, a lot is compliant if the number of items with visible defects does not exceed the Rejection number <i>Re</i> (Tables A, D4).</p> <p>Producer: ISO 2859-2:1985:</p> <p>Sampling: see “Consumer”</p>	<p>Consumer: CAC/GL 50 section 4.2 (Table 10) see specifically: NMKL Procedure No 12, Annex – Section 4 (Table 5) and Fig.1 (see below) and ISO 2859-1:1999: Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection</p> <p>Sampling:</p> <p>Normal inspection: use of a sampling plan with an acceptance criterion that has been devised to secure the producer a high probability of acceptance when the process average of the lot is better than the acceptance quality limit. Normal inspection is used when there is no reason to suspect that the process average differs from an acceptable level. The sample size is taken from Table 1 and Table 2-A.</p> <p>Tightened inspection: use of a sampling plan with an acceptance criterion that is tighter than that for the corresponding plan for normal inspection. Tightened inspection is invoked when the inspection results of a predetermined number of consecutive lots indicate that the process average might be poorer than the AQL. The sample size is taken from Table 1 and Table 2-B.</p> <p>Reduced inspection: use of a sampling plan with a sample size that is smaller than that for the corresponding plan for normal inspection and with an acceptance criterion that is comparable to that for the corresponding plan for normal inspection. The discriminatory ability under reduced inspection is less than under normal inspection.</p>

			<p>Decision:</p> <p>For given LQ corresponding to AQL of consumer sampling plan from ISO 2859-1 if applicable, Table D5) and number of samples n, a lot is compliant if the number of items with visible defects does not exceed the Acceptance number A_c (Table A).</p>	<p>Reduced inspection may be invoked when the inspection results of a predetermined number of consecutive lots indicate that the process average is better than the AQL. The sample size is taken from Table 1 and Table 2-C.</p> <p>Switching rules:</p> <p>when normal inspection is being carried out, tightened inspection shall be implemented as soon as two out of five (or fewer than five) consecutive lots have been non-acceptable on original inspection (that is, ignoring resubmitted lots or batches for this procedure).</p> <p>When tightened inspection is being carried out, normal inspection shall be re-instated when five consecutive lots have been considered acceptable on original inspection.</p> <p>The outline of the switching rules is shown in Figure 1.</p> <p>Decision:</p> <p>for given inspection level, Acceptable Quality Level (AQL) and number of samples n, a lot is compliant if the number of items with visible defects does not exceed the Rejection number R_e (Tables 1 and 2 e.g. for single sampling).</p> <p>Producer:</p> <p>ISO 2859-1:1999: Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance</p> <p>quality limit (AQL) for lot-by-lot inspection</p> <p>Sampling:</p> <p>see “Consumer”</p>
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			<p>Decision: for given inspection level and Acceptable Quality Level (AQL), a lot is compliant if the number of items with visible defects does not exceed the Acceptance number Ac (e.g. Tables 1 and 2 for single sampling).</p>
			<p>NMKL procedure no 12. (Annex - Section 4):</p> <p>Figure 1: Levels of inspection and the switching between those.</p> <pre> graph LR Start[Start here] --> NI[Normal Inspection] NI --> TI[Tighten Inspection] NI --> RI[Reduced Inspection] TI --> NI RI --> NI NI --> NI5[No rejections in 5 consecutive lots] NI5 --> TI NI --> NI2[2 rejections in 5 consecutive lots] NI2 --> TI NI --> NI10[No rejection in 10 lots] NI10 --> RI NI --> NI1[1 rejection] NI1 --> NI </pre>
MI-Q	Fat content in Milkproducts	<p>Variables Plan</p> <p>Prerequisites:</p> <ol style="list-style-type: none"> 1. The lots have not been screened previously for nonconforming items. 2. Continuing series of lots of discrete products all supplied by one producer using one production process 3. quality characteristic must be measurable on a continuous scale 4. the measurement error is negligible, i.e. with a standard deviation no more than 10 % of the 	<p>Consumer and Producer:</p> <p>ISO 3951-1:2013: Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL)</p> <p>for lot-by-lot inspection for a single quality characteristic and a single AQL</p> <p>Sampling:</p> <p>for the “s” method acceptance sampling plan the sample standard deviation is used, for the “σ” method acceptance sampling plan the presumed value of the process standard deviation is used. If there is sufficient evidence from the control charts (e.g. ‘autocontrol’) that the variability is in statistical control, consideration should be given to switching to the “σ” method. If this appears advantageous, the consistent value of s (the sample standard deviation) shall be taken as σ.</p> <p>Normal inspection is used at the start of inspection (unless otherwise designated) and shall continue to be used during the course of inspection until tightened inspection becomes necessary or reduced inspection is allowed. Tightened inspection shall be instituted when two lots on original normal inspection are not accepted within any five or fewer successive lots. Reduced inspection may be instituted after ten successive lots have been accepted under normal inspection, provided that these lots would have been acceptable if the AQL had been one step tighter, production is in statistical control.</p>

		<p>sample standard deviation s or process standard deviation σ</p> <p>In the case that the measurement error is significant, it should be combined with s or σ respectively, according to ISO 3951-1:2013 Annex O</p> <p>5. production is stable (under statistical control) and the quality characteristic x is distributed according to a normal distribution or a close approximation to the normal distribution</p>	<p>In case that switching rules are not applicable, a particular consumer's risk quality (CRQ) associated with a consumer's risk should be fixed (e.g. Table K1 or K2). In case of very short series of lots, ISO 2859-2:1985 might be applied, where the fat content of the sample items with respect to the limit (taking into account the measurement uncertainty) might be classified as attribute (see example FV-Q).</p> <p>Summary table 1 directs users to the paragraphs and tables concerning any situation with which they may be confronted.</p> <p>Sample sizes are given in table A2 for the sample size letters given in Clause 23, Chart A (for agreed and fixed AQL at 95 % probability of acceptance and LQ at 10 % probability of acceptance). This should be verified by inspecting the OC curve from among Clause 24, Charts B to R relating to this code letter and AQL.</p> <p>For the "s" method (CAC/GL 50 section 4.3 (Table 14) and NMKL Procedure No 12, Annex – section 5 (Table 6) see specifically (ISO 3951-1:2013, Clause 15),</p> <p>the procedure for obtaining and implementing a plan is as follows.</p> <p>a) With the inspection level given (normally this will be II) and with the lot size, obtain the sample-size code letter using Table A.1.</p> <p>b) For a single specification limit, enter Table B.1, B.2 or B.3 as appropriate with this code letter and the AQL, and obtain the sample size n and the acceptability constant k. For combined control of double specification limits when the sample size is 5 or more, find the appropriate acceptance curve from among Charts s-D to s-R.</p> <p>c) Take a random sample of size n, measure the characteristic x in each item and then calculate \bar{x}, the sample mean and s, the sample standard deviation (see Annex J). Where a contract or standard defines an upper specification limit U, a lower specification limit L, or both, the lot can be judged unacceptable without even calculating s if \bar{x} is outside the specification limit(s).</p> <p>For the "σ" method (CAC GL 50 section 4.3 (table 17) and NMKL Procedure No 12, Annex – section 5 (table 7)), see specifically (ISO 3951-1:2013, Clause 16) from Table A.1 the sample-size code letter is obtained. Then, depending on the severity of inspection, enter Table C.1, C.2 or C.3 with the sample-size code letter and the specified AQL to obtain the sample size n and acceptability constant k.</p> <p>Take a random sample of this size, measure the characteristic under inspection for all items of the sample and calculate the mean value.</p> <p>The sample standard deviation s should also be calculated, but only for the purpose of checking the continued stability of the process standard deviation (see ISO 3951-1:2013, Clause 19).</p>
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			<p>Decision:</p> <p>a lot is compliant if the average fat content of sample items does not fall below the minimum value fixed by AQL and LQ taking into account the corresponding standard deviation (s or σ) and acceptability constant K. The acceptability constant is given in tables B1 to B3 (s-method) and C1 to C3 (σ-method).</p> <p>If single upper or lower specification limits (U or L) are given, calculate the quality statistic</p> $Q_U = (U - \bar{x})/s \quad \text{or} \quad Q_L = (\bar{x} - L)/s$ <p>where \bar{x} the sample mean and s, the sample standard deviation.</p> <p>The lot is acceptable if</p> $Q_U \geq k \quad \text{or} \quad Q_L \geq k \quad \text{respectively.}$ <p>For the "σ" method, s must be replaced by σ</p>
FO-Q	water content in butter	<p>Variables Plan</p> <p>Prerequisites: see example MI-Q</p>	<p>Consumer and Producer:</p> <p>see MI-Q</p> <p>Sampling:</p> <p>see example MI-Q</p> <p>Decision:</p> <p>A lot is compliant if the average water content of sample items does not exceed the maximum value fixed by AQL taking into account the corresponding standard deviation (s or σ) and acceptability constant K.</p> <p>See also example MI-Q</p>
F-Q	Net weight in prepackaged fish	<p>Special Plan</p>	<p>Consumer and Producer:</p> <p>OIML R 87 (Edition 2004)^{b)}: Quantity of product in prepackages</p> <p>Sampling:</p> <p>see Table 1: Sampling plans for prepackages</p> <p>Decision:</p> <p>for fixed 'Risk Type' (according to fixed AQL given in OIML R 87) the lot is accepted if all of the following criteria are met:</p> <ol style="list-style-type: none"> 1. The average actual quantity of product in a package is at least equal to the nominal quantity, which is evaluated in the following way:

			<p>The total error of the quantity of product in a package is given by the sum of the differences between the individual product weights and the nominal weight. The average error is given by that total error divided by the sample size.</p> <p>The lot is accepted if the average error is a positive number. In case of a negative number, the lot is accepted if the standard deviation of the individual product weights times the sample correction factor of Table 1 is higher than the absolute value of the average error.</p> <p>2. The number of packages containing an actual quantity less than the nominal quantity minus the tolerable deficiency (Table 2) is less or equal the Number of packages in a sample allowed to exceed the tolerable deficiencies (Table 1).</p> <p>3. No package contains an actual quantity less than the nominal quantity minus twice the tolerable deficiency.</p>
M-Q	Nonmeat Protein in Meat products	<p>Variables Plan</p> <p>Prerequisites: see example MI-Q</p>	<p>Consumer and Producer:</p> <p>see MI-Q</p> <p>Sampling:</p> <p>see example MI-Q</p> <p>Decision:</p> <p>A lot is compliant if the average content of nonmeat protein of sample items does not exceed the maximum value fixed by AQL taking into account the corresponding standard deviation (s or σ) and acceptability constant K.</p> <p>See also example MI-Q</p>
MW-Q	Sodium content of prepackaged Mineral Water	<p>Variables Plan</p> <p>Prerequisites: see example MI-Q</p>	<p>Consumer and Producer:</p> <p>see MI-Q</p> <p>Sampling:</p> <p>see example MI-Q</p> <p>Decision:</p> <p>A lot is compliant if the average sodium content of sample items does not exceed the maximum value fixed by AQL taking into account the corresponding standard deviation (s or σ) and acceptability constant K.</p> <p>See also example MI-Q</p>

C-Q	Moisture in rice grains	Variables Plan on Bulk Material Sampling uncertainty implemented	<p>Consumer and Producer:</p> <p>CAC/GL 50 section 5, see specifically: ISO 10725:2000: Acceptance sampling plans and procedures for the inspection of bulk materials / ISO 11648-1:2003: Statistical aspects of sampling from bulk materials — Part 1: General principles / ISO 24333:2009 Cereals and cereal products -- Sampling</p> <p>Sampling: see example C-C</p> <p>Decision: for a given maximum limit, the lot is accepted if the sample grand average of these results \bar{x} is lower than an upper acceptance value $\bar{x}_U = m_L + g D$ with the constant for obtaining the acceptance value $g = K_a / (K_a + K_b)$.</p>
FV-FH	<i>E. coli</i> in Frozen vegetables and fruits	Three-class attributes Plan	<p>CAC/GL 50 section 3.2 and NMKL procedure no 12 Annex sampling plans, Section 3, Table 3 and Table 4 see specifically: ICMSF (1986)^{a)}: Chapter 18 Sampling plans for vegetables, fruits, and nuts</p> <p>Sampling: see Table 28: Sampling plans and recommended microbiological limits for vegetables, fruits, nuts, and yeast</p> <p>Decision: the lot is accepted if not more than 2 item of 5 samples shows the presence of <i>E. coli</i> with a maximal content of 1000 CFU/g. The lot is rejected in the opposite case.</p>
M-FH	<i>Staphylococcus aureus</i> in fresh or frozen poultry meat	Three-class attributes Plan	<p>Consumer and Producer:</p> <p>CAC/GL 50 section 3.2 and NMKL Procedure No 12, Annex – section 3 (tables 1 and 2), see specifically: ICMSF (1986)^{a)}: Chapter 13 Sampling plans for poultry and poultry products</p> <p>Sampling: see Table 22: Sampling plans and recommended microbiological limits for poultry and poultry products</p> <p>Decision: the lot is accepted if not more than 1 item of 5 samples shows the presence of <i>Staphylococcus aureus</i> with a maximal content of 1000 CFU/g. The lot is rejected in the opposite case.</p>
F-FH	<i>Salmonella</i> in fresh, frozen and cold-smoked fish	Two-class attributes Plan	<p>Consumer and Producer:</p> <p>CAC/GL 50 section 3.2 and NMKL Procedure No 12, Annex – section 3 (tables 3 and 4), see specifically: ICMSF (1986)^{a)}: Chapter 17 Sampling plans for fish and shellfish</p>

			<p>Sampling: see Table 27: Sampling plans and recommended microbiological limits for seafoods</p> <p>Decision: the lot is accepted if no item out of 5 samples show the presence of <i>Salmonella</i> in 1g. The lot is rejected in the opposite case.</p>
MI-FH	<i>Staph. aureus</i> in Cheese, 'hard' and 'semi-soft' types	Two-class attributes Plan	<p>Consumer and Producer: CAC/GL 50 section 3.2 see specifically: ICMSF (1986)^{a)}: Chapter 15 Sampling plans for milk and milk products</p> <p>Sampling: see Table 24: Sampling plans and recommended microbiological limits for dried milk and cheese</p> <p>Decision: the lot is accepted if no item out of 5 samples show the presence of <i>Staph. aureus</i> in 1g, where the concentration is higher than 10.000 CFU/g. The lot is rejected in the opposite case.</p>
MW-FH	Microorganisms in Natural Mineral Water	Two-class attributes Plan	<p>Consumer and Producer: CAC/RCP 33-1985: <i>Code of hygienic practice for collecting, processing and marketing of natural mineral waters</i> (see also ICMSF (1986)^{a)}: Chapter 25: Sampling plans for natural mineral waters, other bottled waters, process waters, and ice.)</p> <p>Sampling and Decision: Annex I: Microbiological Criteria, Table: Microbiological Criteria, Point of application: at source, during production and endproduct. Assuming a log normal distribution and an analytical standard deviation of 0.25 log cfu/ml, the sampling plans would provide 95% confidence that a lot of water containing a defined not acceptable geometric mean concentration of specific microorganisms would be detected and rejected based on any of five samples testing positive.</p>
FV-P	Pesticides Residues in Apples for Compliance with MRL	Variables Plan sampling uncertainty not applicable	<p>Consumer and Producer: CAC/GL33-1999: <i>Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs</i></p>

			<p>Sampling:</p> <p>the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.</p> <p>The primary samples should be combined and mixed well, if practicable, to form the bulk sample. The minimum size of each laboratory sample is given by Table 4, 1.2. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing.</p> <p>Decision:</p> <p>analytical results must be derived from one or more laboratory samples. The lot complies with a MRL (Pesticide Residues in Food and Feed, Codex Pesticides Residues in Food Online Database, FAO and WHO 2013) where the MRL is not exceeded by the analytical result(s). Where results for the bulk sample exceed the MRL, a decision that the lot is non-compliant must take into account: (i) the results obtained from one or more laboratory samples, as applicable; and (ii) the accuracy and precision of analysis, as indicated by the supporting quality control data.</p>
<p>FO-P</p>	<p>Pesticides Residues in vegetable oils</p>	<p>Variables Plan sampling uncertainty not applicable</p>	<p>Consumer and Producer:</p> <p><i>CAC/GL33-1999: Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs</i></p> <p>Sampling:</p> <p>the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.</p> <p>The primary samples should be packaged units, or units taken with a sampling device. They should be combined and mixed well, if practicable, to form the bulk sample. The minimum size of each laboratory sample (0.5 l or 0.5 kg) is given by Table 4, 5.4. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing.</p> <p>Decision:</p> <p>see FV-P</p>

<p>MI-P</p>	<p>Pesticides Residues in Cheeses, including processed cheeses</p> <p>units 0.3 kg or greater</p>	<p>Variables Plan</p> <p>sampling uncertainty not applicable</p>	<p>Consumer and Producer:</p> <p>CAC/GL33-1999: <i>Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs</i></p> <p>Sampling:</p> <p>the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.</p> <p>Whole unit(s) or unit(s) of the primary samples should be cut with a sampling device. Cheeses with a circular base should be sampled by making two cuts radiating from the centre. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides. The minimum size of each laboratory sample (0.5 kg) is given by Table 5, 3.3. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing.</p> <p>Decision:</p> <p>see FV-P</p>
<p>M-P</p>	<p>Fat soluble Pesticides Residues in cattle carcass for Compliance with MRL</p>	<p>Variables Plan</p> <p>Sampling uncertainty not applicable</p>	<p>Consumer and Producer:</p> <p>CAC/GL33-1999: <i>Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs</i></p> <p>Sampling:</p> <p>the minimum number of primary samples to be taken from a lot is determined from Table 1a, or Table 2 (in the case of a suspect lot). The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.</p> <p>Each primary sample is considered to be a separate bulk sample. The Minimum size of each laboratory sample is given in Table 3, 2.1. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing.</p> <p>Decision:</p> <p>see FV-P</p>

<p>C-P</p>	<p>Pesticides Residues in rice grains</p>		<p>Consumer and Producer:</p> <p>CAC/GL33-1999: <i>Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs</i></p> <p>Sampling:</p> <p>the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. Sampling devices required for grain are described in ISO recommendations.</p> <p>The primary samples should be combined and mixed well, if practicable, to form the bulk sample. The minimum size of each laboratory sample (1 kg) is given by Table 4, 2. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing.</p> <p>Decision:</p> <p>see FV-P</p>
<p>FV-C1</p>	<p>Aflatoxin in ready-to-eat Treenuts</p>	<p>Variables Plan on Bulk Material</p> <p>Sampling, sample preparation, and analytical variances used to compute operating characteristic curves</p>	<p>Consumer and Producer:</p> <p>CODEX STAN 193-1995: <i>General standard for contaminants and toxins in food and feed</i></p> <p>Sampling:</p> <p>see ANNEX 2. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 25 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 25 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 25 tonnes. It is recommended that a lot or a subplot should not exceed 25 tonnes. The minimum lot weight should be 500 kg. Representative sampling should be carried out from the same lot.</p> <p>In the case of <i>static lots</i> of treenuts contained either in a large single container or in many small containers, it is not ensured that the contaminated treenut kernels are uniformly dispersed throughout the lot. Therefore, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. The minimum number of incremental samples, the minimum incremental sample size and the minimum aggregate sample size depend on the lot weight and are given by Table 1.</p>

			<p>In the case of <i>dynamic lots</i>, the samples are taken from a moving stream of treenuts. The size of the aggregate sample depends on the lot size, the flow rate of the moving stream and the parameters of the sampling device.</p> <p>Two laboratory samples each of 10kg are taken from the aggregate sample. The laboratory samples should be finely ground and mixed thoroughly. The test portions taken from the comminuted laboratory samples by a random process should be approximately 50 grams.</p> <p>Decision:</p> <p>if the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxin in the test samples from both laboratory samples, the lot is accepted.</p>
FV-C2	Total Aflatoxins in Peanuts intended for further Processing	<p>Variables Plan on Bulk Material</p> <p>Sampling, sample preparation, and analytical variances used to compute operating characteristic curves</p>	<p>Consumer and Producer:</p> <p>CODEX STAN 193-1995: <i>General standard for contaminants and toxins in food and feed</i></p> <p>Sampling:</p> <p>see AFLATOXINS TOTAL, ANNEX 1: Each lot which is to be examined must be sampled separately. Large lots should be subdivided into sublots to be sampled separately. The weight or number of sublots depend on the lot size and is laid down in Table 1. The number of incremental samples to be taken depends also on the weight of the lot, with a minimum of 10 and a maximum of 100 (Table 2).</p> <p>For the sampling procedure see example FV-C1.</p> <p>The weight of the incremental samples should be approximately 200 grams or greater, depending on the total number of increments, to obtain an aggregate sample of 20 kg. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. A minimum test portion size of 100 g should be taken from the finely ground and mixed laboratory sample.</p> <p>Decision:</p> <p>if the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxin in the test sample, the lot is accepted.</p>
FO-C	Erucic acid in vegetable Oil (bulk or packages)		<p>Consumer and Producer:</p> <p>CODEX STAN 193-1995: <i>General standard for contaminants and toxins in food and feed</i></p> <p>COMMISSION REGULATION (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs</p>

			<p>Sampling:</p> <p>Large lots shall be divided into sublots on condition that the subplot may be separated physically. The weight or number of sublots of products traded in bulk consignments shall be as given in Table 1. The weight or number of sublots of other products shall be as given in Table 2. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot indicated in Tables 1 and 2 may be exceeded by a maximum of 20 %. The aggregate sample shall be at least 1 kg or 1 litre except where this is not possible e.g. when the sample consists of one package or unit.</p> <p>The minimum number of incremental samples to be taken from the lot or subplot shall be as given in Table 3.</p> <p>In the case of bulk liquid products the lot or subplot shall be thoroughly mixed insofar as possible and insofar it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants is assumed within a given lot or subplot. It is therefore sufficient to take three incremental samples from a lot or subplot to form the aggregate sample.</p> <p>The incremental samples shall be of similar weight or volume. The weight or volume of an incremental sample shall be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1 kg or 1 litre.</p> <p>If the lot or subplot consists of individual packages or units the number of packages or units which shall be taken to form the aggregate sample is given in Table 4.</p> <p>Decision:</p> <p>The lot or subplot is accepted if the analytical result of the laboratory sample does not exceed the respective maximum level laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.</p> <p>The lot or subplot is rejected if the analytical result of the laboratory sample exceeds beyond reasonable doubt the respective maximum level laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.</p>
<p>F-C</p>	<p>Dioxins and dioxin like PCB's in Fish (individual packages or units)</p>	<p>Variables Plan Sampling uncertainty implemented</p>	<p>Consumer and Producer:</p> <p>CODEX STAN 193-1995: <i>General standard for contaminants and toxins in food and feed</i></p> <p>COMMISSION REGULATION (EU) No 589/2014 of the European Community laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012, ANNEX II</p>

		<p>Sampling:</p> <p>As far as possible incremental samples shall be taken at various places distributed throughout the lot or subplot. The aggregate sample shall be made up by combining the incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled or when the product has a very high commercial value. The minimum number of incremental samples to be taken from the lot or subplot shall be as given in Table 4. Specific provisions for the sampling of lots containing whole fishes of comparable size and weight are given in Paragraph 3.</p> <p>Large lots shall be divided into sublots on condition that the subplot can be separated physically. For weight and number, Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20 %. The aggregate sample uniting all incremental samples shall be at least 1 kg.</p> <p>Decision:</p> <p>The lot is accepted, if the result of a single analysis</p> <ul style="list-style-type: none"> — performed by a screening method with a false-compliant rate below 5 % indicates that the level does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006, — performed by a confirmatory method does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measurement uncertainty. <p>For screening assays a cut-off value shall be established for the decision on the compliance with the respective maximum levels set for either PCDD/Fs, or for the sum of PCDD/Fs and dioxin-like PCBs.</p> <p>The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound analytical result obtained with a confirmatory method and confirmed by duplicate analysis, exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty. The mean of the two determinations, taking into account the measurement uncertainty is used for verification of compliance.</p>
<p>MI-C</p>	<p>Aflatoxin M1 in Milk (bulk or bottles)</p>	<p>Consumer and Producer:</p> <p>CODEX STAN 193-1995: <i>General standard for contaminants and toxins in food and feed</i></p> <p>COMMISSION REGULATION (EC) No 401/2006 of 23 February 2006</p> <p>laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. F.1.: Method of sampling for milk, milk products, infant formulae and follow-on formulae, including infant milk and follow-on milk.</p>

			<p>Sampling:</p> <p>The minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The number of incremental samples determined is function of the usual form in which the products concerned are commercialised. In the case of bulk liquid products the lot shall be thoroughly mixed insofar as possible and insofar it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.</p> <p>The incremental samples, which might frequently be a bottle or a package, shall be of similar weight. The weight of an incremental sample shall be at least 100 grams, resulting in an aggregate sample of at least about 1 kg or 1 litre.</p> <p>Decision:</p> <p>Acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty (or decision limit).</p> <p>Rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty (or decision limit).</p>
M-C	benzo(a)pyrene in meat	<p>Variables Plan</p> <p>Sampling uncertainty implemented</p>	<p>Consumer and Producer:</p> <p>CODEX STAN 193-1995: <i>General standard for contaminants and toxins in food and feed</i></p> <p>COMMISSION REGULATION (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs</p> <p>Sampling:</p> <p>As far as possible, incremental samples shall be taken at various places distributed throughout the lot or subplot. The aggregate sample shall be made up by combining the incremental samples. In case of sampling for PAH analysis plastic containers shall be avoided if possible as they could alter the PAH content of the sample. Inert, PAH-free glass containers, adequately protecting the sample from light, shall be used wherever possible. Where this is practically impossible, at least direct contact of the sample with plastics shall be avoided, e.g. in case of solid samples by wrapping the sample in aluminium foil before placing it in the sampling container. The aggregate sample shall be at least 1 kg or 1 litre except where it is not possible, e.g. when the sample consists of 1 package or unit. The minimum number of incremental samples to be taken from the lot or subplot shall be as given in Table 3. If the lot or subplot consists of individual packages or units, then the number of packages or units which shall be taken to form the aggregate sample is given in Table 4. Large lots shall be divided into sublots on condition that the subplot may be separated physically.</p>

			<p>For products traded in bulk consignments (e.g. cereals) Table 1 shall apply. For other products Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20 %.</p> <p>Decision:</p> <p>Acceptance of a lot/sublot:</p> <p>The lot or subplot is accepted if the analytical result of the laboratory sample does not exceed the respective maximum level as laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.</p> <p>Rejection of a lot/sublot:</p> <p>The lot or subplot is rejected if the analytical result of the laboratory sample exceeds beyond reasonable doubt the respective maximum level as laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.</p>
MW-C	Arsenic in Natural Mineral Water	<p>Variables Plan on Bulk Material</p> <p>Sampling uncertainty implemented</p>	<p>Consumer and Producer:</p> <p>CAC/GL 50 section 5, see specifically: ISO 10725:2000: Acceptance sampling plans and procedures for the inspection of bulk materials / ISO 11648-1:2003: Statistical aspects of sampling from bulk materials — Part 1: General principles</p> <p>Sampling:</p> <p>see example C-C</p> <p>Decision:</p> <p>for the given maximum limit $m_L=0.01$ mg/kg (CODEX STAN 193-1995: <i>General standard for contaminants and toxins in food and feed</i>), the lot is accepted if the sample grand average of these results \bar{x} is lower than an upper acceptance value $\bar{x}_U = m_L + g D$ with the constant for obtaining the acceptance value $g = K_a / (K_a + K_b)$.</p>
C-C	Cadmium content in wheat	<p>Variables Plan on Bulk Material</p> <p>Sampling uncertainty implemented</p>	<p>Consumer and Producer:</p> <p>CAC/GL 50 section 5, see specifically: ISO 10725:2000: Acceptance sampling plans and procedures for the inspection of bulk materials / ISO 11648-1:2003: Statistical aspects of sampling from bulk materials — Part 1: General principles / ISO 24333:2009 Cereals and cereal products -- Sampling</p> <p>Sampling:</p> <p>sampling from a commodity is classified into two different procedural types:</p>

			<ul style="list-style-type: none"> • sampling of bulk materials for the accurate estimation of an average value of the <u>quality characteristic assessed</u> in the lot by suppliers • inspection procedure for bulk materials for making a <u>decision concerning lot acceptance</u> by consumers. <p>ISO 11648 is an International Standard for the first type of procedure, ISO 10725 for the second type, which is based on the assumption that the value of the individual standard deviation of the specified quality characteristic is known and stable.</p> <p>The sample size can be estimated using Tables 3 - 22 of the standard ISO 10725:2000 with fixed producer's risk α and consumer's risk β and fixed cost ratio level from the relative standard deviations $d_I = \sigma_I/D$ and $d_T = \sigma_T/D$ (ISO 10725:2000, 6.3.4) with the sampling increment standard deviation σ_I and test sample standard deviation σ_T. The number $2n_I$ increment samples should be taken from the lot and each two of them should be pooled to two composite samples. From each of the two composite samples $2n_T$ test samples should be prepared (e.g. homogenized).</p> <p>For imprecise standard deviations, one measurement per test sample should be performed (ISO 10725:2000, 6.3.2.2).</p> <p>As an alternative, the number and size of the increment samples and of the test samples are given in ISO 24333 Table 1 or Table 2 for flowing or static bulk material respectively. That standard also gives information on suitable sampling devices.</p> <p>Decision:</p> <p>as emphasized above, prerequisite is the determination of the estimation standard deviation σ_E (ISO 10725:2000, 6.2.7 / ISO 11648-1:2003) by monitoring of the cadmium content and to assess that it is stable. It is permitted to use the values of standard deviations specified by an agreement between the supplier and the purchaser (e.g. 'autocontrol') (ISO 10725:2000, 6.2.1).</p> <p>Taking into account the discrimination interval $D = (K_a + K_b) \sigma_E$ (formula C6 in C.4.2) and assuming that the measurement standard deviation is negligible compared to σ_E (which should be proven), the following four quantities might be fixed by agreement: the acceptance quality limit for the lot mean m_A (corresponding to AQL, producers' risk), the probability α of wrongly rejecting a conforming lot, the non-acceptance quality limit for the lot mean m_R (corresponding to LQ, consumers' risk), and the probability β of wrongly accepting a nonconforming lot.</p> <p>For a given acceptance quality limit m_A, the lot is accepted if the sample grand average of these results \bar{x} is lower than an upper acceptance value $\bar{x}_U = m_A + g D$ with the constant for obtaining the acceptance value $g = K_a / (K_a + K_b)$.</p>
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<p>FO-R</p>	<p>Residues of Veterinary Drugs in Fat</p>	<p>Variables Plan sampling uncertainty not applicable</p>	<p>Consumer and Producer:</p> <p>CAC/GL71-2009: <i>Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals</i></p> <p>Sampling: see example F-R, The minimum quantity required for laboratory samples is 500 g (Table A II Group 031).</p> <p>Decision: see example F-R</p>
<p>F-R</p>	<p>Residues of Veterinary Drugs in Packaged Fish</p>	<p>Variables Plan Sampling uncertainty not applicable</p>	<p>Consumer and Producer:</p> <p>CAC/GL71-2009: <i>Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals</i></p> <p>Sampling:</p> <p>for non-suspect lots a statistically-based, unbiased sampling program is recommended (sampling is conducted at random throughout the lot under inspection, although often systematic sampling is employed). In stratified random sampling the consignment is divided into non-overlapping groups or strata e.g. geographical origin, time. A sample is taken from each stratum. In systematic sampling units are selected from the population at a regular interval (e.g., once an hour, every other lot, etc.). Where non-compliant results are detected it is possible to derive a crude estimate of the likely prevalence in the general product population (e.g. 'autocontrol'). The number of primary samples required to give a required statistical assurance can be read from Appendix A, Table 4.</p> <p>For exact or alternative probabilities to detect a non-compliant residue, or for a different incidence of non-compliance, the number of samples n to be taken may be calculated from:</p> $n = \ln(1-p) / \ln(1-i)$ <p>where p is the probability to detect a non-compliant residue (e.g. 0.95), i is the supposed incidence of non-compliant residues (e.g. 0.10) in the lot.</p> <p>In biased or estimated worst case sampling, investigators use their judgment and experience regarding the population, lot, or sampling frame to decide which primary samples to select. Such directed or targeted sampling protocols on a sub-population (biased sampling) are designed to place a greater intensity of inspection/audit on suppliers or product considered to possibly have a greater potential than the general population of being non-compliant. If compliant results from biased sampling confirm non-biased program results, they provide increased assurance that the system is working effectively.</p> <p>The canned or packaged product should not be opened for sampling unless the unit size is at least twice the amount required for the final laboratory sample. The final laboratory sample should contain a representative portion of juices surrounding the product. The minimum quantity required for laboratory samples is 500 g of edible tissue (Table C VII Class B – Type 08, A).</p>

			<p>Decision:</p> <p>for purposes of control, the maximum residue limit for veterinary drugs (MRLVD) is applied to the residue concentration found in each laboratory sample taken from a lot. Lot compliance with a MRLVD is achieved when the mean result for analysis of the laboratory test portions does not indicate the presence of a residue, which exceeds the MRLVD. Regulatory action is only taken on samples containing residues, which can be demonstrated to exceed the regulatory action limit with a defined statistical confidence.</p>
Mi-R	Residues of Veterinary Drugs in Raw Milk	<p>Variables Plan on Bulk Material</p> <p>Sampling uncertainty not applicable</p>	<p>Consumer and Producer:</p> <p><i>CAC/GL71-2009: Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals</i></p> <p>Sampling:</p> <p>see example F-R, The minimum quantity required for laboratory samples is 500 mL (Table B I Group 033).</p> <p>Decision:</p> <p>see example F-R</p>
M-R	Residues of Veterinary Drugs in Meat/Meat products	Variables Plan sampling uncertainty not applicable	<p>Consumer and Producer:</p> <p><i>CAC/GL71-2009: Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals</i></p> <p>Sampling: see example F-R, The minimum quantity required for laboratory samples is 500 g (Table A I Group 030).</p> <p>Decision: see example F-R</p>

Table 2: Example sampling plans

a) Microorganisms in Foods 2. Sampling for microbiological analysis: Principles and specific applications. 1986. 2nd Ed. International Commission on Microbiological Specifications for Foods.

b) International Organization of Legal Metrology (OIML), Bureau International de Métrologie Légale 11, rue Turgot - 75009 Paris - France, Publication OIML R 87 Edition 2004 (E)